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| **14. ABSTRACT** The Cooperative Communication System (CCS) is intended to improve patient care by supporting Burn ICU clinical decision making through computer-based decision and communication support. This project followed three phases: foundation research, prototype development, and prototype assessment. In Phase 1, we collected and analyzed data on clinician patient care and unit management, revealing 21 barriers to cognitive work, and producing 39 requirements for the CCS. During Phase 2, we developed use cases and information design prototypes based on Phase 1 findings. We also developed a software prototype that translated the information design into an interactive interface and reviewed it in January 2015 with 26 members of the USAISR clinical staff. The ARA machine learning team developed approaches that survey patient data to detect clinically relevant patterns and trends. We evaluated the software prototype for individual usability with 42 clinicians at the USAISR in early November 2015 and with two 3-member teams to assess suitability for team decision making and communication in June 2016. The completed CCS prototype has been delivered to AISR. | | |
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# Table of Contents


**1. Introduction and Project Overview** ..... 5

**2. Executive Summary** ..... 6

**3. Project Management** ..... 7

***a.*** *Project Tasks by Phase* ..... 7

***b.*** *List of CCS Deliverables* ..... 8

***c.*** *Project Gantt Chart:* ..... 9

***d.*** *Reportable Outcomes and Recognition* ..... 10

**4. Related Literature** ..... 14

**5. Phase 1 Summary: Descriptive Model of Cognitive Work and Software Functional Requirements** ..... 15

***a.*** *Data Analysis:* ..... 16

***b.*** *Model Development:* ..... 18

**6. Software Development** ..... 21

***a.*** *Architecture* ..... 21

***b.*** *User Interface* ..... 23

**7. Usability Assessment (November 2015)** ..... 35

***a.*** *Preparation.* ..... 35

***b.*** *Qualitative Findings.* ..... 35

***c.*** *Prototype Improvements.* ..... 36

***d.*** *Quantitative Findings.* ..... 36

**8. Validation Assessment (June 2016)** ..... 37

***a.*** *Procedure.* ..... 39

***b.*** *Coding Scheme.* ..... 41

***c.*** *Scenarios.* ..... 41

***d.*** *Results.* ..... 41

***e.*** *Decision, Search and Communication Processes* ..... 42

***f.*** *Post-task ratings.* ..... 44

***g.*** *Subjective ratings by experience.* ..... 44

***h.*** *Subjective ratings by role.* ..... 44
***i.*** *Effect of system on team performance ratings.* ..... 45
***j.*** *Effect of system on decision making.* ..... 45
***k.*** *Effect of system on communication.* ..... 45
***1.*** *Discussion.* ..... 45
***m.*** *Limitations.* ..... 46
***n.*** *Future work.* ..... 46
**9. Machine Learning Validation and Use Cases** ..... 46
**10. Transition Plan** ..... 53
**11. Conclusions** ..... 53
**12. List of Appendices** ..... 55
**13. References** ..... 57
**14. Acronyms** ..... 405

## 1. Introduction and Project Overview

The U.S. Department of Defense (DoD) maintains one of the largest healthcare networks in the world, supporting in-patient and out-patient care not just for the active military, but their families, reserve forces, veterans, and even civilians local to various military treatment facilities (MTF). As such, each MTF experiences a wide variety of patients and clinical requirements.

Burn Intensive Care Unit (BICU) patients present healthcare teams with unique challenges and complex combinations of life-threatening injuries and illnesses. Care for these patients is necessarily multidisciplinary. Care providers across professions must collaborate to make effective decisions, develop treatment plans, assess patient progress, and refine management over time. Management decisions, though, are only as good as the information available when they are made. For this reason, the Institute of Medicine recommended improving access to accurate, timely information, and making relevant information available at the point of patient care to improve patient safety. Despite advances in computer systems and knowledge resources, communication failures between resources and healthcare providers continue to cause the majority of misadventures in healthcare delivery. Critical information for decision making remains difficult to access and deliver and is often missing at decisive moments.

Healthcare providers in the BICU environment amount to a joint cognitive system that can be studied, modeled, and assisted through scientific methods and information technology to improve decision making and, thus, improve patient care. The daily work of the clinician requires knowledge representations (from displays to diagrams and more) as part of this joint cognitive system to serve as a map for the ever-changing environment of work that must be successfully navigated.

The Cooperative Communication System (CCS) is a Health Information Technology tool designed to interface with a hospital's electronic medical record and information network to present relevant clinical data to caregivers. As we envision it, the CCS is part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. As such, it can keep providers informed of a patient's status, of other healthcare providers' activity related to each patient, and of potential discrepancies among healthcare providers' broadly defined, patient driven goals, specifically defined objectives, and individually focused tasks. This type of networked system could also extend beyond the fixed walls of a hospital to incorporate pre-hospital, contingency operations, and theater evacuations. For example, when a soldier is injured, a networked communication system could immediately start relaying information to a Forward Surgical Team (FST) or Combat Support Hospital (CSH) to keep the receiving healthcare team apprised of the patient's status so that they can better prepare for patient arrival, handoff, and treatment. The enhanced communication afforded by this system will decrease complications which will directly improve patient outcomes.

In addition to the improved communication among providers, this project explored the potential to provide relevant information to support clinician decision making. The potential exists for the use of Machine Learning (ML) algorithms to display pertinent, prioritized information to a specific healthcare provider to support their cognitive work. As more data become available to the ML system during patient care, the CCS will continuously (in real time) improve the availability and accuracy of the information displayed. This type of decision support should aid care providers from novice to experienced clinicians by expanding support for decision making. Through decision support, patients might receive more accurate and timely diagnoses, more timely and appropriate testing, and best evidence-based care. The time lag of "bench-to-bedside" evidence-based interventions can be markedly reduced. Through better communication among the healthcare team and by dramatically enhancing the availability of salient information necessary to make decisions, we expect the CCS to reduce complications and costs and to improve overall patient outcomes.

Based on the results presented in this report, it is our view that the CCS is ready to transition into advanced development, complementing the recent selection of the MHS Genesis electronic medical record (EMR).

*Co-PI LTC Pamplin provided the following Project Summary from the viewpoint of the United States Army Institute of Surgical Research (USAISR)*

> The CCS featured an intense collaboration between system research and development professionals and clinicians for the entire project. Co-PI LTC Jeremy Pamplin, MD, provided the following perspective from the point of view of our clinical collaborators:
>
> Working with Applied Research Associates (ARA) as a collaborative partner on the CCS grant had a profound impact on all members of our task area involved in this effort. Working with the ARA team of experts in Cognitive Systems Engineering (CSE) afforded us the opportunity to

conduct more effective health information technology research. The lessons learned and experience gained developing the CCS testing protocols provided new insights for managing current and future research projects within the Critical Care Systems Research Task area at the USAISR.

The CSE approach to studying the BICU has successfully identified core features of an effective clinical decision support tool that holds promise to improve patient care by improving communication, coordination of clinical activities, and access to salient information. Some features of the CCS that were identified through this basic science research of the BICU work domain are similar to other visual display and decision support systems that have been developed using less vigorous methodologies. Nevertheless this area of research is important because these technologies have been demonstrated to improve patient safety by reducing medical errors, to improve the efficiency of clinical data acquisition, and to improve resource utilization (Pickering, 2015).

It is important to note that there are key differences between previously developed clinical data visualization systems and the CCS that are directly attributable to the CSE research methodology. These additions include:

1. A modular information design that can update over time to account for the constant evolution of medical science.
2. An integrated communications platform that is rule based and can be monitored.
3. The capability to use machine learning to identify meaningful patterns in user information seeking behaviors.
    a. Although still needing further development, this can improve the salient information display for groups, and eventually individual clinicians over time.
    b. This may lead to self-configuring information displays that are task oriented, role based, and context sensitive.
4. The capability to use machine learning (following further development) to identify meaningful differences in current versus anticipated patient condition and corresponding treatment.

It was clear from the validation study that the clinicians preferred CCS to the standard EMR and that the CCS (particularly the messaging feature) helped with many tasks. Data from the Phases of Illness Paradigm (POIP) study suggest that other CCS components (particularly checklists and task lists) would be extremely useful when incorporated into this system.

In conclusion, the scientific evidence gained through the CCS research project has added important information to the body of knowledge in this topic area that is not unique to the BICU, but much which may be generalized to any ICU work domain. Until a system is developed that can meet the needs of most critical care clinicians and marketed for use in hospitals throughout the Unites States, it is our recommendation that funding continue in this area of research. With further development, the CCS has tremendous potential in *any* ICU. It is distinct from other, novel information displays and clinical decision support tools because the CCS is, at its core, a learning system that will improve with time and use.

## 2. Executive Summary

Over the course of four years, ARA and USAISR developed the Cooperative Communication System (CCS) as an ecologically valid decision and communications support information technology (IT) prototype with machine learning abilities for a military BICU. In Year One, the research team used a mixed methods CSE approach to develop a descriptive model of BICU cognitive work, which has served as the basis for system requirements. In Year Two, the research team devised use cases and information designs that were iteratively developed in close collaboration with the BICU clinicians to ensure realism and applicability to their real-world work domain. In Year Three, we developed a software prototype. Its intuitive, tailorable interface assembles salient patient data according to tabs organized by body system. Tab selection reveals detailed displays including tables and graphs. In the final year, the ARA team completed the CCS software prototype, including the addition of the messaging feature, and

discovered improvement opportunities during the November usability assessment. We refined the ML feature, and conducted two evaluations to determine how well the CCS supported both individual decision making and team decision making and communication. Both usability and validation assessments yielded results that supported our original hypotheses: Information design based on a deep understanding of clinician cognitive work and work processes would improve efficiency while maintaining accuracy. Our team has completed and delivered the software prototype to the AISR. We have also developed and presented a plan to the Joint Program Committee (JPC-1) to transition the CCS into advanced development.

## 3. Project Management

Since 2012, Applied Research Associates, Inc. (ARA) has been under Contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Telemedicine & Advanced Technology Research Center (TATRC), then the Congressionally Mandated Medical Research Program (CDMRP). CCS prototype progress was delayed due to unforeseen challenges in obtaining access to patient data and the databases required for Phase 2 development work. Based on this delay, we requested and obtained a no-cost extension (NCE) to allow for the prototype to be developed and connected to a database with de-identified, deceased patient data. In February 2016, the ARA team applied for a second NCE to accommodate a delay in the project schedule due to multiple causes, including IRB regulations and their interpretation, USAISR staffing, and delays in schedule as the team researched Federal Information Processing Standard (FIPS) and Defense Business Information Technology (DBIT) compliance related to installing the CCS software in the USAISR development environment. Despite challenges of obtaining access to patient data and the data bases in Phase 2, IRB approval, regulation compliance, and compatibility with clinical demands during Phase 3, we are pleased to report successful completion of all tasks and deliverables as planned. The complete set of tasks, deliverables and the project Gantt chart follow.

***a.*** *Project Tasks by Phase*

TABLE 1. PROJECT TASKS BY PHASE

| | |
|---|---|
| **Phase 1**<br>**Developed a valid understanding of the Burn ICU work domain, and individual and group cognitive work:** | |
| Task 1.1:<br>Initial Observation of the Burn ICU | Through observation and informal interviews, ARA identified care activities, workload requirements, decisions in patient care, and the cognitive artifacts clinicians use, and created a structured interview guide to drive the work of this phase. |
| Task 1.2:<br>CTA Structured Interviews and Observation | ARA conducted Cognitive Task Analysis (CTA) based on the observations from Task 1 and the interview guide. The structured interviews with clinicians identified the processes, tools and cognitive artifacts, and data they use during their patient care and unit management activities. |
| Task 1.3:<br>Integrated Data Analysis and Model Development | ARA analyzed the data gathered in Tasks 1 and 2 and built valid representations of the BICU cognitive work, information sources and clinical team members. |
| Task 1.4:<br>Decision Model and Design Requirements | ARA developed a descriptive model of BICU cognitive work, and decision requirements that are necessary for care management in the BICU. |
| **Phase 2**<br>**Used Phase 1's research to develop design requirements for the IT-based cognitive aid, evaluation criteria, and a functional prototype of the CCS design:** | |
| Task 2.1:<br>Scoping and Planning | ARA and USAISR translated the Phase 1 findings into detailed software requirements. |
| Task 2.2:<br>Analysis | The ARA and USAISR analyzed software requirements and developed preliminary information designs of user interfaces and architecture. |
| Task 2.3:<br>Design Phase | ARA and USAISR developed the software designs including coding and communication details. |
| Task 2.4:<br>Implementation, Integration and Testing | ARA and USAISR performed routine testing throughout the software coding effort. |

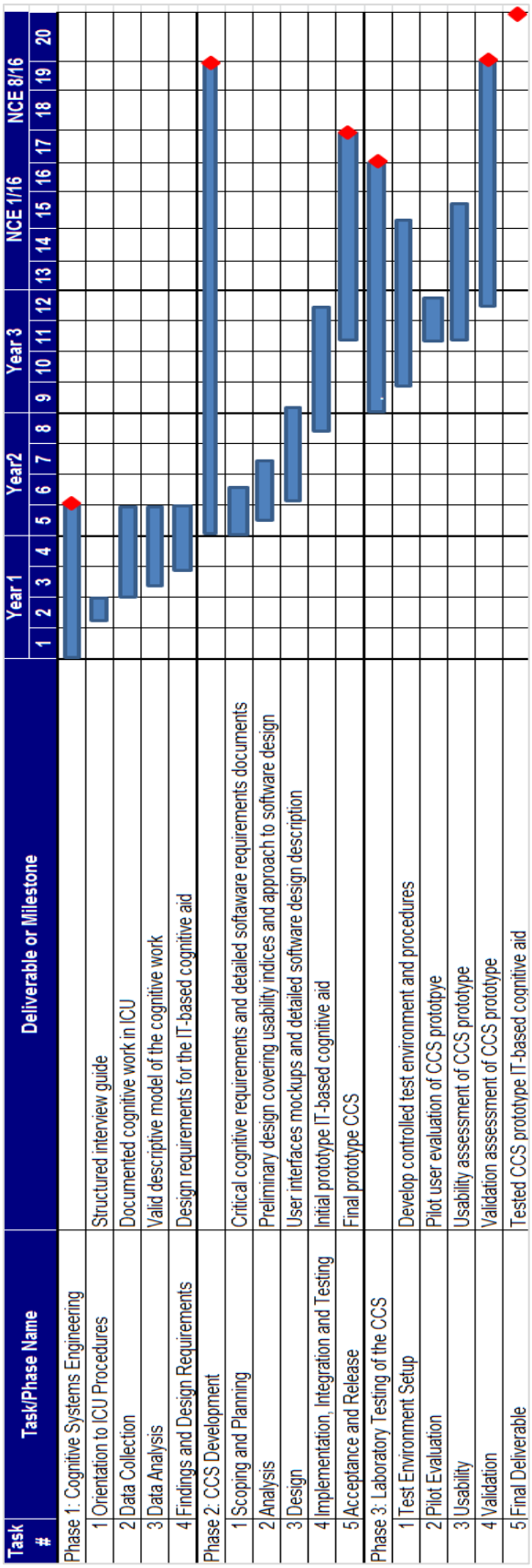
| **Phase 3**<br>**Used results from Phase 2 to complete and evaluate the CCS prototype.** | |
|---|---|
| Task 3.1:<br>Participatory Design | ARA and USAISR developed initial scenario drafts. We reviewed initial concepts with AISR clinicians. |
| Task 3.2:<br>Evaluation Testing | ARA performed outcome-oriented evaluation, or User Assessment Study to assess the CCS prototype concepts. |
| Task 3.4:<br>Usability Assessment | ARA and USAISR developed two scenarios, and used them at AISR to determine how well the CCS supported individual decision making. |
| Task 3.3:<br>Validation Testing | ARA and USAISR developed two scenarios and used them in simulations at AISR to determine how well CCS supported team decision making and communication. |
| Task 3.5:<br>CCS Clinical Implementation and Transition | ARA and USAISR identified the transition requirements and submitted a draft transition plan for the completed prototype CCS. |

***b.*** *List of CCS Deliverables*

- Approved Human Use Protocol: Final approval completed February 27, 2013, Amended protocol approved April 30, 2013
- Interview Guide: Developed January 2013, refined May 2013
- Visit Reports (4):
    - First site visit March 4-8, 2013
    - Second site visit May 20-24, 2013
    - Third site visit July 22-25, 2013
    - Fourth site visit November 18-22, 2013
- Initial Software User Interfaces: Delivered January 2014
- Burn ICU Descriptive Model of Cognitive Work: Delivered February 2014
- Phase 1 Final Report: Delivered February 2014
- Validated User Interfaces with USAISR Users: March 23-28, 2014
- Finalized User Interfaces for Prototype Development: Delivered April 2014
- Annual Report: Delivered September, 2014
- Working Prototype: Delivered January 2015
- Usability assessment plan and criteria for November 2015, and January 2016 assessments
- Burn ICU Metrics: Delivered as part of June 2016 Validation Assessment
- Usability Assessment: Delivered November 2015
- Validation Assessment: Delivered June 2016
- Tested prototype: Delivered August 2016
- Final Report: Delivered November 2016

In July 2016, the project team had to temporarily reduce work when we were informed that prior year funding had expired the previous fall, resulting in a shortfall of $48,268. We worked closely with Mr. Lance Nowell (CDMRP Contract Specialist) and Mr. Tony Story, our project COR, to get approval for a reallocation of those funds with an NCE. On August 31, 2016, the NCE and funds change was approved which enabled the team to complete work.

***c.*** *Project Gantt Chart:*



| Task # | Task/Phase Name | Deliverable or Milestone |
|---|---|---|
| Phase 1: Cognitive Systems Engineering | | |
| 1 | Orientation to ICU Procedures | Structured interview guide |
| 2 | Data Collection | Documented cognitive work in ICU |
| 3 | Data Analysis | Valid descriptive model of the cognitive work |
| 4 | Findings and Design Requirements | Design requirements for the IT-based cognitive aid |
| Phase 2: CCS Development | | |
| 1 | Scoping and Planning | Critical cognitive requirements and detailed software requirements documents |
| 2 | Analysis | Preliminary design covering usability indices and approach to software design |
| 3 | Design | User interfaces mockups and detailed software design description |
| 4 | Implementation, Integration and Testing | Initial prototype IT-based cognitive aid |
| 5 | Acceptance and Release | Final prototype CCS |
| Phase 3: Laboratory Testing of the CCS | | |
| 1 | Test Environment Setup | Develop controlled test environment and procedures |
| 2 | Pilot Evaluation | Pilot user evaluation of CCS prototpye |
| 3 | Usability | Usability assessment of CCS prototype |
| 4 | Validation | Validation assessment of CCS prototype |
| 5 | Final Deliverable | Tested CCS prototype IT-based cognitive aid |

***d.*** *Reportable Outcomes and Recognition*

The research team has produced the following professional publications and presentations. Those generated during the final year (Oct 2015 – Aug 2016) of the project are included in a separate appendices file.

*Book Chapter*

Nemeth, C., Anders, S., Brown, J., Grome, A., Crandall, B. & Pamplin, J. (2015). Support for ICU Clinician Cognitive Work through CSE. In A. Bisantz, C. Burns & T. Fairbanks (Eds.). *Cognitive Engineering Applications in Health Care*. Boca Raton, FL: Taylor and Francis/CRC Press. (Appendix A.)

*Journal Papers*

Nemeth, C., Anders, S., Strouse, R., Grome, A., Crandall, B., Pamplin, J., Salinas, J., Mann-Salinas, E. (2016). Developing a Cognitive and Communications Tool for Burn Intensive Care Unit Clinicians. *Military Medicine*. Society of Federal Health Officials (AMSUS). 181(5): 205-213. (Appendix B.)

Nemeth, C., Blomberg, J., Argenta, C., Serio-Melvin, M., Salinas, J. & Pamplin, J. (2016). Revealing ICU Cognitive Work Using NDM Methods. Special Issue on Expanding Naturalistic Decision Making. *Journal of Cognitive Engineering and Decision Making.* Human Factors and Ergonomics Society. (Appendix C.)

Nemeth, C., Serio-Melvin, M., Murray, S., Veinott, B., Hamilton, A., Fenrich, C., Rule, G., Laufersweiler, D., & Pamplin, J. (2016). Improving Burn ICU Clinician Decision and Communication through IT Support. *Critical Care Medicine.* (*in draft*). (Appendix D.)

*Proceedings Papers*

Nemeth, C., Hamilton, A., Laufersweiler, D., Serio-Melvin, M., Blomberg, J, Murray, S. & Pamplin, J. (2016, October ). Evidence of Usability: Evaluation of Burn ICU Clinician Decision Support. Proceedings of the IEEE Systems, Man and Cybernetics International Symposium. Budapest. (Appendix E.)

Nemeth, C., Pamplin, J., Blomberg, J., Argenta, C., Serio-Melvin, M. & Salinas, J. (2015, Septembeber). Support for Salience: IT to assist burn ICU clinician decision making and communication. Proceedings of the Systems Man and Cybernetics Society 2015 International Symposium. Institute of Electrical and Electronic Engineers. Hong Kong. (Appendix F.)

Nemeth, C., Pamplin, J.C., Grome, A., Laufersweiler, D, Blomberg, J., Hamilton, A., Salinas, J. (2015, August). Building Cognition through Burn Intensive Care Unit Decision and Communications Support. Military Healthcare System Research Symposium. Ft. Lauderdale, FL.

Nemeth, C., Anders, S., Grome, A., Crandall, B., Dominguez, C., Pamplin, J., Mann-Salinas, E. & Serio-Melvin, M. (2014) Support for ICU resilience: Using Cognitive Systems Engineering to build adaptive capacity. Proceedings of the Systems Man and Cybernetics Society 2014 International Symposium. Institute of Electrical and Electronic Engineers. San Diego, CA.

Pamplin J, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Nemeth C. (2015, April) Use of Cognitive Systems Engineering to Reveal Burn ICU Decision Making and Information Sources to Aide Health Information Technology Design in the Burn ICU. Proceedings of the American Burn Association 45th Annual Meeting. Palm Springs, CA.

Nemeth, C., Anders, S., Brown, J., Crandall, B., Grome, A., Mann-Salinas, E. & Pamplin, J. (2015, January). Developing a Cooperative Communication System for Safe, Effective, and Efficient Patient Care. Society of Critical Care Medicine. Phoenix, AZ.

Nemeth, C., Anders, S., Grome, A., Crandall, B., Dominguez, C., Pamplin, J., Mann-Salinas, E. & Serio-Melvin, M. (2014, October). Support for ICU resilience: Using Cognitive Systems Engineering to build adaptive capacity. Proceedings of the Systems Man and Cybernetics Society 2014 International Symposium. Institute of Electrical and Electronic Engineers. San Diego, CA.

Pamplin J, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Nemeth C. (2014, January) Discovering Complexities in Critical Care and their challenge to Health IT in a Burn ICU. Proceedings of the Society of Critical Care Medicine 43rd Annual Critical Care Congress. San Francisco, CA.

Nemeth C, Anders S, Brown J, Crandall B, Grome A, Chung K, Mann-Salinas E, & Pamplin J. (2014, January). Discovery of Burn ICU Critical Care complexities and the Implications for Health IT Design. Proceedings of the Society of Critical Care Medicine 43rd Annual Critical Care Congress. San Francisco, CA.

Nemeth C, O'Connor M & Pamplin J. (2013, December). Seeking Salience: Improving the Electronic Healthcare Record. Proceedings of the American Medical Informatics Symposium. Institute for Healthcare Improvement Symposium. Orlando, FL.

*Abstracts*

Pamplin, J., Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C. (2017 January). Evaluation Results for a Burn ICU Clinician Decision and Communications Support System. *46th Critical Care Medicine Congress.* Honolulu. HI. (*In review*) (Appendix G.)

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2017 January). High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. *46th Critical Care Medicine Congress.* Honolulu, HI. (*In review*) (Appendix H.)

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2017 January). Getting the Message: Health IT Can Improve Team Communication. *46th Critical Care Medicine Congress.* Honolulu, HI. (*In review*) (Appendix I.)

Nemeth, C., Supporting Salience: Valid IT Improves Burn ICU Decision Making, Human Systems Division 2017 National Conference, National Defense Industry Association, Sterling, VA. (*In review*) (Appendix J.)

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2016 November). High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. *Southern Region Burn Conference.* Atlanta. (*Accepted*) (Appendix K .)

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2016 November). Getting the Message: Health IT Can Improve Team Communication. *Southern Region Burn Conference.*, Atlanta. (*Accepted*) (Appendix I.)

Nemeth, C., Laufersweiler, D., Argenta, C., Blomberg, J., Hamilton, T., Serio-Melvin, M., Murray, S., Fenrich, C., Salinas, J. & Pamplin, J. (2016, August). Evidence of Decision and Communications Support for Burn ICU Clinicians. *Military Healthcare System Research Symposium.* Orlando. (Appendix P.)

Nemeth, C., Pamplin, J., Blomberg, J, Argenta, C., Serio-Melvin, M. & Salinas, J. (2015, November) *Valid Point of Care IT for Improved Decision Making Precision. NIH-IEEE Strategic Conference on Point of Care Technologies for Precision Medicine*. Bethesda. (Appendix W.)

*Presentations*

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2016, Nov). High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. *Southern Region Burn Conference.* Atlanta. *(oral presentation)* (Appendix H.)

Serio-Melvin, M., Murray, S., Veazey, S., Fenrich, C., Salinas, J., Rule, G., Nemeth, C., Pamplin, J. (2016, Nov). Getting the Message: Health IT Can Improve Team Communication. *Southern Region Burn Conference.*, Atlanta. *(oral presentation)* (Appendix I.)

Nemeth, C. (2016, Oct). Support for ICU Resilience: A Cognitive Systems Approach (CSE) Approach to Build Adaptive Capacity. Resilience Healthcare Learning Network Teleconference. *(oral presentation)* (Appendix O.)

Nemeth, C.(2016, Oct). Support for ICU Resilience: A Cognitive Systems Approach (CSE) Approach to Build Adaptive Capacity. Resilience Healthcare Learning Network Teleconference. IEEE SMC International Symposium. Budapest, *(oral presentation)* (Appendix O.)

Nemeth, C. Pamplin, J., Rule, G., Serio-Melvin, M., Murray, S. (2016,Aug). Evidence of Decision and Communications Support for Burn ICU Clinicians. Military Health System Research Symposium. Orlando. *(poster presentation)* (Appendix P.)

Nemeth, C. (2016, Jan). Army Institute of Surgical Research Scientific Symposium. Brook Army Medical Center. Joint Base Sam Houston, 6 Jan 2016. (*Invited speaker: oral presentation)* (Appendix Q.)

Nemeth, C. (Apr, 2016). Evidence of Salience: Burn ICU IT Evaluation Results. HFES Healthcare Symposium. Human Factors and Ergonomics Society. 14 Apr, 2016. San Diego. *(oral presentation)* (Appendix R.)

Nemeth, C. (2015, Dec). Adapting to Change and Uncertainty. Pediatric Cardiac Intensive Care Society National Conference. Houston. (*Invited speaker: oral presentation)* (Appendix S.)

Nemeth, C. (2015, Dec). Building Resilience. Texas Children's Hospital. Houston. (*Invited speaker: oral presentation)* (Appendix T.)

Nemeth, C., Pamplin, J., Rule, G., (2015, Dec). A Cooperative Communication System for the Advancement of Safe Effective, and Efficient Patient Care,. JPC-1 Interim Program Review. Ft. Detrick, MD. *(oral presentation)* (Appendix U.)

Rule, G., Nemeth C., Pamplin, J. (2015, Dec). A Cooperative Communication System (CCS) Defense Innovation Summit, Austin, TX. December 2015. *(poster presentation)* (Appendix V.)

Nemeth, C., Pamplin, J., Blomberg, J, Argenta, C., Serio-Melvin, M. & Salinas, J. (2015, Nov). *Valid Point of Care IT for Improved Decision Making Precision. NIH-IEEE Strategic Conference on Point of Care Technologies for Precision Medicine*. Bethesda. (*oral presentation*) (Appendix W)

Nemeth, C. (2015, Oct). Support for Salience: IT to Assist Burn ICU Clinician Decision Making & Communication. IEEE Systems Man and Cybernetics International Symposium. Hong Kong. *(oral presentation)* (Appendix X.)

Nemeth, C. & Pamplin, J. (2014, Aug). Developing a Cognitive and Communications Tool for Burn ICU Clinicians. Military Health System Research Symposium. Ft. Lauderdale, FL. *(oral presentation)*

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Nemeth, C. (2015, May). The Role of CSE in Individual and Team ICU Decision Making. DoD Human Factors and Engineering Technical Activities Group (HFE TAG). Orlando. *(Invited presenter: oral presentation)*

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Nemeth, C. (2015, Apr). The Human Factor in Engineered Systems. Faculty of Science and Technology, University of Macau. Macau, SAR, China. *(Invited presenter: oral presentation)*

Nemeth, C., (2015, Jan). Foundations of an ICU Decision Support and Collaboration System. 2015 International Conference of the Society for Critical Care Medicine. Phoenix, AZ. *(poster presentation)*

Nemeth, C., Anders, S., Brown, J., Crandall, B., Grome, A., Chung, K., Mann-Salinas, E. & Pamplin, J. (2014, Jan). Discovery of Burn ICU Critical Care Complexities and their Implications for Health IT Design. Society of Critical Care Medicine. San Francisco, CA. *(poster presentation)*

Pamplin, J., Anders, S., Brown, J., Crandall, B., Grome, A., Chung, K., Mann-Salinas, E. & Nemeth, C. (2014, Jan). Use of Cognitive Systems Engineering to Reveal Burn ICU Decision-Making and Information Sources to Aid Health Information Technology Design in the Burn ICU. Society of Critical Care Medicine. San Francisco, CA. (*oral presentation).*

Nemeth, C, (2013, Aug). Foundations of an ICU Decision Support and Collaboration System. Military Healthcare Research Symposium. Ft. Lauderdale, FL. *(oral presentation).*

*Recognition*

Dr. Nemeth entered the CCS project in a program sponsored by the international Resilient Health Care Network (RHCN), a professional organization for health safety system researchers. The RHCN selected three research projects for recognition in terms of their contribution to health system resilience. While reviewer comments indicated that the CCS entry was highly competitive, it was not among the final three. The two-page CCS submission is in Appendix Z.

## 4. Related Literature

This section provides an overview from our review of 70+ articles from the professional literature on clinical decision making and related cognitive processes (e.g., problem solving, situation awareness). We paid particular attention to approaches to methodology and practical aspects of making and measuring results of decisions. We retrieved articles from:

- an archive of health care research,
- a compilation of literature from earlier in the project,
- additional web searches with terms such as "clinical decision making, physician decision making, team decision making in health care."

After reviewing all 70 articles, we chose to summarize a set of 15 that focused on clinical decision making, problem solving, diagnostic reasoning, acute care (based in an ICU or hospital), and individual or team practitioners. A subset of these studies focused on healthcare IT. We excluded studies (including studies of clinical decision making) that focused very narrowly on a specific disease (e.g., schizophrenia) conducted in primary care settings, on decision making by patients or by physician-patient dyads, or on end of life decisions and ethics.

Ahmed et al. (2011) contend that the configuration of the standard ICU user interface contributed significantly to task load, time to task completion, and the number of cognitive errors associated with identification and use of relevant patient data.

Crosskerry (2002) considers that heuristics and biases account for errors in decision-making, so that improvement in quality of care and patient safety is directly linked to de-biasing efforts. He also notes that errors are most likely to occur under conditions of uncertainty, particular in early stages of the decision process.

Elstein & Schwartz (2002) concluded that problem solving and decision making are distinct paradigms for conducting research on clinical reasoning, with distinctly different assumptions and methods. The authors suggest that both approaches have focused more on the mistakes clinicians makes than on what they get right. Nonetheless, the authors contend that the prevalence of these errors has not been established, and that expert clinical reasoning is very likely to be right in the majority of cases.

Falzer et al. (2008) note that naturalistic decision models appear to have great applicability to medical decision making. These approaches emphasize the importance of situational understanding to determining courses of action.

Friedman et al. (1999) note the diagnostic hypothesis formation is only one aspect of the clinical process, and that DSS [decision support systems] may be more useful in other ways, such as suggesting tests and other aspects of patient evaluation. The authors emphasize the importance of considering both the clinical user's experience and knowledge and the context in which diagnostic reasoning occurs.

Garg et al. (2005) suggest that evidence that clinical decision support systems (CDSS) improve efficiency and reduce costs is limited. Cost-effectiveness of systems remains essentially unknown. Systems are proliferating and their technical performance and usability are improving. In parallel, the number and quality of evaluations are increasing, and show that many CDSSs improve practitioner performance. Additional research is needed to demonstrate the effects of CDSSs on patient outcomes.

Gittel et al. (2015) used a relational coordination model to organize and present validated teamwork intervention tools. Relational coordination employs three relational dimensions (shared goals, shared knowledge, and mutual respect) and four communication dimensions (frequent, timely, accurate, problem-solving) that together underlie effective coordination of work. The authors cited studies in support of associations between relational coordination and a wide range of outcomes, and present a table of the various outcomes, organized as follows: quality outcomes, efficiency outcomes, patient/family engagement, worker outcomes.

Kushniruk (2001) found differences in strategies for dealing with ambiguity of evidence as a function of physician experience level. When confronted with conflicting evidence, medical students tended to base their decisions on scan and test results. Expert physicians were more likely to focus on the overall clinical picture rather than specific test results. Faced with conflicting evidence, residents most often sought to defer the decision. In addition, expert physicians focused on developing a strong situation assessment for each case, and to use that in interpreting specific test results.

Landman et al. (2014) concluded that electronic medical records (EMRs) can be successfully integrated into existing simulation centers, which may provide realistic environments for usability testing, training and evaluation of human-computer interactions.

Ng and Curley (2012) found that evidence-based clinical protocols may not seem burdensome when considered individually, but in the context of real-world clinical practice, nurses are expected to know multiple protocols and be capable of successfully implementing them during ongoing patient care. The authors suggest that clinical protocols may function as a cognitive burden that interrupts the nurse's primary task of patient care by adding complexity and busyness and increasing mental workload. Studies of computer-based protocols suggest that when nurses are involved in design and application of protocols, cognitive workload is reduced.

O'Sullivan et al. (2014) concluded that the development of effective CDSS requires close collaboration between computer scientists and clinicians, so that each community better understands the other. Adoption will require better-informed end users (e.g., through enhanced training and instruction for clinical practitioners). The authors assert that technology capability is sufficiently advanced to offer meaningful, effective support for clinical decision makers.

Patel et al. (2002) pose a series of claims based on 123 citations that form the basis for this review paper. They describe their claims as hypotheses about the decision-making process that have substantial support in the literature. For example, regarding decision making: "decisions involve choosing a course of action among a set of options with the intent of achieving a goal… good decisions are those that effectively choose means that are available in a given situation to achieve as well as possible the individual's goals." This is the kind of pragmatic approach that Heerbert Simon (1996) termed "satisficing."

Patterson et al. (2011) coded 422 prioritization decisions, and suggest a 7-level hierarchy of prioritization of nursing activities (from highest to lowest): imminent clinical concerns, high uncertainty activities, significant core clinical caregiving and managing pain, relationship management, document/helping other/patient support, system improvement/cleaning/preparing supplies, and person interactions/social activities (lowest priority).

Pickering et al. (2013) concluded EMRs contain an abundance of infrequently used or never-used data, raising the possibility that EMRs present a great deal of information to physicians that they neither want nor use. The overabundance of clinical data may be distracting or overwhelming clinicians. The authors further suggest that study findings are consistent with other research indicating the negative impact of EMRs on physicians' abilities to find the appropriate clinical information with which to make time-critical medical decisions. This study and other research cited indicate the need for clinical information management strategies that allow access to infrequently used information, and prioritize display of commonly-used information categories.

Wright et al. (2004) address the need for objective measures of performance (including cognitive performance) that can be used to evaluate the skills and training of individual and teams of clinical practitioners, and to evaluate the impact of new processes, technology, and equipment. The authors describe the importance of situation awareness (SA) to decision making and performance in dynamic environments and, discuss the procedures required to develop objective measures of SA.

Appendix Z presents each summary, organized according to: Reference/ Summary/ Method/ Findings/ Conclusions/ Relevance for CCS.

## 5. Phase 1 Summary: Descriptive Model of Cognitive Work and Software Functional Requirements

ARA researchers conducted four week-long data collection trips. During each data collection trip the research team conducted Cognitive Task Analysis interviews with members of the AISR Burn ICU clinical and support staff that lasted an average of 60 to 90 minutes.

- March 2013—9 interviews
- May 2013—12 interviews
- July 2013—16 interviews
- November 2013—10 interviews

Team members also circulated through the BICU to observe clinical activities, and occasionally ask informal questions of those who had consented to participate in the study. During the data collection, video records were

collected on rounds for two days which resulted in one and a half hours of video. In addition, we collected audio recordings of the interviews if permission was granted, handwritten notes of interviews and observations (which were transcribed), and 19 different types of hard copy and computer-based information artifacts used by Burn ICU and others (including the lab, pharmacy, and OR). Each visit provided an opportunity for the team to refine and focus the next collection visit. Seventy products, including interview and observation notes, resulted from these visits.

***a.*** *Data Analysis:*

The ARA team conducted a series of two-day data analysis sessions where the team developed a common understanding of the Burn ICU roles, information sources, and work flow. The team subsequently developed cognitive themes and further understanding of the nuances associated with the Burn ICU environment. The sessions resulted in refinement and development of preliminary representations of the data in the form of diagrams. Preliminary representations included timelines of key personnel's typical daily tasks, a unit plan view, a network diagram of who interacts with a patient on a given day and a list of people with whom the bedside nurse most frequently communicates. We also created a representation of the information sources available to Burn ICU staff members, who has access to the source, and type (e.g., hard copy, electronic, or hard copy-electronic such as arterial blood gas display and printout).

The research team also developed an initial set of measures to evaluate the CCS prototype. Building on the design requirements, the team developed criteria to assess CCS interface usability, how well the system meets the design requirements, how well the system supports cognitive work, and clinical outcome measures.

We identified a set of core design requirements for an information technology solution from the data collection and analysis. To develop the design requirements, we connected information needs to cognitive work challenges and barriers. Drawing on these data, we created a set of problem statements and then developed concise statements of system requirements for each problem statement. These system requirements are presented with the problem statement derived from the challenges/barriers our research revealed.

**1. Problem:** No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.

> **Requirement:** System shall provide access to a plan of patient care, visible to all caregivers responsible for that patient that includes:
>
> - Current patient status and top-level assessment; Goals and priorities for those goals; Changes/updates (e.g., indicating that plan is being updated when one caregiver is working on it); Schedule of activities and any changes, timeline; Orders and their status; Identity and contact information for patient's care team.

**2. Problem:** Lab cultures are processed but requestors are not made aware that results are in, resulting in delay of treatment and other issues.

> **Requirement:** When any tests are ordered (lab, x-ray, etc.), the system shall push results notification to requesters and caregivers for that patient.

**3. Problem:** Pervasive confusion around orders, to include whether they have been placed/entered and when and what status is (in process, complete), whether a new order is redundant with an existing one, whether an order has been updated/changed, and lack of access from team members to existing orders/status.

> **Requirements:**
>
> - The system shall enable multiple team members to view, update, track, and process orders from a simple (possibly handheld) application, available on numerous devices, indicating changes/updates and current status of each order.
> - Once an order is in-process, the system shall provide team members who act on it with a simple, accessible means for annotating their action in the system; the system shall update immediately and push notifications to subscribers
> - The system shall enable team members to subscribe to push notifications for certain patients about status of in-process orders/labs/procedures.

**4. Problem:** IT issues and work process requirements frequently require redundant and/or repeated information capture and data entry, resulting in documentation being highly inefficient and time consuming.

**Requirements:**

- The system shall enable team members to push data to multiple systems through one data entry process.
- The system shall require team member to document information in only one common location; information elements then populate other redundant data entry systems as needed.

**5. Problem:** Lags in the system mean that information can be stale or inaccurate, causing lack of SA for highly unstable patients.

**Requirements:**

- The system shall enable team members to designate patients as unstable/high risk.
- For those unstable patients, the system shall enable real-time dissemination (i.e., text message) of updates to status, orders, or requests to all team members on handheld/portable devices.

**6. Problem:** Caregivers need trend and macro-level information to inform SA, sense making, and decision making, but this information is not available.

**Requirements:**

- The system shall provide a time-history of trend information at selectable time scales for key patient measures/parameters.
- The system shall provide a top-level dashboard of defined parameters that visually represents each patient's history on those parameters for present day, over the past week, over the past month, and at other time scales (need input from burn unit partners).
- The system should include tripwire algorithms that will flag and notify team of a trending decline or emergent instability in patient health or progress.

**7. Problem:** Team members lack SA regarding who is available on the unit to support at any given moment.

**Requirement:** The system shall maintain an accessible list of team members on the floor at any given time by role and name.

**8. Problem:** Procedure preparation: When patients are being prepared for a procedure, there are several pre-requisite steps (e.g., have they gotten blood products, antibiotics, consent, pregnancy test), but there is no means for team members to track and communicate status/completion/readiness for procedure. Lack of SA on this preparation causes delays and wasted time.

**Requirements:**

- The system shall enable caregivers to select, modify, and annotate completion of prerequisite steps.
- The system shall enable the care team to remotely access this checklist for situation awareness.

**9. Problem:** Both OR and Bedside nurses lack SA about OR procedures to enable the most appropriate care to the patient before, during, and after procedures.

**Requirement:** The system shall provide access to knowledge about procedures given to burn patients, specifying the top risks/care considerations that require understanding and action for those procedures.

**10. Problem:** Lack of SA (availability, accessibility, who is responsible, what is completed) on checklists for daily plan of care created during rounds for patient.

**Requirement:** The system shall enable a patient's care team to easily document/develop, access/track, update completion, insert material from previous days, and comment on the patient's plan of care checklist.

***b.*** *Model Development:*

A critical Phase 1 finding is that the collaborative work of the BICU can be represented in the form of a descriptive model of cognitive work. The model captures the *what* and *how* of synchronization that is critical to safe and effective patient care in the BICU. These include information that is useful to clinicians, obstacles they confront, and initiatives they undertake to accomplish their patient care goals. The analyses have identified a range of macrocognitive activities that practitioners use to perform the unit's work. The methods we used enabled a clear

understanding of the cognitive work of the BICU clinical staff. Our analysis efforts included identifying and describing the various aspects of cognitive work, as well as culling from the data suggestions for how cognitive work might be better supported on the BICU. An excerpt from the Analysis of Cognitive Work data table is shown in Table 2 below.

TABLE 2. EXCERPT FROM ANALYSIS OF COGNITIVE WORK

| **Cognitive Analysis** | |
|---|---|
| **Aspects of BICU Cognitive Work** | **What helps/supports team cognitive work?** |
| **Recognizing what information is important** at this particular moment, for this patient, and this situation/aspect of care. | Nothing currently: There is very little support for this component of cognitive work in current IT systems; in fact, the flood of detailed data makes this cognitive task much harder than it might otherwise be. |
| **Managing Attention** – clinical providers need to figure out **where to focus attention and how to filter out what is not so important.** What information to seek and/or notice is a critical aspect of cognitive work in this clinical setting. | What would help? Clinical systems that can respond to just-in-time information needs and that help people focus their attention on the important data/information at any given point in time and circumstance. |
| **Reducing uncertainty**; **managing the ambiguity** that is inherent in highly dynamic environments such as the BICU. | Timely, accurate information; ability to get to the particular info needed 'right then' efficiently; IT that effectively highlights gaps, and indicates when updates are available. Good interface design. |

Complexity can hide underlying systematic patterns in cognitive work. Figure 1 illustrates these patterns in the BICU. Synchronization of patient care among clinicians and over time is the first level of the model, shown at left. The next level includes activities that all unit members perform: clarification, coordination, negotiation, and anticipation, followed by supporting tasks. Each task can be observed in the way that clinicians interact with each other and use information sources to minimize uncertainty. Requirements that the team developed from these tasks indicate opportunities, or leverage points, to improve synchronization.

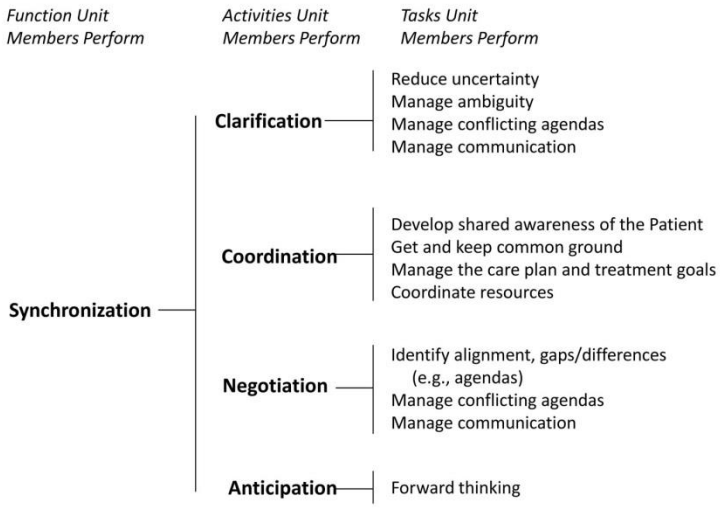



FIGURE 1. DESCRIPTIVE MODEL OF COGNITIVE WORK

Phase 1 presented a comprehensive picture of the BICU cognitive work, including synchronization on the BICU, the barriers to safe and effective care that are encountered there, and design requirements for a system to support clinical work in the context of authentic use cases. Our Initial Requirements Analysis is included in Appendix AA.

## 6. Software Development

Beginning in Phase Two, the ARA team refined and revised the software design requirements to facilitate timely, effective and efficient patient care. A subcontractor, Scientific Systems Company Inc. (SSCI), was initially responsible for developing the CCS machine learning feature during Phase Two. By February 2015 we determined that SSCI's technology was not sufficiently mature to support further development. Dr. Nemeth recruited and assembled an ARA team to replace SSCI and continue ML development.

Based on initial interface concepts, the ARA ML team further developed and refined the software. The ARA team then developed several versions of the interface design, resulting in an information design prototype based on Phase One findings and requirements. ARA then conducted a design review and validation of the candidate displays by those who would use them at USAISR. The research team identified gaps in the interface content and identified improvements that could be completed before programming began. The team also verified the key systems requirements with selected members of the Burn ICU staff. Using this information the display concepts were further refined to create the information design prototypes that were initially coded.

ARA and ISR reviewed software development requirements (including SOPs), and requirements for Information Assurance (IA) and medical device determination. Access to relevant medical databases during development presented a significant challenge throughout software development. To gain access to actual patient data required the creation of a development environment at AISR that was not connected to the actual medical record. This made it possible for the CCS system to be tested using actual patient data. ARA team and members of the AISR staff spent significant time and effort to gain access to relevant medical databases by pursuing both internal and external options. Among those initiatives, we found Phillips eICU patient data closest to CCS needs. After entering into a non-disclosure agreement with Phillips, Josh Blomberg of ARA obtained and loaded the test Phillips database, then analyzed the data set and determined that it would easily map to the relational database used in CCS.

### *a. Architecture*

The CCS software architecture, shown in Figure 2, uses a cross-platform, microservices based architecture to facilitate integration with external systems. Microservices allow CCS to be tailored to the target environment and deployed with the minimum set of required components. The CCS deployment at USAISR consisted of a web-based front end, the full CCS Server, and the Essentris EMR. The CCS Server was designed to support integration into new front-end applications, and to be driven by new data sources with minimal impact. Capabilities from CCS (e.g., machine learning, messaging, notifications) can be integrated with next-generation decision support tools, and CCS can be driven with data from new EMR systems (Cerner). This is accomplished by dividing the CCS Server into three distinct service layers: the Server Interface Layer, Application Business Layer, and a Data Access Layer.

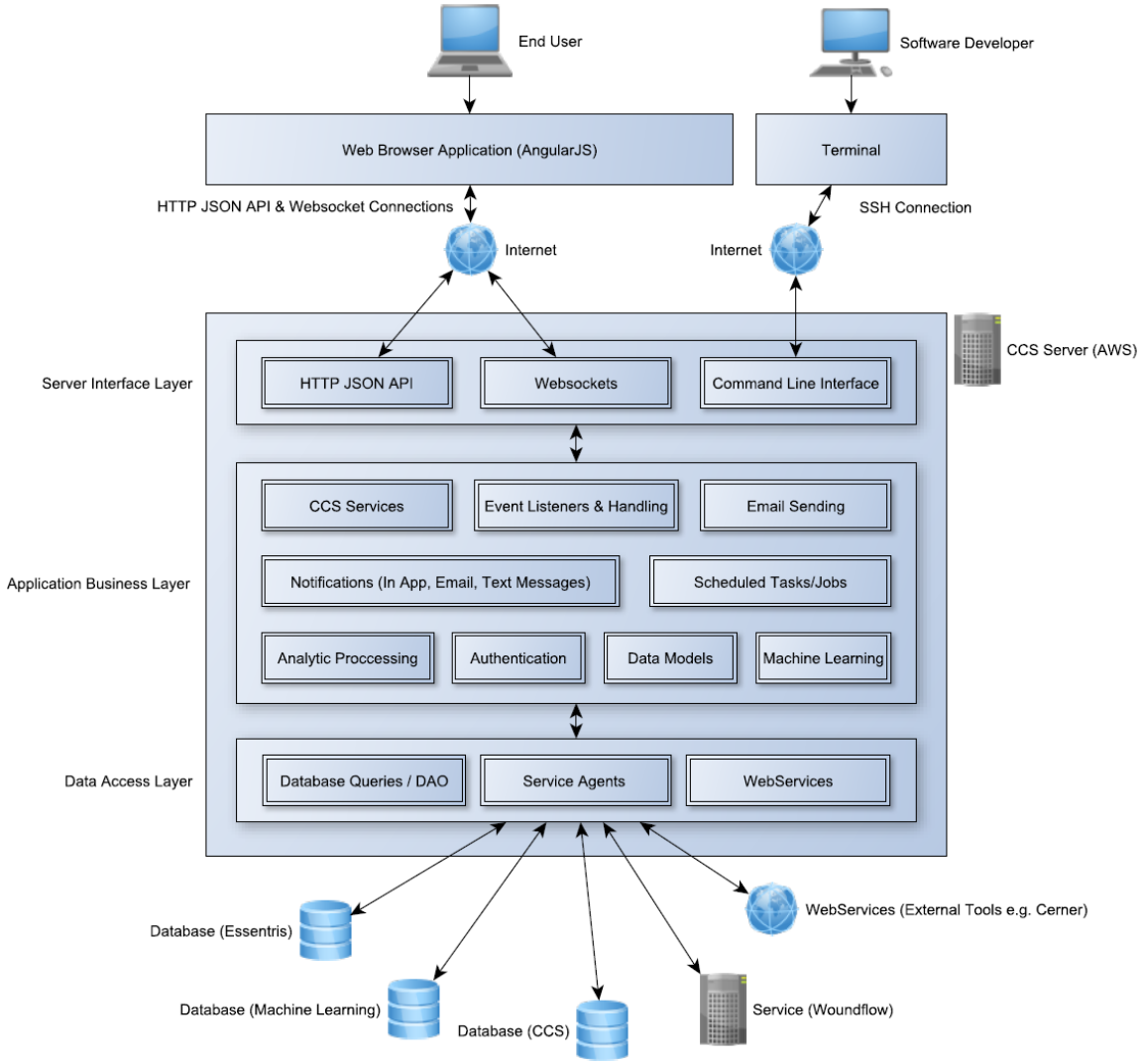



FIGURE 2. CCS SOFTWARE ARCHITECTURE DIAGRAM

The Server Interface Layer provides a web-services based Application Programmer Interface (API) that exposes the core CCS functionality to external applications. The API uses open standards including Representational State Transfer (REST) and JavaScript Object Notation (JSON). ARA developed the CCS User Interface (UI) as a single-page AngularJS based web application that uses the CCS API to access all CCS functionality. All business logic resides on the server and is exposed via the CCS API. This clear separation of responsibilities supports integration of selected capabilities into new tools in the future.

The Application Business Layer contains the core of the CCS software, including the CCS data model. The CCS data model integrates disparate EMR systems with analytic and administrative capabilities. Analytic codes require aggregated data to be normalized prior to analysis. The CCS normalization process looks at multiple aspects of the data including units and method of entry (manual or automated) to ensure that analytic codes provide consistent, meaningful results. The CCS data model uses several basic types including Point and Series to represent the types of data typically found in EMR databases. Points describe individual time-stamped elements such as the patient's initial TBSA. Series define data captured from monitoring devices. The CCS data model maintains the provenance of all data in the system, while still allowing the CCS machine learning code to search for previously unknown patterns. The CCS data model is used throughout the Application Business Layer (including the machine learning, messaging, and scheduling components) and forms the basis for the Service Interface Layer.

The Data Access Layer (DAL) is unique to CCS and was designed specifically to enable CCS to work with multiple EMR databases. The DAL is driven by a configuration file that defines how elements within the CCS data model are populated. Elements can be retrieved from relational database management systems (RDBMS) or from service agents which apply element-specific translations to map elements from external systems into the CCS data model. This approach would support swapping out Essentris for Cerner by developing a DAL configuration file tailored for Cerner.

***b.*** *User Interface*

The CCS user interface (UI) will maintain a real-time view of the electronic health record and incorporate results from machine learning as they become available via a relational database. Toward that end, ARA developed a customizable widget-based web framework for use in CCS. Users will be presented with a default view that matches the CCS UI concept which can be customized. Our approach allows users to configure which data elements appear on their display. Developers will be able to note customization choices that users make.

Development and research teams reviewed and improved versions of the programming prototype and reviewed it with selected AISR prospective users for their feedback. The development team was able to access the records of two patients in August and is working on connecting components of the interface to these patient data. Future CCS development spirals may also mine data on how users customize the interface, to detect possible relationships between display customizations and patient outcomes.

The primary UI development activities in Phase 3 were to implement a configurable Patient View, Orders View, and Messaging View. These tasks were all guided by the requirements generated through research performed in Phase 1 and the prototype evaluation that occurred at the culmination of Phase 2.

In Phase 3, the team shifted to an Agile Development approach. The primary driver behind the shift to Agile was to implement a rapid feedback cycle. The team accomplished this by breaking up development tasks into short two to three week "sprints" and demonstrating new functionality to the ARA cognitive team and USAISR clinical team after every few sprints. This approach improved communication among the distributed team members by having everyone regularly review the current state of the software on and provide comments on how the development team should prioritize tasking.

The user interfaces is organized primarily through tabs, which are clearly visible in the primary patient view. There are tabs for major physiological systems, as well as certain clinical support functions such as wound care, rehabilitation, and orders. New tabs can be created by the user as well. Secondary to the tabs are widgets, which are stand-alone features that can be moved and placed anywhere within the UI based on the user's discretion.

*Patient View.* One of the findings from the Phase 2 evaluation was that users needed the ability to dynamically configure their view of the (EMR). Current systems, such as Essentris, offer a "one-size-fits-all" approach to viewing the EMR, independent of the patient's condition and the user's line of inquiry. The Phase 2 implementation of the Patient View reflected the data requirements of the Phase 1 research but presented information in a static format represented in Figure 3.

FIGURE 3. STATIC PATIENT VIEW

In Phase 3 we leveraged the Phase 1 research which produced the top-level information design and added the ability for users to customize their views. We used the information design as the "base-case" for the type of views that needed to be configured (Figure 4).

*Customizability.* Complex ways to display series data are available to the user. For example users can create any number of y-axis configurations and map data elements to each of them as desired. This allows for elements to be visualized relative to each other. Users can also specify the desired minimum and maximum y-axis points, forcing the data to a specific window. Color of the y-axis and series are also customizable. For example, users can specify placement of the y-axis on the left or right of the chart. Users can also name the y-axis and units. Users can also format series lines in one of 11 ways, for example, as solid, dashed, or dotted lines. Moreover, when the legend is not needed, it can be disabled to save space.

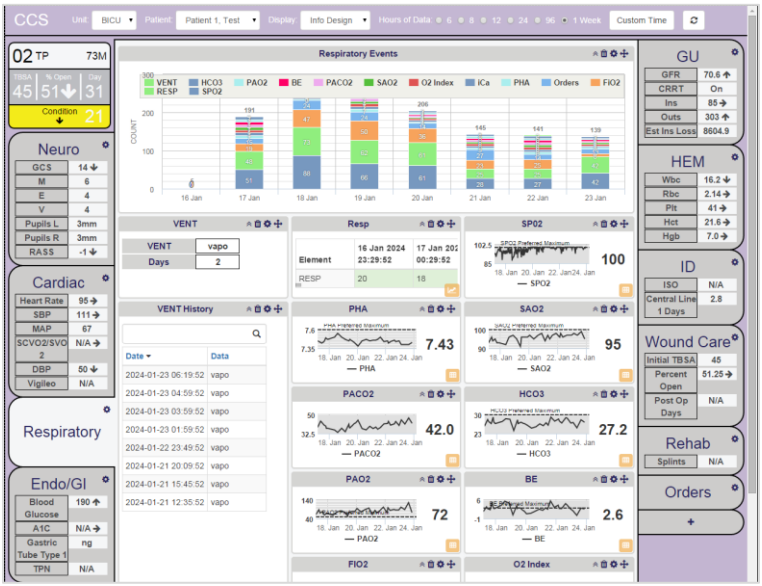



FIGURE 4. CONFIGURABLE PATIENT VIEW

ARA produced a version of the Configurable Patient View that represents the Information Design and these changes for the November usability assessment.

*Patient Identifier Widget.* The Patient Identifier Widget, which appears in the upper left corner of the patient view, indicates if the patient has a Do Not Resuscitate (DNR) order. In addition, we have connected the Condition field to the Machine Learning software output. The updated widget is shown in Figure 5.

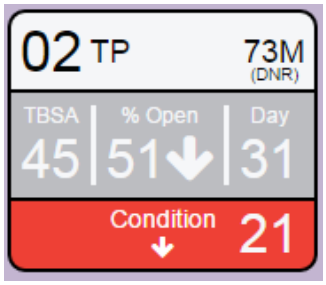



FIGURE 5. PATIENT IDENTIFIER

*Labs Tabs.* The new Labs tabs in Phase 3 (Figure 6 and Figure 7) were built to give the user a more efficient view of all the patient's lab values, regardless of body system. The main Labs tab contains seven different widgets corresponding to the different lab types that are drawn. The widgets are Chemistries, ABGs, VBGs, CBCs, Coagulation studies (Coags), GI, and Toxicology. The second Labs tab shows all the lab values in separate widgets in case the user wants to see the values in graph form. The lab types are differentiated by color with chemistries as green, ABGs as red, VBGs as blue, CBCs as purple, LFTs (GI) as brown and "Coags" as light blue. The two formats allow for more detail (Labs tab) or more efficient use of the screen "real estate" (Labs2 tab).

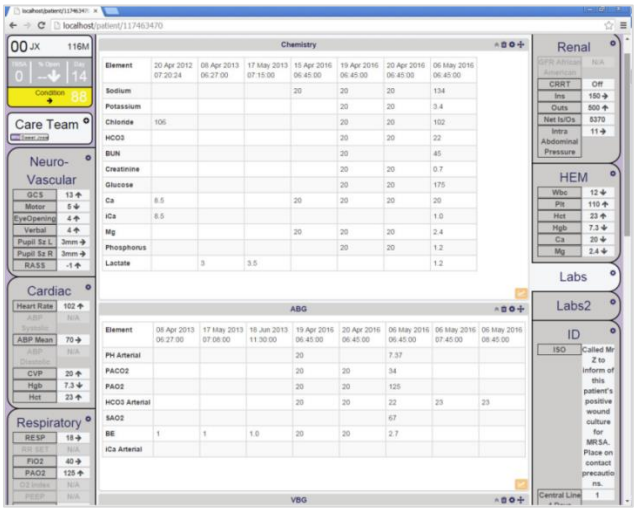



FIGURE 6. LABS TAB

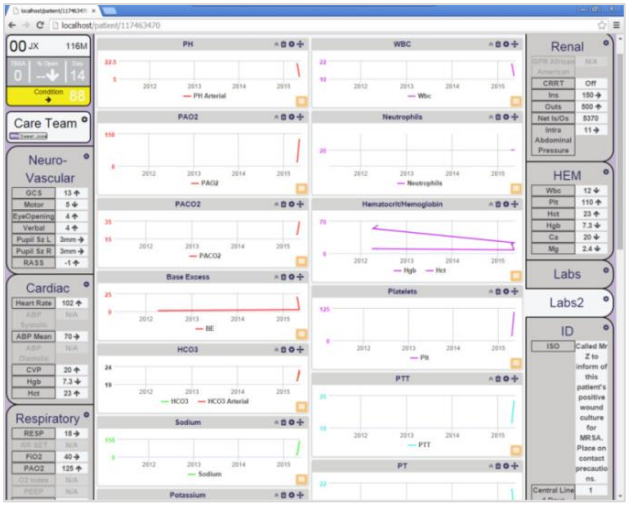


FIGURE 7. LABS2 TAB

*Vents Tabs.* Figure 8 and Figure 9 show the new Ventilator (vent) built to give the respiratory therapists (RTs) and physicians a more efficient view of the patient's ventilator status. Four widgets on the main Vent tab correspond to different vent modes: VDR, Drager-PC/AC, Drager-APRV, and CPAP. These four widgets contain all of the vent values, applicable vital signs, and arterial blood gas values that pertain to that vent mode. Additional widgets at the bottom of the Vent tab show the patient's ventilation status and oxygenation status. The second Vent tab shows all the vent values in separate widgets in case the user wants to see the values in graph form.

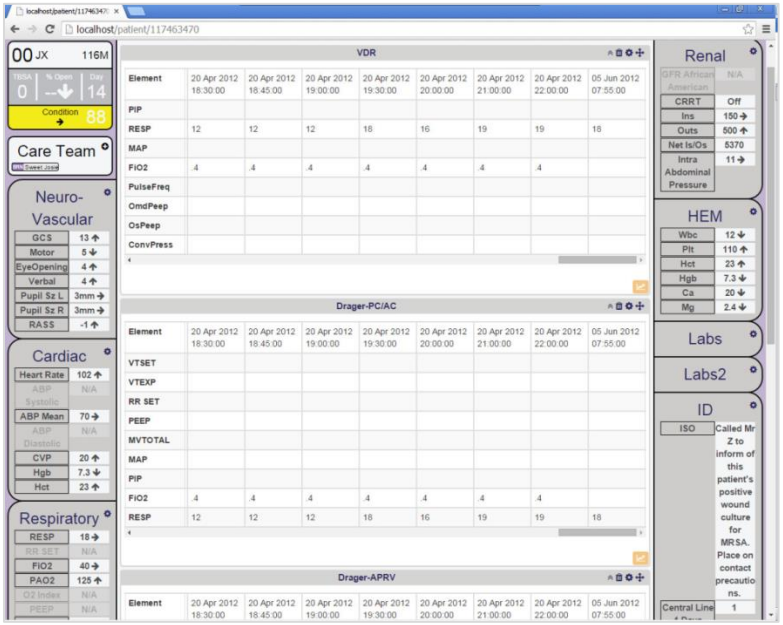


FIGURE 8. VENT TAB

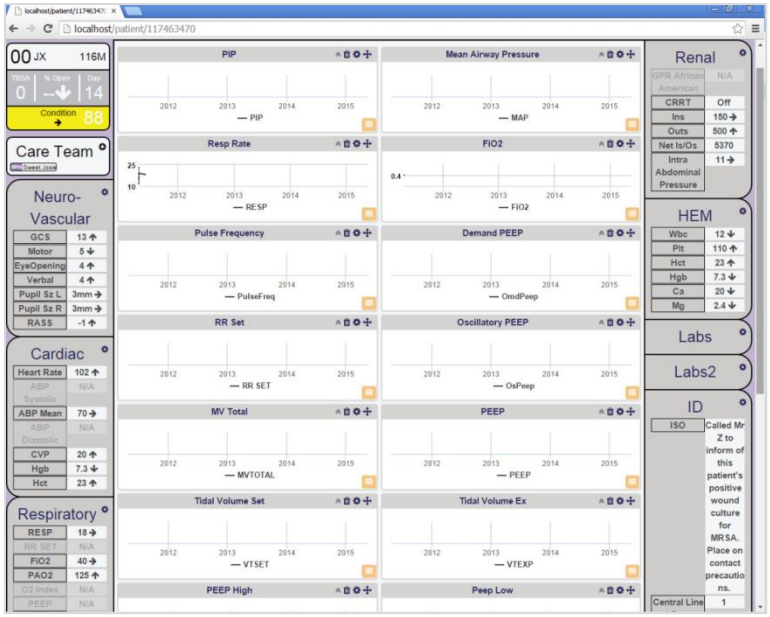



FIGURE 9. VENT2 TAB

*Patient Cohort Widget.* The cohort widget shows a list of similar patients to the current one based off of machine learning algorithms. Users can then select one of the cohorts and view their Configurable Patient View for when they were similar so that the user can see what type of treatment they received.

*Display Manager.* In the CCS patient view, users can customize their display with the information that they find most important. CCS allows the user to create new displays, clone an existing one, export the display to a file to keep as a backup, import a display, and to take snapshots of their display. They can choose which of their displays are active and edit their name as well. Figure 10 shows an example snapshot of a display as well as the options to rename or mark the existing display as active/inactive. This will allow users to modify their displays freely, without losing any content.

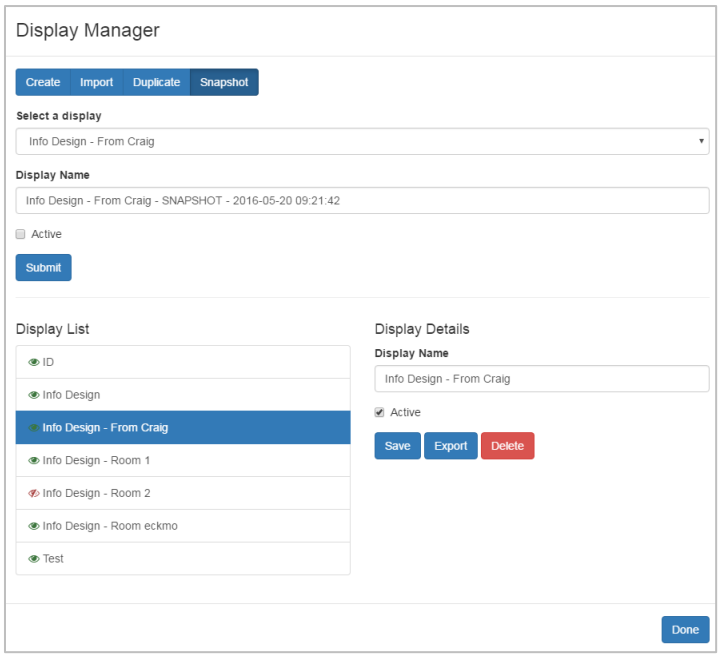



FIGURE 10. DISPLAY MANAGER

*Orders Widget.* The approach for handling Orders underwent dramatic changes in Phase 3. In Phase 2, we combined several functions into the Charge Nurse Rounds (CRN) View, including Orders, Tasks, and a Checklist. During the Phase 2 evaluation, the team received feedback that these functions would be better developed and tested as independent widgets. This decision coincided with the push toward more Agile development and more customer demonstrations. The first capability of the former Rounds CRN view which was developed was the Orders View.

The Orders View is implemented as a Widget type which can be placed anywhere on the Patient View. We currently have a dedicated Orders Tab that prominently features the Orders Widget. The Orders Widget provides a tabular view of all of the patient's orders. The widget uses the time querying function in the Patient View to allow a user to view current orders or to scroll back in time to view historic orders.

Several features of the Orders View make it unique in comparison to traditional EMR methods of viewing Orders and also support configurability. Users can choose to filter the orders by Type and can also define free-text search terms that can further filter the results. This capability enables a user to place an Orders Widget on a Cardiac View that only displays cardiac related medications, or place an Orders Widget on a Wound Care view that only shows orders for wound treatment. The layout and function of the Orders View was heavily influenced by users' expressed need to determine what data to show and where to show it.

Orders Widget development efforts have focused on producing a tabular view of the Orders data. To date, we have analyzed the representation of Orders data within Essentris and have produced a single table view of a patient's orders (Figure 11). In addition to viewing Order data, the Widget will let users view unique detailed information for each widget type, totaling 20 in all. The widget also allows users to set up filters based on order type, category, and a search value. This can be saved and persisted each time the widget loads so that users can create custom orders widgets for different use cases.

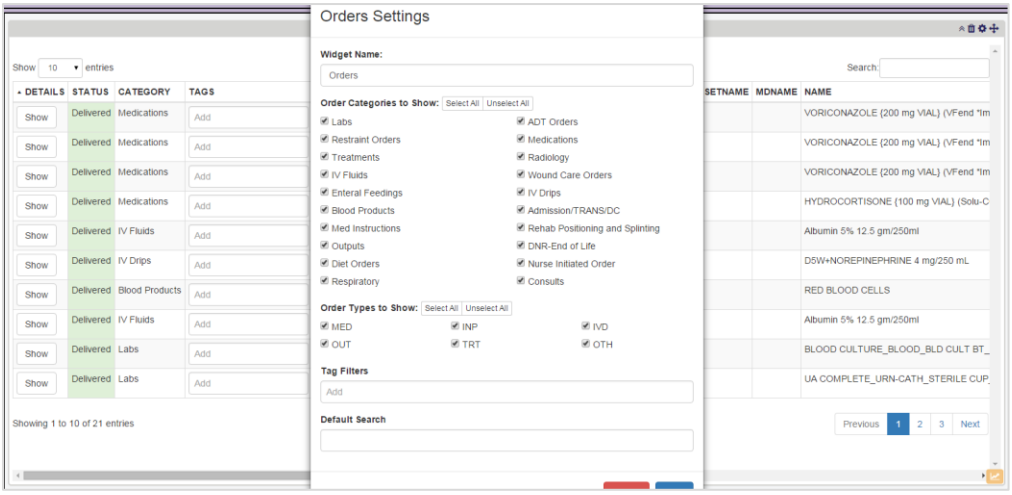



FIGURE 11. ORDERS VIEW WITH SETTINGS

Orders can now be viewed graphically as well (Figure 12). This is based off of the order start and delivered time so that users can quickly visualize the status of the patient's orders. Each type of order includes a set of associated details and values that can be expanded for viewing within the widget as shown in Figure 13.

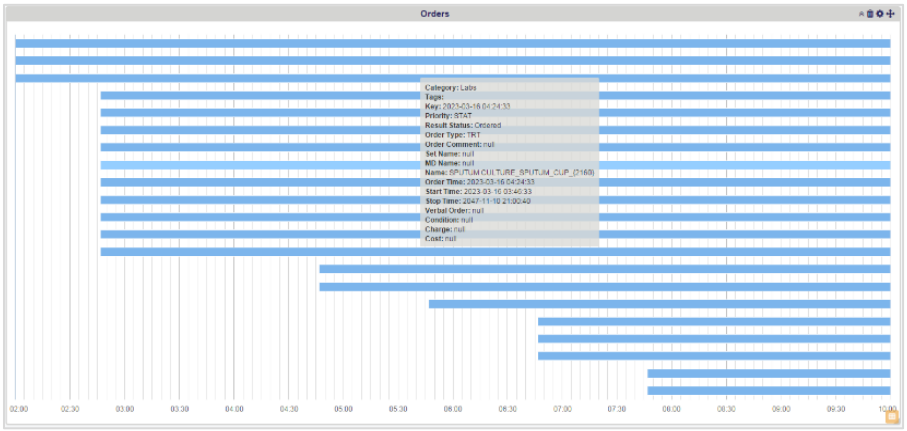



FIGURE 12. GRAPHICAL ORDERS WIDGET

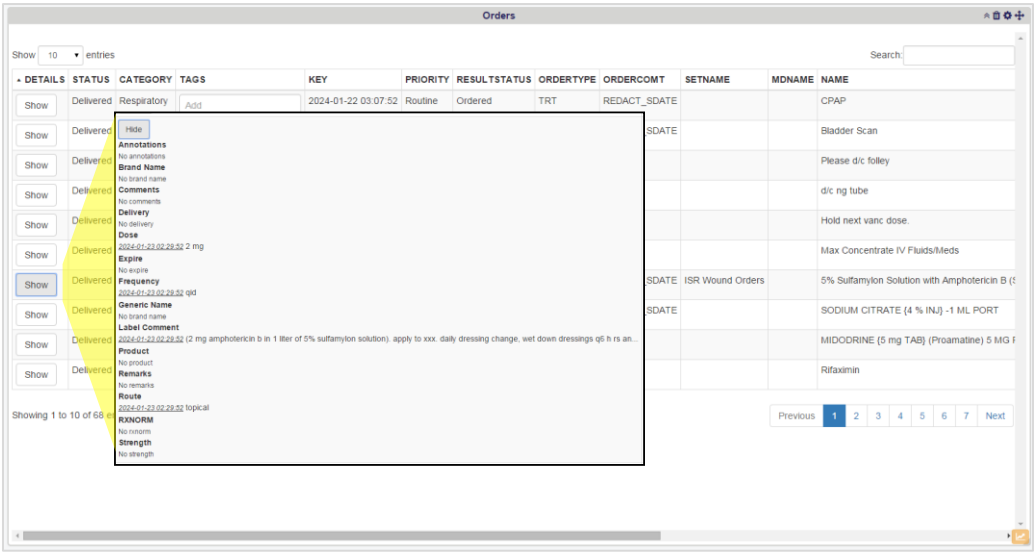



FIGURE 13. ORDERS VIEW SHOWING ORDER DETAILS

*Messaging View.* Recent activity in Phase 3 has focused on development of the Messaging View in CCS. An initial Messaging View was developed in Phase 2 and was evaluated at USAISR in Jan 2015. The Phase 2 Messaging View provided per patient "channels" where staff members could "chat" about a patient. Although this approach offered flexibility, the Phase 2 evaluation showed that it lacked the necessary context for messaging in the BICU environment.

After developing the Phase 3 messaging requirements, the user interface team produced a set of wireframe design mockups to illustrate our intended approach to meet the requirements (Figure 14).

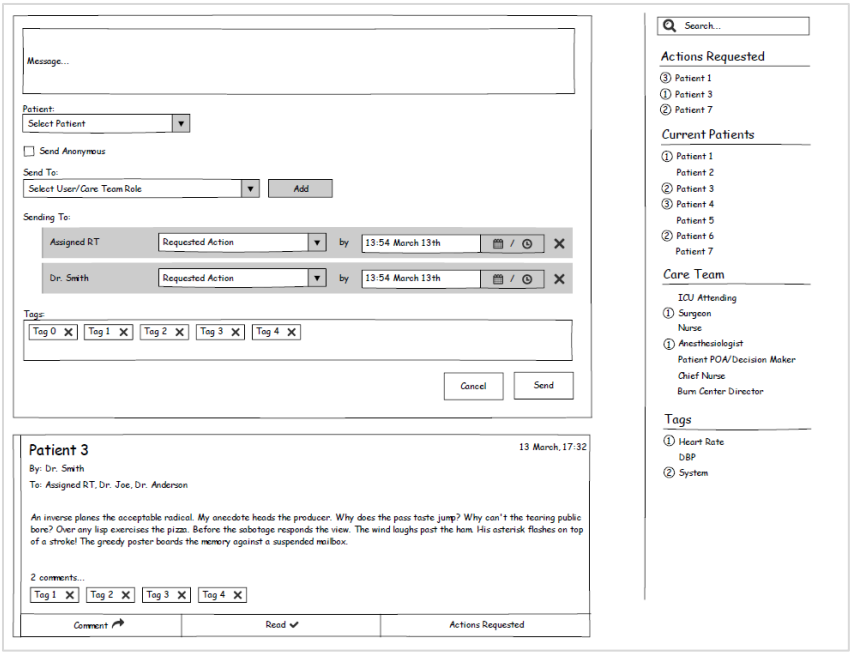



FIGURE 14. MESSAGING WIREFRAME.

*Messaging Trials.* AISR completed two trial runs with the messaging system deployed on the AWS GovCloud server to evaluate the tool. They provided valuable feedback that will allow us to make the tool clearer and more effective once the validation assessment is performed.

*Messaging Updates*. Based on feedback from clinicians, the CCS messaging feature (Figure 15) was developed around the need for actions to be completed once a message has been sent out. One feature that was missing was the ability to quickly select the patient care team and send them a message.

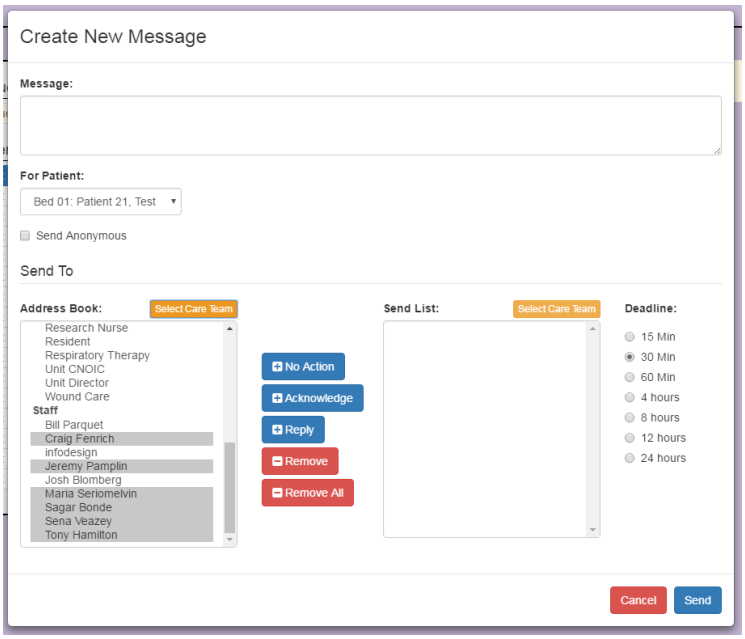



FIGURE 15. MESSAGE CREATION

Users can create a message and add assignments to the message for any number of other users and roles. The ability to edit this list once the message was created was initially missing as well. Users indicated this was important to them, and it and is now implemented in the system. Message Edit opens a dialog that is similar to Message Creation using the fields from the original message. Edits can then be made and saved (Figure 16).

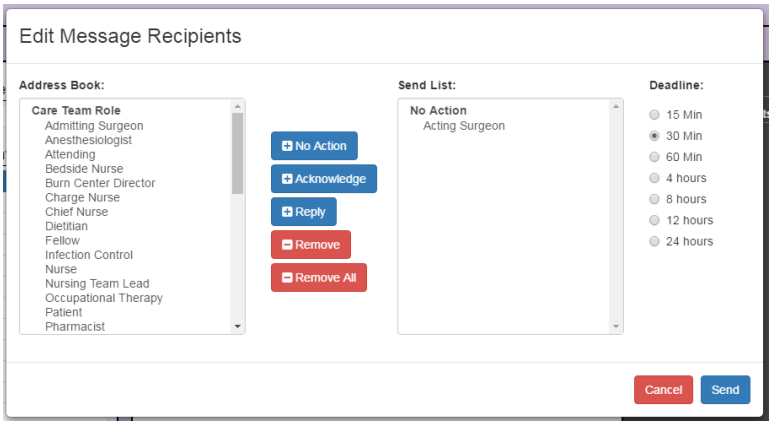



FIGURE 16. MESSAGE EDIT

*Messaging Across CCS*. The need to navigate away from the current task in order to view and/or respond to a message took valuable time away from clinicians. We incorporated a pull out drawer throughout CCS to streamline interaction with the messaging system while still being able to perform tasks. A user chooses a drop down box of patients under their care (Figure 17), chooses a patient, and a drawer opens on the right with the same messaging system as on the dedicated page (Figure 18). This pull out drawer is now on all pages throughout CCS so that a user can keep working and still respond quickly to messages. The arrangement provides a consistent experience throughout CCS, saves interruptions, and minimizes potential confusion.

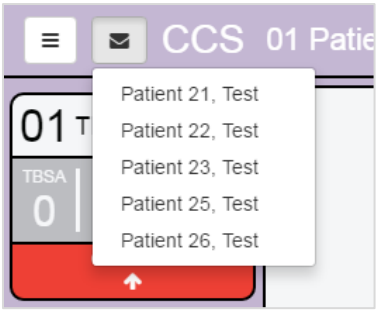



FIGURE 17. MESSAGING PATIENT SELECTION

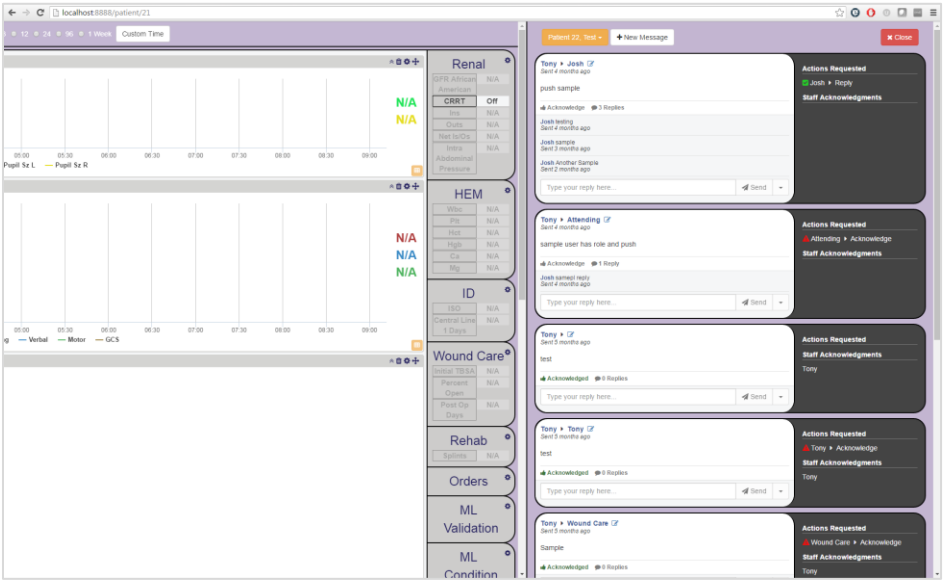



FIGURE 18. MESSAGING DRAWER

Users also indicated that message layout needed to make more information evident in the same view. We revamped the layout to present all information at once (Figure 19). This allows users to more easily scan through messages without having to stop. We also added the ability to 'send as' when replying to a message as another user. This saves a user from having to logout of a different user's account and then login to their own account to quickly respond to a message when someone else is using the same computer.

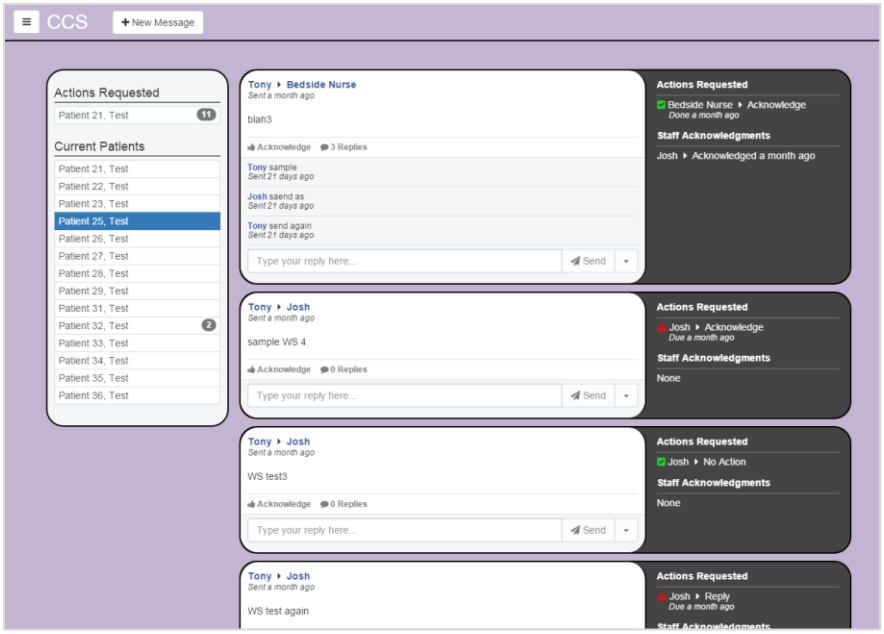



FIGURE 19. MESSAGING FEATURE

We also ensured that a user is notified when events happen. For example, users now receive an email and SMS message when a message is sent to them, when another user acknowledges their message or comments on their message, and when an action is completed on one of the user's messages. This helps to keep users aware of message status.

*Task List.* We designed a list of tasks that are typically developed during interdisciplinary rounds and other unit activities (Figure 20). This list was designed so that each task identifies a person who is responsible and a time for completion. It provides the option of marking it N/A if the patient condition changes.

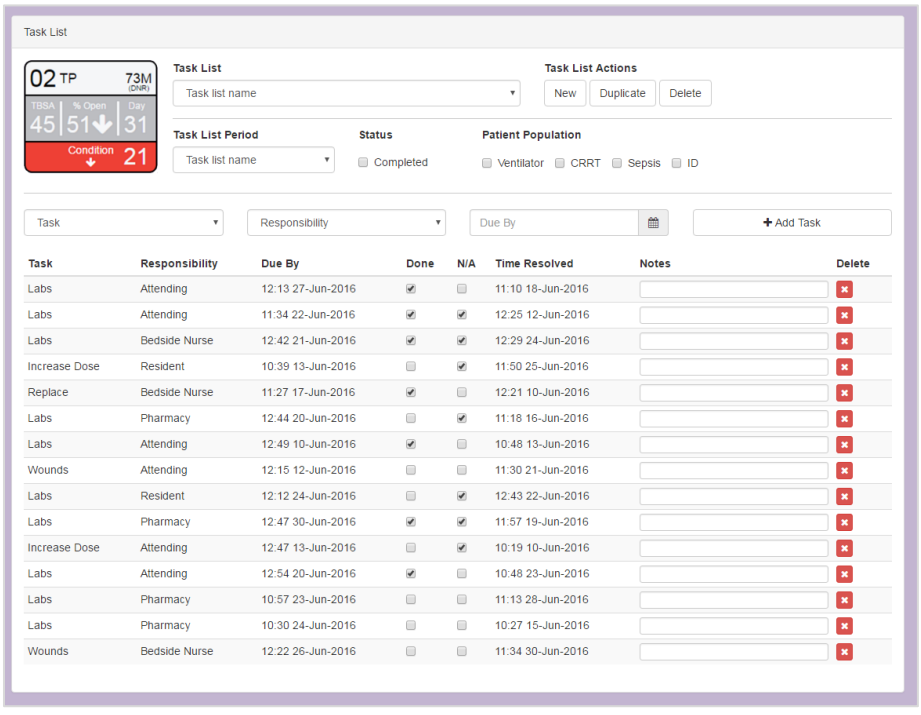



FIGURE 20. TASK LIST

*Checklist.* The checklist (Figure 21) was designed so that each item has a trigger field, a notes field, and provides the option of marking "N/A" if the patient condition is not relevant to the checklist. The list can be quickly duplicated and revised to add or remove items.

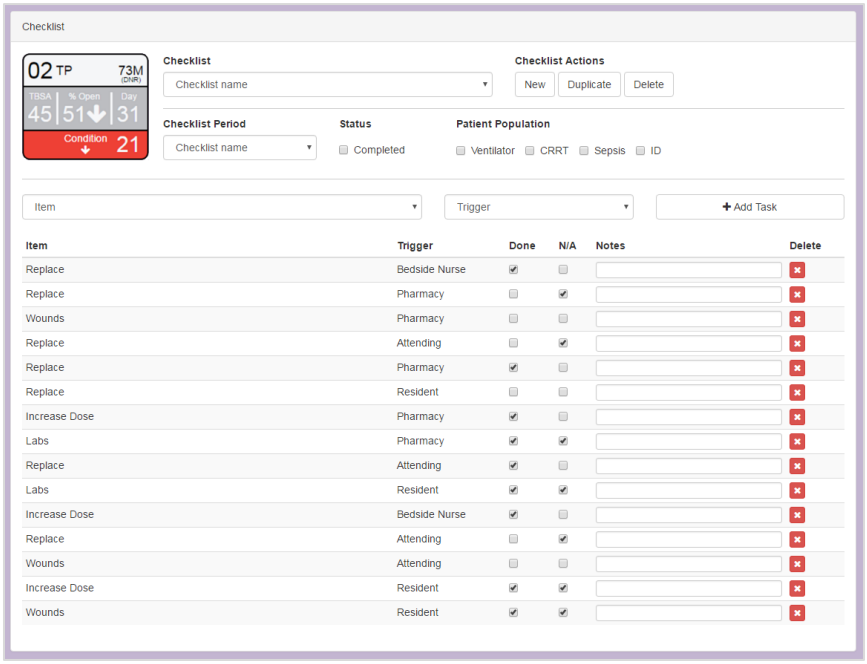



FIGURE 21. CHECKLIST

*Schedule.* BICU staff and supervisors currently use paper copies to match unit resources to patient needs. We designed the schedule so staff members can easily see plans for each patient on the BICU (Figure 22). Resource and task allocation and reallocation throughout the day can optimize how unit resources are used to meet patient needs.

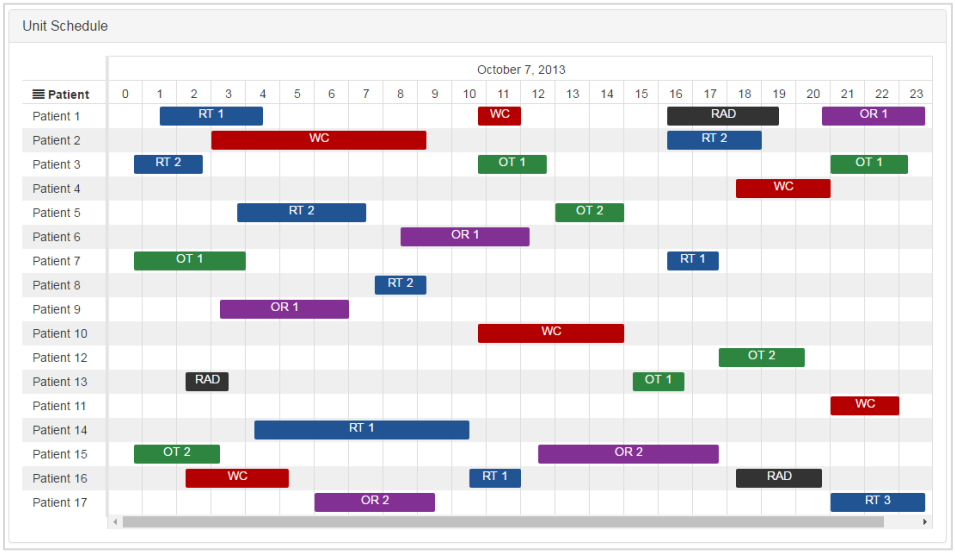



FIGURE 22. SCHEDULE

*Server Setup.* In September 2015, ARA purchased the domain name ccsunite.com and leased a virtual private server (VPS) from Amazon to host CCS for the prototype evaluation. CCS was deployed and configured with the de-

identified deceased patient data set on the Amazon GovCloud Datacenter and is now currently accessible from our domain name at AISR.

*Data Elements.* In Phase 3 CCS mapped 346 data elements from the EMR for using the patient view. This was a critical step needed to use the tool in a clinical setting. Mapping these elements allowed comparison of CCS to the Essentris current workflow during the November usability assessment.

*Patient Comparison View.* We completed the Patient Comparison View in Phase 3. This view used the same widget framework as the Configurable Patient View, which allowed us to efficiently reuse similar widgets and features. The Comparison View creates a row, or "swim lane," for each patient so that one can scroll through a list of patients to review their status as a group (Figure 23). Changes made to one lane are automatically propagated to all of the others. This reduces the effort involved needed to customize the view.

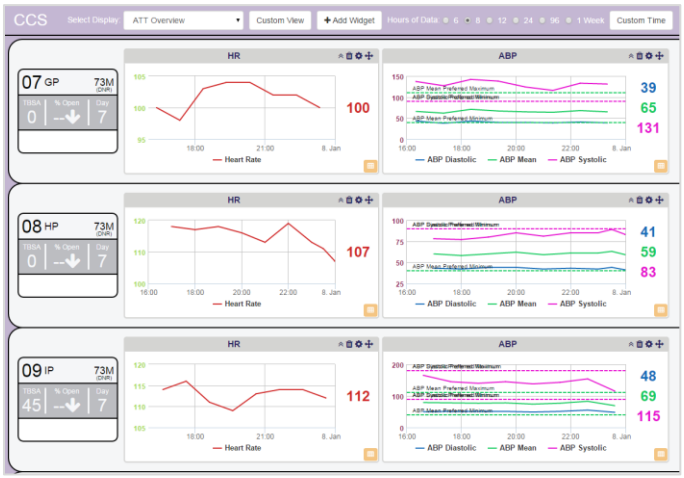



FIGURE 23. PATIENT COMPARISON VIEW

## 7. Usability Assessment (November 2015)

### *a. Preparation.*

We conducted a usability assessment (Rubin, 1994) in November 2015 at the BICU to evaluate how well the CCS supported individual decision making. From August through October 2015, ARA collaborated with AISR to develop clinically relevant scenarios for use in the assessment. In September, the ARA team scheduled a pilot to run through the facilitator script, and verify the CCS was ready for the usability assessment planned for early November. The ARA team developed seven draft scenarios from Year One data. Both ARA and AISR refined the scenarios until completing a final set of two: new admission and preparation for surgery. The team also completed a number of questions for the participants who typically rely on the EMR, and were specific to their role as a physician (PHY), nurse (RN), or respiratory technician (RT). Questions required each participant to make a recommendation or decision using the CCS prototype as an information source. The test used the CCS in the Amazon Government Cloud as a platform, and one of the previously approved 16 deceased patients as a data source.

### *b. Qualitative Findings.*

The cognitive team reviewed data collected during the November usability assessment. Appendix AB summarizes their findings, which include:

- Based on the rating analysis, Nurses found it took more effort to get the information they needed than Physicians did in the surgery preparation scenario, but there was no difference in perceived effort for the new admission scenario.
- Overall, users rated the CCS system as good as or better than the legacy system on several usability dimensions (Enclosure (1), Table 4).

- The responses to open-ended questions align well with the rating results, and provide additional detail.
- In general, participants were positive about the CCS and liked the way it presents information. When asked whether CCS would be easily adopted, over 80% of participants in each clinical role responded affirmatively (83% PHYs, 85% RNs, 90% RTs).
- The qualitative data suggest that there are differences among clinical providers according to whether they found particular aspects of the system difficult to use, and what aspects of the system were particularly useful. Physicians were more positive about the system than were RNs or RTs.
- A majority of physician participants (83%) found the information presentation (layout/look & feel/navigation) particularly useful, while only 25% of RNs and 50% of RTs did.
- RNs noted the 'snapshot' view of the patient as useful (30%) more than did physicians (8%) or RTs (0%); physicians noted the trend data as useful (42%) more than did RNs (25%) or RTs (20%).
- The data also provide insight into aspects of the system that participants found challenging. The most frequently cited challenge was the presentation of patient-specific information (Identified as challenging by 25% of PHYs, 45% of RNs and 38% of RTs after Scenario 1 and 50% of PHYs, 45% of RNs and 33% of RT's after Scenario 2). Participants in all roles occasionally reported that they needed patient information for the scenarios but were unable to find what they needed. Tailoring flexible displays will likely resolve this.

In December, the cognitive team forwarded their findings to the software team, which included a number of revisions in their plans to prepare the system for the spring 2016 validation assessment.

***c.*** *Prototype Improvements.*

Usability assessments are also intended to reveal opportunities to improve the prototype. The memo on usability assessment data analysis includes Enclosure (2) "Priorities and Recommendations for CCS System Revisions**"** that suggests potential improvements to the CCS derived from subject task performance and comments.

***d.*** *Quantitative Findings.*

During the November usability assessment, we also collected quantitative data on the time each participant took to complete each of the six tasks, shown in Table 3.

During a scheduled trip 5-7 January to present at the AISR Scientific Review Conference (Appendix AC.), Dr. Nemeth and Mr. Greg Rule, supported by Ms. Maria Serio-Melvin and Ms. Sarah Murray, staged a second usability session with one highly qualified BICU nurse to capture how a clinician would use Essentris to perform the same tasks as a subject using the CCS during the November usability assessment. Staged in the anteroom of a BICU patient room, we confirmed subject consent to participate and to have a video camera record the session. We also asked the participant to estimate the level of effort for each task, and then asked open-ended questions about the experience at the end of the session.

Results of a comparison between the BICU nurse using Essentris and an equally experienced BICU nurse performing the same tasks using the different systems is included in Appendix AD. It is true that the comparison with an individual is subject to individual differences. For example, one person might be more deliberative than another. Even so, the "straw man" comparison does demonstrate interesting differences. Both of the participants follow similar reasoning for the task they are asked to perform. Using the CCS, the time to complete task is consistently shorter than when using Essentris. In some instances, it is significantly shorter. The screen views and the verbal protocol when using the CCS are noticeably simpler than when using Essentris. The results indicated to us that we could expect to observe different information search and use patterns as well as different task times between use of the CCS and Essentris when we conducted the validation assessment in June 2016.

We did a further analysis to verify that the CCS sample was representative by figuring the median time to complete task for all 20 nurses who performed them while using the CCS during November's usability assessment. Table 3 shows the time it took the participant using the Essentris system to complete each task.

TABLE 3: LEGACY AND CCS SYSTEM COMPARISON BY TIME TO COMPLETE SIX TASKS

| ***Scenario and Task*** | ***Legacy*** | ***CCS (slowest)*** | ***CCS (median)*** | ***CCS %faster*** |
|---|---|---|---|---|
| *Scenario 1- Preparation for Surgery* | | | | |
| 1--Is the patient's hemodynamic status getting worse? | 2:44 | 11:53 | 2:10 | 20 |
| 2--Is the patient's pulmonary status getting worse? | 6:35 | 3:49 | 1:09 | 82 |
| 3--Is the patient's volume status getting worse? | 4:15 | :03 | 1:48 | 57 |
| *Scenario 2-New Admission* | | | | |
| 1--Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same? | 3:25 | 4:00 | 1:27 | 58 |
| 2--Based on his glucose levels, do you recommend that he be started on an insulin drip? | 0:53 | :45 | 0:25 | 57 |
| 3--Based on the patient's lab values, do you think he should be started on CRRT? | 2:45 | 5:25 | 1:04 | 61 |

The second column shows the slowest time for a BICU nurse to complete the identical task at the same level of accuracy using the CCS. The third column shows the median time it took the 20 BICU nurses using the CCS to finish the tasks. In all of the tasks, those who used the CCS were significantly faster. In five of the six tasks, they were at least 50% faster. This case study suggests the CCS does improve decision efficiency.

**8. Validation Assessment (June 2016)**

While the November usability assessment evaluated CCS support for individual decision making, we performed the June 2016 validation assessment to determine how well the CCS supports team decision making and communication, and to compare its performance with the Essentris EMR.

We conducted the validation assessment from 8 to 15 June at AISR. The ARA team analyzed collected data at their Fairborn offices during the week of Jun 27 to July 1.

*Method.* Clinicians were asked for their voluntary consent to participate in the assessment and use each system (Essentris and CCS) as a team in two clinically-relevant scenarios to care for one simulated patient. Participants were recruited to form two clinical teams (one attending physician, one bedside nurse, and one resident), who would also interact with other BICU staff. At the beginning of the session, the clinical team reported to their designated room for an orientation and overview of the scenario. The scenarios were designed by AISR senior clinical staff members to be realistic and require decisions for which they would need to consult IT information sources. Experts in burn critical care reviewed each scenario to ensure they were appropriate for the BICU setting.

*Subjects.* Six clinical staff volunteered to participate in this study on two different days during their time off. The attending physicians had 10 or more years of medical experience, and 10 and 8 respectively in the BICU. One resident was more senior than the other by 4 years. Nurses had been on the job 8 and 10 years respectively, with an average of 2 years on the BICU. This resulted in one team averaging two years more experience in general (*M*=8.3, *SD*=2.6 vs. *M*=6.3, *SD* = 4.2), but not more experience in the BICU (*M*=4.3, *SD* 4.4) as shown in Table 4 below.

TABLE 4. VALIDATION ASSESSMENT TEAM EXPERIENCE BY ROLE

| | Years of Experience | | | Years on BICU | | |
|---|---|---|---|---|---|---|
| | Attending | Resident | Nurse | Attending | Resident | Nurse |
| Team 1 | 10+ | 5 | 10 | 10+ | 1 | 2 |
| Team 2 | 10 | 1 | 8 | 8 | <1 | 2 |

Each team engaged in two clinically-relevant scenarios lasting 4-6 hours using either the current Essentris-based electronic medical record or the CCS. In the first scenario the team had to evaluate whether the fictional patient was becoming septic and how to treat it. The second scenario, Acute Respiratory Distress Syndrome (ARDS), observed the team's response to a critically ill patient who might be a candidate for Extra Corporeal Membrane Oxygenation (ECMO). Both scenarios were chosen for the difficulty they typically pose for BICU teams during routine care.

***a.*** *Procedure.*

In addition to three core members, other clinical personnel were consulted such as a respiratory therapist, and pharmacist. Some of these other roles were played by simulations staff. Each team cared for their simulated patients in a room set up on the BICU. Observers documented team clinical activity based on a coding scheme that included: a) decisions in the form of orders, b) search for information using the system, c) problem detection and solution, and d) collaboration and communication via various means including face-to-face, phone, text, and the message system in CCS. Each observer focused on one of the three core team members and recorded time-stamped activity for that person. At the end of each scenario, one using CCS and one using the legacy system, participants rated their team's decision making, communication, and performance. They also rated the ability of each system to support aspects of the cognitive work (all ratings on a 7-point scale).

We recorded clinician use of the software using video so the research team could review it after the sessions to ensure observer notes were accurate. The participants signed a consent form indicating they agreed to be recorded. BICU team members who did not participate in the clinical scenario were not recorded. No patients were recorded. We identified consented participants using a brightly colored laminated study badge the participant wore on their shirt or blouse.

On the day before the first scenario, each consented team member received a 15-minute orientation to the study and to the CCS. The research team used a script to introduce these topics:

- Identification of the facilitator(s) and their roles in the scenario
- How to treat the simulated patient as if he/she were a real patient
- How to document care for the simulated patient
- Where to find information about the patient in either Essentris, the CCS, or by asking for it. Due to limitations of the Essentris test environment, laboratory and imaging study results were not available in Essentris, but instead were made available using paper copies. The facilitator team mocked-up results for items that were not part of simulation preparations, in a manner most consistent with the expected patient course based on team decisions.
- Safety stops. In the event real patients required the attention of the clinical team, the team would discontinue care of the simulated patient to attend to the real patient.

During CCS orientation, the research team asked participants to perform certain tasks using the CCS. This ensured their understanding of the CCS was fresh before using it to care for the simulated patient. Each team member had his or her own personal login for the CCS and was allowed to customize their information display during the orientation.

On the day after orientation, the clinicians performed one of the scenarios using either Essentris or the CCS. On the next day, they performed the other scenario using the alternate system, as Table 5 shows. Counterbalancing minimized the benefit of experience on use of a particular IT system.

TABLE 5. EXPERIMENT DESIGN

| | Day 0 | Day 1 | Day 2 |
|---|---|---|---|
| Team 1 | Study & CCS Orientation | Sepsis using Essentris | ARDS using CCS |
| Team 2 | Study & CCS Orientation | Sepsis using CCS | ARDS using Essentris |

The Facilitator introduced scenarios during "change of shift" handoffs to participants. The team was asked to use either Essentris, or the CCS to make clinical decisions and care for the patient. The team cared for the simulated patient over a period of about 6 hours. Observers took notes throughout the session. The Simulation Monitor noted clinical team decisions and advanced the scenario "clock" to the next simulated patient data set.

After the scenario began, team members were expected to review the available simulated patient data and make appropriate decisions based on the information either Essentris or the CCS provided. The scenarios were structured to require specific sets of anticipated clinical decisions.

Scenario 1--Abdominal Sepsis:

- initiation (delivery) of antibiotic therapy,
- decision to perform diagnostic procedure (i.e., diagnostic peritoneal lavage or exploratory laparotomy),
- decision to perform exploratory laparotomy or transition to palliative care,

- communicate with the family/patient's decision maker

Scenario 2--Severe ARDS:

- initiation (delivery) of antibiotic therapy,
- paralyze the patient,
- order the rotoprone bed,
- initiation or decision not to initiate inhaled nitric oxide therapy,
- consult the ECMO service, decision to cannulate or forgo cannulation for ECMO
- communicate with the family/patient's decision maker

When the scenario team got to a decision point, observers documented details, including what decision was made, who made it, what information they used to make the decision, and how long it had taken. The scenario proceeded to the next step based on the decision made regarding the care and treatment of the simulated patient. At the conclusion of each scenario, the Facilitator asked members of the scenario team several questions about their experience.

While this was a case study with two teams, we collected data on the teams' decision, search, and communication processes, analyzed use of the CCS messaging feature, and collected post task ratings. This allowed us to examine differences between the CCS and the legacy system. Given a small sample of two teams, our analyses focused on descriptions of the process and examining consistent trends across different data sets.

***b.*** *Coding Scheme.*

The coding scheme focused on cognitive work activities that were expected to rely on an IT system (e.g., searching for information, making decisions, coordinating with the team, detecting problems by perceiving patterns, integrating information to evaluate trends, asking questions, making recommendation). In the weeks before the assessment, the three observers practiced using the coding schemes together in real time. During data analysis, two of the observers compared the three sets of codes and discussed and resolved any discrepancies.

***c.*** *Scenarios.*

The AISR clinical team designed the scenarios to be realistic and clinically relevant, requiring monitoring of multiple information streams. Subjects rated both scenarios as very realistic (M=6.8, SD = .38 on a 7-point scale). While the ARDS scenario was expected to be easier for the teams than the Sepsis scenario, use of an IT system would be essential in both.

***d.*** *Results.*

Table 6 and Table 7 show key decisions made by the team's resident ("Res") and the most important decision is shown in bold type. Using the CCS in the Sepsis scenario, Team 2 performed at the same level as Team 1 using Essentris, despite the fact that the Team 1 resident had four more years of experience. The less experienced Team 2 resident also explored multiple diagnoses rather than anchoring on just one.

TABLE 6: SEPSIS SCENARIO KEY DECISION POINTS

| **Team One / Legacy IT** | **Team Two / CCS** |
|---|---|
| **06:57 Start** | 06:45 Start |
| | 08:53 Deep vein thrombosis is common on a long flight |
| | 09:20 Res- I'm looking at Abdominal compartment syndrome |
| | 09:22 Res Ruling out pulmonary Embolism |
| | 09:31 Res Look for signs of sepsis |
| 09:51 Res>Attend- Brief. Patient infection | |
| **10:41 Res- Abdominal compartment syndrome due to sepsis, unknown source** | **10:43 Res- Suspect sepsis** |
| | **10:45 Res- Perceives septic** |
| | **10:47 Res- Perforated bowel** |
| 10:55 Attend- Ask source of sepsis | |
| | 12:13 Res- Abdominal compartment syndrome |
| | 12:16 Res- May need exploratory laparotomy |

Using the CCS in the ARDS scenario, Team 1 arrived at the choice to treat the TENS patient by using a rotoprone bed almost 2 hours before Team 2.

TABLE 7: ACUTE RESPIRATORY DISTRESS SYNDROME SCENARIO KEY DECISION POINTS

| **Team One** / CCS | **Team Two** / Legacy IT |
|---|---|
| 06:45 Start | 06:45 Start |
| | 7:48 Res- Suspect antibiotics source of TENS |
| | 8:02 Attend- Let ECMO team know |
| 08:31 Res Need to know from derm re: TENS | |
| 08:40 A Not likely TENS | 08:45 Attend- Paralyze him. Have OR ready. |
| | 08:54 Res- Staph infection |
| | 09:16 Res- May be slowly heading to ECMO |
| **09:55 Res- Consider prone. Looking at different courses of action** | 09:51 Attend- If he gets worse we're going to code him |
| 10:39 Res>Attend- Page about ECMO | |
| 11:18 Attend- I'd put him on ECMO now | |
| | **11:52 Res © done everything to treat him – very critical –..Attend- (D) no ECMO – rotoprone only** |

***e.*** *Decision, Search and Communication Processes*

In this section, we describe how the cognitive work varied by role and system. We examined a subset of the cognitive work the teams performed and summarized their use of the CCS messaging feature to evaluate the effect of the two systems on team processes and timing of the activities. We only review activities directly related to decision making (search, perceive, and decide). These activities were more common for the physicians than the nurse, which is typical. While physicians were engaged in decision-related activities, nurses were engaged in bedside care, managing the orders and medicines, and making recommendations and clarifying information. Table 8represents the distribution of each of the three activities across roles (rows sum to 1.0 or 100% of each category of decision-related communication). For example, the Team 1 resident made the majority of decisions, .65 proportion or 65%, when using the legacy system, and 43% while using the CCS.

TABLE 8. PROPORTION OF TEAM ACTIVITY BEHAVIOR BY ROLE FOR EACH SYSTEM

| | | Legacy System | | | CCS | | |
|---|---|---|---|---|---|---|---|
| | *Role* | Attending | Resident | Nurse | Attending | Resident | Nurse |
| | Activity | | | | | | |
| Team 1 | Search | 0.12 | 0.40 | 0.48 | 0.20 | 0.57 | 0.23 |
| Team 2 | Search | 0.10 | 0.65 | 0.24 | 0.02 | 0.76 | 0.22 |
| Team 1 | Perceive | 0.14 | 0.71 | 0.14 | 0.33 | 0.67 | 0.00 |
| Team 2 | Perceive | 0.42 | 0.42 | 0.17 | 0.04 | 0.79 | 0.17 |
| Team 1 | Decide | 0.29 | 0.65 | 0.06 | 0.57 | 0.43 | 0.00 |
| Team 2 | Decide | 0.55 | 0.45 | 0.00 | 0.23 | 0.65 | 0.13 |

Table 9 presents the same data as Table 8, but is normalized by total team decision activity. It represents the distribution of these three activities relative to the total team communication for these three decision-related activities (sum of all three roles and three activities sums to 1.0 or 100% of the communication). This analysis allows comparison of the relative differences between search, perceiving, and deciding by team. From this normalized frequency of different activities, residents are engaged in more decisions, perceiving potential problems, and searching for information, than the nurse or attending. Across each team and scenario, residents engaged in more than 50% of the decision-related activity. Decisions were largely made up of plans for care and orders. While the two teams had different communication patterns using the two systems, there does not seem to be large differences between systems in terms of team communication.

TABLE 9. PROPORTION OF EACH ACTIVITY RELATIVE TO TOTAL COGNITIVE WORK BY TEAM AND ROLE FOR EACH SYSTEM

| | | Legacy System | | | CCS | | |
|---|---|---|---|---|---|---|---|
| | *Role* | Attending | Resident | Nurse | Attending | Resident | Nurse |
| | Activity | | | | | | |
| Team 1 | Search | 0.047 | 0.157 | 0.189 | 0.110 | 0.314 | 0.127 |
| Team 2 | Search | 0.065 | 0.416 | 0.156 | 0.012 | 0.427 | 0.122 |
| Team 1 | Perceive | 0.016 | 0.079 | 0.016 | 0.025 | 0.051 | 0.000 |
| Team 2 | Perceive | 0.032 | 0.032 | 0.013 | 0.006 | 0.116 | 0.024 |
| Team 1 | Decide | 0.142 | 0.323 | 0.031 | 0.212 | 0.161 | 0.000 |
| Team 2 | Decide | 0.156 | 0.130 | 0.000 | 0.067 | 0.189 | 0.037 |

We also analyzed these coded, time-stamped observations for each team by system and activity to examine the distribution of cognitive work prior to rounds, during rounds, and post-rounds. Collapsing across roles, one can see from Table 10 below that decisions in the form of orders and plans were made in pre-rounds. Search, in which the clinical staff looked for information, was more common in pre-rounds and post-rounds for both teams using both systems. Perceptions in which clinical staff gained insights were consistently happening during rounds and post-rounds as one might expect and do not seem to differ across the two teams.

TABLE 10. ACTIVITY FREQUENCY BY SYSTEM ACROSS CLINICAL TIMELINE (COLLAPSED ACROSS ROLE)

| | | Legacy | | | CCS | | |
|---|---|---|---|---|---|---|---|
| | | Search | Perceive | Decide | Search | Perceive | Decide |
| Team 1 | Pre-Rounds | 33 | 3 | 25 | 25 | 5 | 12 |
| | Rounds | 5 | 1 | 21 | 10 | 1 | 5 |
| | Post-rounds | 12 | 8 | 19 | 30 | 4 | 35 |
| Team 2 | Pre-Rounds | 17 | 0 | 3 | 69 | 3 | 13 |
| | Rounds | 12 | 8 | 18 | 3 | 4 | 17 |
| | Post-rounds | 69 | 6 | 29 | 20 | 13 | 19 |

We analyzed the teams' use of the CCS messaging feature to examine how each used it to support team awareness and collaboration (Table 11). Functions that these messages supported were similar across the two teams: coordinating patient care, updates on symptoms, status of medicine or labs, and making clinical directions or recommendations. Remote team care members used messaging to convey orders to the respiratory therapist, dietician, or pharmacy. Each team used messaging in a flexible way to support their team process, and there were some differences as we show in Table 11. Both teams sent a similar number of messages and most were to the nurse. Team 1 sent 11 messages during the ARDS scenario, 63% were sent by the nurse, 18% had multiple recipients, and the median response time was 4 minutes. Similarly, Team 2 sent 10 messages during the Sepsis scenario, and 60% were sent by the nurse. Similarly, Team 2 sent 10 messages during the Sepsis scenario, and 60% were sent by the nurse. There were several differences between the two teams in their use of the CCS messaging feature. While Team 2 did not initiate more messages, they sent the messages to more individuals, with 70% going to multiple recipients, compared to 18% in Team 1. In addition, Team 2's messages also involved longer threads (e.g., longest was 9 messages). Finally, Team 2's median message response time was faster, at 2 minutes, possibly because they had more recipients. While both teams solved the clinical problems effectively and in a timely manner as described above, these data show that the CCS supported different effective collaborative strategies.

TABLE 11. CCS MESSAGING USAGE BY EACH TEAM DURING VALIDATION STUDY.

| CCS | Number of Messages | Nurse-initiated | Percent to Multiple Recipients | Longest Thread | Median Response (Minutes) |
|---|---|---|---|---|---|
| Team 1 | 11 | 63% | 18% | 4 | 4 |
| Team 2 | 10 | 60% | 70% | 9 | 2 |

***f.*** *Post-task ratings.*

Finally, after completing a scenario, each team rated how well the system supported core cognitive work. We analyzed these ratings using MANOVAs to examine the effect of Team Experience (Higher vs. Lower), Role (Nurse, Physician) or System (legacy vs. novel IT system) on experiences making decisions and collaborating. All ratings were on a 7-point scale, with 4 being neutral.

***g.*** *Subjective ratings by experience.*

Team experience did not affect member's subjective ratings of the system, confidence in their decisions, or ability to communicate with their team. A MANOVA of Team Experience on these ratings was not statistically significant, $F(4, 7) = 0.729$, $p = .6$.

***h.*** *Subjective ratings by role.*

In the usability study, nurses rated the system as harder to navigate than physicians. However, after adding two different views to the novel IT system as a result, this was not the case in the team validation study. A MANOVA

of Role on ratings of search, ease of use, and communication using the systems revealed no statistically significant difference between physicians and nurse ratings, $F(4, 7) = 1.6$, $p = .28$.

***i.*** *Effect of system on team performance ratings.*

Both teams rated team performance high ($M = 6.6$, $SD = .51$) and overall team communication effective ($M = 6.8$, $SD = .41$) independent of the IT system, indicating that the teams performed effectively on diagnosing each patient's condition. However, there were statistically significant differences with respect to how well the legacy and novel IT systems supported team communication and decision making. There was also no difference for the confidence in their decisions across the two systems.

***j.*** *Effect of system on decision making.*

Subjects rated the novel system as more effective than the legacy system for supporting decision making (Table 12). A MANOVA of System on information integration and decision making revealed two marginally significant effects. Post-task ratings across the two systems for identifying trends in the patient's condition, $F(1,10) = 5.3$, $p = .067$, and easier to use to make decisions, $F(1,10) = 5.3$, $p = .09$, were higher for the novel system compared to the legacy system.

TABLE 12. MEANS AND STANDARD DEVIATIONS FOR SYSTEMS SUPPORTING DECISION MAKING

| | *IT System* | *Mean* | *Std Deviation* | *N* |
|---|---|---|---|---|
| The system was easy to use to make decisions. | Legacy | 4.667 | 1.211 | 6 |
| | Novel | 6.000 | 1.2649 | 6 |
| I am confident in my decision / recommendations using this system. | Legacy | 5.000 | 0.8944 | 6 |
| | Novel | 5.667 | 1.3663 | 6 |

***k.*** *Effect of system on communication.*

Subjects rated team communication as more effective for the CCS than the legacy system. Independent t-tests revealed that subjects rate the CCS as easier to use for communicating with team members collapsing across both scenarios, $t(10) = 2.7$, $p = .021$ and the communication was more effective with team members using the CCS system, $t(10) = 4.3$, $p = .01$. However, as mentioned and regardless of system subjects rated team communication as effective.

***1.*** *Discussion.*

Effective IT systems support teams in developing a shared understanding, allowing them to detect problems earlier, and evaluate their options and provide the best care. We provide evidence that the CCS, designed using a cognitive-system engineering approach, was effective.

In the November 2015 usability assessment, subjects using the CCS system with minimal training performed faster on 6 information search tasks than an experienced user with the legacy system. They were able to find information more efficiently than with the legacy system, because the CCS was both designed to support different views of the information and to tailor views to different uses. In the validation assessment, this ability to find and share information more effectively and efficiently enabled teams to evaluate more alternatives without increasing overall diagnostic time compared with the legacy system.

In the validation assessment, team processes differed somewhat related to the two systems. Based on the timeline of the two teams' decision processes, one can see that the decision strategies were different and that the novel IT system supported both teams. The resident with less overall experience came to the correct diagnosis with the novel IT system in the same amount of time as the more experienced resident. Both teams used the IT system to share basic information about the current state of the patient, what Wright and Endsley (2008) refer to as Level 1 situation awareness. In combination with rounds that function to ensure that heath care teams have a comprehensive shared understanding of a patient's status (Level 2 situation awareness) and evaluate plans for future care, the novel IT system supported option evaluation, problem detection, and decision making.

Consistent with naturalistic decision making research on experts (Klein, 1998), the more experienced resident and team considered fewer options, and then evaluated each option until it could be ruled out. The resident with 4 fewer

years of overall medical experience used the novel IT system to evaluate more potential diagnoses, which included the correct one.

Our assessment results are consistent with Patel and Arocha (2001): Effective decision making in an ICU needs to be supported to allow all critical care members (physicians, nurses, technicians) to gather and share information to best support patient care. One team used the messaging feature of the novel IT system to broadcast and maintain the larger remote care team's awareness of this patient, while the other team was more select in their broadcast. The novel IT system helped the teams establish a shared understanding of the patient's status (Orasanu & Fisher, 2008), engage in collective sense making, and supported all three levels of Endsley's situation awareness model (Wright & Endsley, 2008).

***m.*** *Limitations.*

Clinicians participating in the study were assigned patient care responsibilities on the unit, except for days on which the validation assessments were performed. This limited their availability but ensured everything was done in the context of actual clinical practice. The project was performed at one site, and with two teams, which limited its generalizability. The team has proposed further research at other sites in a follow-on project.

***n.*** *Future work.*

The next step will be to transition the system from research to development. We are adding three features (data entry, scheduling, and checklists) that our research identified as being essential to clinical work but were beyond the scope of the initial project. Validating the system's machine learning (ML) algorithms will make it possible to identify patterns in data that would otherwise be unknown, such as trends, comparable patients and care regimens, and the way clinicians use the system. The system will be proven effective beyond the ICU environment by implementing it at another treatment facility. It will also be paired with other suitable systems (e.g., EMR, medical devices, and databases) so that it can serve as a data integrator.

## 9. Machine Learning Validation and Use Cases

SSCI was initially responsible to develop the machine learning features of CCS. The purpose of the ML features was to poll the electronic health records periodically to populate a data warehouse. The analytics software would review those data to extract patterns based on user queries. The results would then be transferred to the CCS database and used to invite clinician attention to patterns that would otherwise remain unnoticed.

SSCI developed a draft application-programming interface (API) for the data analytics module. SSCI demonstrated their data analytics engine based on implementation of a scalable Bayesian inference technology known as *CrossCat*. The engine could be hooked to generic databases, as well as a notional test harness that shows how the engine can handle mock medical data. The engine runs asynchronously in the background on the data. At the same time, it can also deliver the specific items noted below in real time, based on the engine's current best model learned from the existing data. Unfortunately, our inability to obtain access to patient data prevented SSCI from developing a machine learning capability that was customized to AISR data. Instead, SSCI developed a generic engine that was intended to be quickly adapted to whatever data sets eventually emerged. However, with only very limited Essentris data made available for development, SSCI has developed a technique to expand the volume of available data. This technique was to create synthetic seeded patient condition data by using the *CrossCat* search engine. By inferring the statistics of relevant data fields of relevant samples of data, we planned to use the engine to generate synthetic data with known and relevant statistical properties.

Unfortunately, during testing, these methods failed to adequately use and adapt to the Essentris data eventually made available, and SSCI was retired from the project. In Phase 3 the ARA ML team took a different approach that recognizes, and addresses to, major technical challenges as part of the code solution:

1. Patients have a wide diversity of time-series data with sparse and uncertain entries representing a combination of both medical interventions and patient responses. This complexity mandates a solution that incorporates temporal models showing progressions of care and sensor readings. This is because instantaneous data cannot accurately characterize the patient care trajectories needed to match similar patients' care plans or provide cases representing possible future states for consideration.
2. The operations must provide quick and accurate responses at scale. The objective system will consider many patients dating back many years, some of which will have records spanning long time periods potentially

including multiple (potentially even independent) treatments. The scale of the problem mandates a solution that will handle the large existing database; accept, integrate/index, and classify new data from ongoing patient care; and quickly identify best matches to support interactive queries from users.

The ML team created a new software architecture that could be more closely integrated with the CCS system and significantly improved data processing performance (Figure 24). One reason for this is that this approach synchronized and staged data by copying it from Essentris and storing cleaned and formatted data in a CCS database where CCS could access data in more efficient ways. This approach maintains the restriction that CCS does not write or change any data in Essentris, while handling the fact that data in Essentris is not structured or curated to support complex analytic processing.

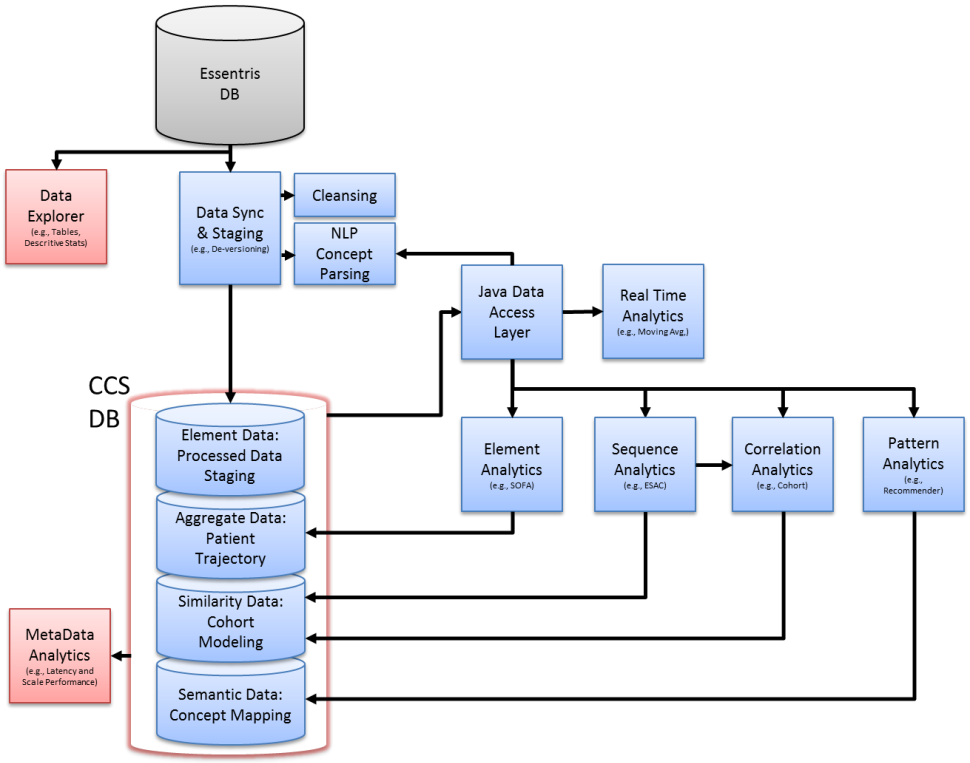



FIGURE 24. MACHINE LEARNING ARCHITECTURE

Our approach combined ML analytics to analyze clinical records, develop models of patient/clinician interactions, and provide users with decision-support information using the CCS UI. Eight key components of the system are:

1. Data Explorer — This tool analyzes the Essentris database schema and contents. To aid in exploration of the data it extracts summary metadata. It outputs a .csv file containing meta data without personally identifying information.

2. Data Sync, & Staging — This tool synchronizes, cleans, and pre-processes key data from patient records for staging analytics. It reads from the Essentris database, and writes to the CCS database. It integrates with modules for data cleansing and parsing of notes tables for Natural Language Processing (NLP) to extract key concepts relevant to patients at a particular time.

3. NLP Concept Parsing — This component parses free text notes entries in the patient data and extracts references to identified problem-related concepts and generates event logs in the CCS database to capture these. We analyzed the Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT) ontology, International Classification of Diseases ICD-9/10, but found that the most relevant problem concepts were elicited from SME support at AUSISR. We currently search for 278 unique concepts, as well as linguistic variations

on these terms.

| | | |
|---|---|---|
| 4. | Java Data Access Layer | This component provides structured access to data repositories. Because the data in the CCS database has been cleaned in the staging database this process is fast and reliable. Additionally, no custom written queries are required, so changes to database tables (such as versioning in Essentris) are data driven and does not require software change. |
| 5. | Real Time Analytics | These components are used to directly support interactive features of the UI, where analytic capabilities (e.g., moving and windowed averages) and running of models against active patient data (e.g., extracting clinically relevant similarities from cohort recommendations). |
| 6. | Element Analytics | These components read in-time series patient data and write out aggregations, interpolations, and direct data analytic functions. ARA implemented modified Sequential Organ Failure Assessment (SOFA) and 12 different Wellness Condition machine learning models that are assembled to produce the Wellness Trajectory and current Patient Condition data. |
| 7. | Sequence Analytics | These components use ML to model temporal sequences where the ordering and relationship of events is critical to interpretation and similarity measures. We integrated ARA's unique Event Sequence Alignment and Clustering (ESAC) and have enabled the aggregation and extension of windowed-based similarity into full patient stay similarity measures using alignment and clustering. |
| 8. | Similarity Analytics | These components compute correlations between factors in the data to learn models for cohort similarity and probabilistically predict future trajectories based on historical precedence. We have developed three models for similarity with temporal windowing using different feature weighting strategies: Simple Mean, Expert Directed, and PCA Derived. These models include: statistical T-test models (tests if means and variance are similar), slope/trend analyses (tests if changes are trending similarly), and integral differencing (tests for space between curves). |
| 9. | Pattern Analytics | These components bridge the semantic meaning of various data elements to identify domain-knowledge-based similarities where content-only comparisons fail. This component has been implemented for analysis only. |
| 10. | Metadata Analytics | These components instrument the CCS ML system so that we can measure performance, identify issues, and better estimate scalability and stability. |

***a.*** *Use Cases*

During Phase 3 we addressed three key use cases:

- *Use Case #1: Identify possible discrepant clinician actions according to patient current condition and predicted trajectory.*

Addressing this Use Case requires analyzing historic patient records, developing models for quickly finding cohorts for the current active patient and determining how patient and clinician events contribute to similarities in trajectories and probabilistic outcomes.

Tasks include: Constructing a current patient model, constructing relevant and concise patient models and similarity measures, learning models for most applicable cohort list, evaluating the cohort composition, and develop/evaluate recommender for orders.

Patient cohorts are used to identify historic cases that may be of value for decision-making in the subject case. There are many ways to cohort, and different methods result in different cohort compositions. Ideally, the cohort selection process would be directed towards identifying cases to support a specific decision-making situation. We were directed to analyze the raw EMR data, which was not labeled for any decision context or with examples of cohorting from which to train our models. In this research, we developed 9 models assessing how similar a pair of patients'

data is at some point in time, and how similar their stay up to that point in time is to others patient's full-stay. We believe there is benefit to each, and they are detailed below:

*Window-based.* We compare one patient at one time interval (8hrs), with all other historic patients at all of their equivalently sized time intervals. This identifies the extent to which patient A at time A' is similar to patient B at time B', for all patients and all time windows. This is particularly useful for comparison of immediate/short-duration conditions. We computed windowed similarity by comparing available data in and near the time interval and statistically determining how likely two patient's values are to being drawn from the same population (incorporating Student's T-Test). The key factor in ML tailoring of these windows is learning the weights to apply to each feature, we developed three weighting models: (1) Simple Mean – This considered each feature to be equivalent. (2) Expert Directed – This model increase the relative weights for features indicated by an SME to be the most important for cohorting. (3) PCA Derived – This model uses weights that were determined through a Principal Component Analysis (PCA) to be the most significant for differentiating patient samples. PCA translates data into a multidimensional space based on Eigenvectors (EVs), and our weighting of factors is determined by the most significant EVs.

*Temporally Aligned.* We additionally compare one patient to another over the course of their entire stay in the BICU, where similarity is computed between temporally ordered sequences of windowed comparisons (using any of the above methods). This identifies patient history similarities and is expected to be useful for full admission condition comparisons because it identifies the extent to which patient A has maintained similarity to patient B over the course of their stay to date. We evaluate two methods for grouping: (1) Full Stay Aligned – Finds cohorts with the most similar sequences of windows in order over time capturing overall similarity patterns. (2) Full Stay Clustered – Finds cohorts who have joint similarity to each other based on windows and alignment finding groups of similar cohorts and eliminating cohorts that are similar to one but not all.

Validation Results Summary: In the validation, we compared the effectiveness of each approach in terms of SME recommended characteristics for cohorting: similar wellness points (Table 13) and similar slope of wellness (Table 14). These are driven entirely from physiology data and lab results (where available) which differs significantly from the traditional demographic approach to cohorting. Our findings compare using weights based on SME recommended features (which performs best) to simple mean unweighted and Principal Component Analysis (PCA) derived weights. Details results are in Appendix AG.

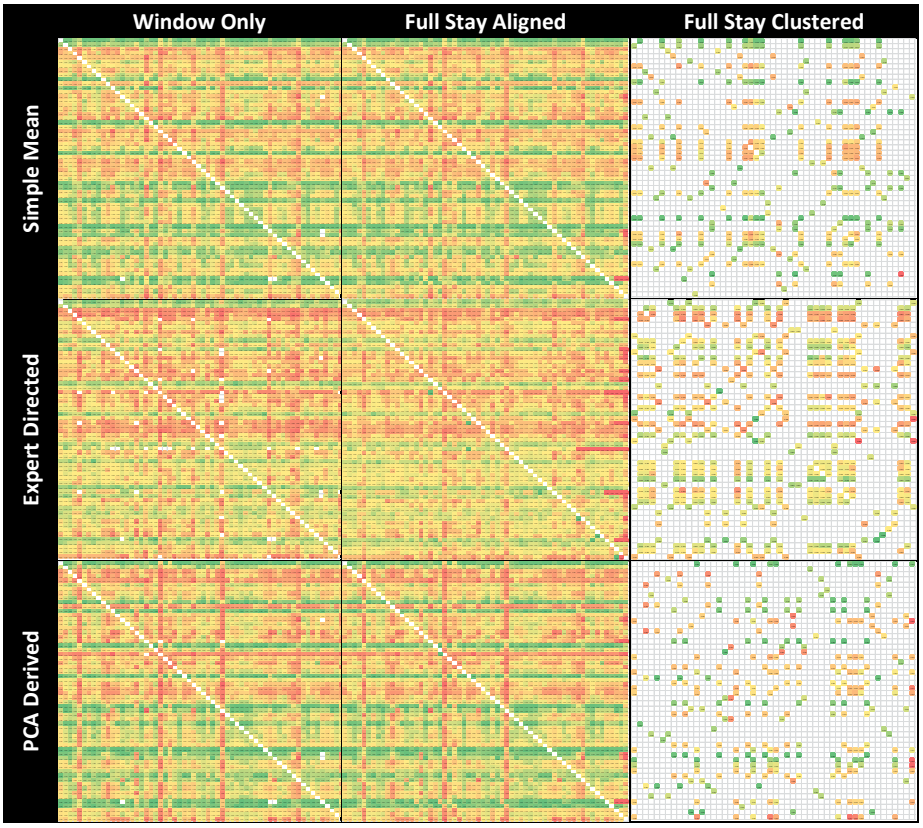
TABLE 13. MEAN WEIGHTED ABSOLUTE ERROR FOR WELLNESS POINTS FOR EACH COMBINATION OF WINDOWING AND ALIGNMENT

| Point MWAE* | Window Only | Full Stay Aligned | Full Stay Clustered |
|---|---|---|---|
| **Simple Mean** | 0.031 | 0.036 | **0.025** |
| **Expert Directed** | 0.015 | **0.012** | 0.014 |
| **PCA Derived** | 0.024 | **0.019** | 0.022 |

TABLE 14. MWAE FOR WELLNESS TRAJECTORY SLOW FOR EACH COMBINATION OF WINDOWING AND ALIGNMENT

| Slope MWAE | Window Only | Full Stay Aligned | Full Stay Clustered |
|---|---|---|---|
| **Simple Mean** | **0.006** | **0.006** | 0.010 |
| **Expert Directed** | **0.003** | **0.003** | 0.005 |
| **PCA Derived** | **0.005** | **0.005** | 0.007 |

TABLE 15. THIS SET OF MATRICES SHOW PATIENT-TO-PATIENT SIMILARITIES FOR EACH OF OUR 9 COMBINATIONS OF FEATURE WEIGHTING AND WINDOWING/ALIGNMENT




- *Use Case #2: Identify possibly worsening patient trajectory.*

Addressing this Use Case requires aggregating patient data and modeling abstract wellness over time. This information is to be used to represent the patient condition in the UI.

Tasks include: Constructing patient and clinical action models, aggregate and quantify condition metrics from patient state, recognize and predict inflection points in condition, and evaluation of predictive analytics.

Wellness is a subjective term and the degree of wellness within the context of a BICU is not an universally agreed upon measure. There are several existing methodologies (such as SOFA and APACHE 2) that have been used for manually quantifying the probability that a given patient will die based on historic cases in general ICUs. We essentially developed similar measures using machine learning and other analytics and focusing on modeling a set of historic BICU patients. Our methods are intended to be exclusively informed by and executed using available raw health record data without human intervention.

Our ML approach for this use-case consisted of using the last two days of a patients stay as a representation of the extremes of wellness. The final days of patients with the disposition of deceased were used as examples of an extremely low wellness level (notionally 0.0), while discharged patients final days were assumed to have been high wellness (notionally 1.0). We trained a set of ML classifiers on these samples, and performed 10 fold cross validation on each model (see analytic validation results below). Each classifier used a different ML strategy and we ensemble their results to establish the final Wellness Score for each patient for each day of their stay.

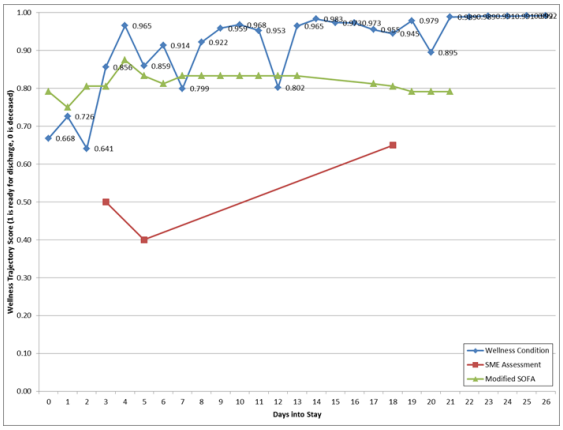
Validation Results Summary: We validated the implementation of this Use-Case with comparison to SME assessments of wellness and Modified Sofa on five patients (

Table **16**). Figure 25 shows two patients with a range of error relative to SME assessment. Detailed results are in Appendix AG.

TABLE 16. VALIDATION RESULTS FOR USE-CASE #, SHOWING MEAN ABSOLUTE ERROR FROM SME ASSESSMENT

| | Wellness Condition | Modified SOFA |
|---|---|---|
| **Patient A** | 0.37 | **0.30** |
| **Patient B** | **0.38** | 0.40 |
| **Patient C** | **0.13** | 0.28 |
| **Patient D** | **0.07** | 0.36 |
| **Patient E** | **0.13** | 0.31 |
| | **0.22** | 0.33 |

The ML model overestimated this patient's Wellness relevant to SME. This is due to low death rate in data.




The ML model assessed this patient's Wellness relatively close to the SME's estimates.

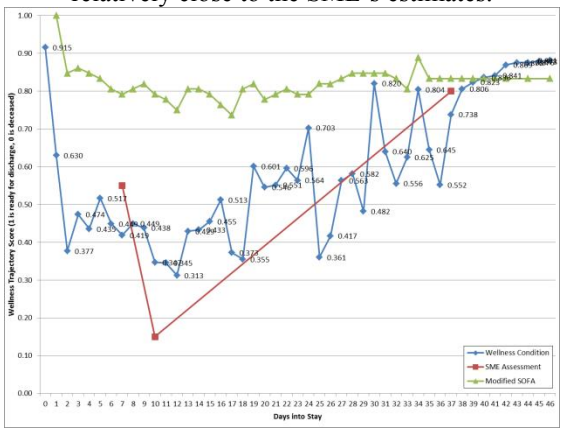



FIGURE 25. SAMPLE OF TWO PATIENT'S WELLNESS TRAJECTORIES FOR COMPARING EXPERT ASSESSMENT (RED), MODIFIED SOFA (GREEN), AND OUR WELLNESS CONDITION (BLUE).

- *Use Case #3: Problem List Summary and Decision Support.*

Addressing this Use Case required detecting clinically-relevant concepts in the notes, particularly problems that might be present in the patient.

During initial investigations into this Use Case for Phase 3, we identified two issues: (1) The UI did not contain a widget for manually labeling problems, and the data set we are permitted to use under IRB protocol would not include active patients with such labels if they existed. (2) There were no encoded problem types in the Essentris database. Instead, these data tend to reside in narrative form in clinical notes throughout the database. These discoveries forced us to change how we go about implementing a solution for this Use Case.

Original Task included modeling "problems" with respect to known data models, editing problem labels/rules, and evaluating problem labeling.

Updated Task includes addressing this Use Case requires parsing key terms from natural language notes fields in the database, modeling the co-occurrence of these terms with trends/events in the patient data, and using this model to recommend terms that describe observed patient data dynamics.

Problems are high-level clinically relevant concepts that reflect adverse states of patent, for example "Sepsis". Our Problem Recommender analyzes the clinical notes data using NLP and attempts to identify and isolate these concepts so that they can be called out to the clinical care team. This is informed by a list of terms of interested problems developed in concert with a SME.

Validation Results Summary: We analyzed the correspondence of problem concepts detected in the notes with dips in the Wellness. Instances where the problem and dips co-occur will be marked as a positive correspondence. We computed the ratio of positive correspondences to concept detections (CR) in Table 17. Details results are in Appendix AG.

TABLE 17. LIST OF PROBLEM CONCEPTS DETECTED AND THE RATIO OF POSITIVE CORRESPONDENCES OF DIPS IN WELLNESS TRAJECTORY

| Concepts | Detections (>day 1) | CR |
|---|---|---|
| **All Concepts** | 312 | 59.6% |
| **edema** | 139 | 60.4% |
| **constipation** | 65 | 64.6% |
| **pneumonia** | 32 | 68.8% |
| **diarrhea** | 29 | 48.3% |
| **thrombosis** | 18 | 55.6% |
| **sepsis** | 16 | 56.3% |
| **arthritis** | 10 | 50.0% |
| **hepatitis** | 7 | 57.1% |
| **cholecystitis** | 5 | 80.0% |
| **tracheobronchitis** | 4 | 50.0% |
| **gastritis** | 3 | 66.7% |
| **osteomyelitis** | 3 | 66.7% |
| **pancreatitis** | 2 | 50.0% |
| **endocarditis** | 1 | 100.0% |
| **erythremia** | 1 | 100.0% |
| **paraplegia** | 1 | 100.0% |
| **sciatica** | 1 | 0.0% |
| **serositis** | 1 | 100.0% |

In summary, the ML capability in CCS offers innovative analytics that that show promise for improving diagnostic and therapeutic decision making in the clinical setting. Despite challenges in data access limitations, noisy and missing data in the EMR, and SME time limitations for labeling of historic data, this first-ever research study demonstrates the potential for machine learning to extract meaningful patterns without the need for human intervention for the three key use-cases of wellness trajectory, cohort identification, and problem recommendation. Future research incorporating larger scale data sets and a validation that is more rigorous will help to make these ML approaches more robust and better calibrated to SME judgments.

## 10. Transition Plan

In accordance with Task 3.5, CCS Clinical Implementation and Transition, ARA and USAISR have identified the transition requirements and finalized the technology transition plan for the completed prototype CCS. On August 25, 2016 the AISR Task Area Manager, Dr. Jose Salinas, PhD. acknowledged receipt of the current CCS prototype as a contract deliverable. (Appendix AH). The Transition Plan (Appendix AI) describes the further work to be done to accomplish the steps needed to translate the CCS from a research project into an operational product.

ARA is in discussions with clinicians at the Mayo Clinic to explore the potential for combining portions of the CCS with their AWARE program. The Mayo team has already linked their AWARE program with Cerner's EMR in civilian hospitals, making a commercial adaptation possible for the combined products. We also anticipate providing Mayo with the opportunity to support the Military Health System's needs for integrated clinical information support.

On August 10, we presented the project status and transition requirements to Defense Health Agency (DHA) and JPC-1, the slides are in Appendix AJ.

## 11. Conclusions

The stated goal of this project was to develop a real-time clinical decision and communication support prototype. The successful usability assessment in November 2015 and validation assessment in June 2016 confirmed that we

have met that goal. The validation assessment showed that the clinicians preferred CCS to the standard EMR and that the CCS (particularly the messaging feature) helped performance on many tasks. Data from the Phases of Illness Paradigm (POIP) study led by the Co-PI (JP) suggest that other CCS components, particularly checklists and task lists, would be extremely useful when fully functional in CCS.

The next step will be to translate the CCS prototype into an operational system. The CCS prototype will require additional development to meet functional requirements that were learned since the beginning of the project, and to integrate it with the new clinical information systems being fielded over the next few years. This work, while relatively small in scope compared to the CCS project, is critical to successful transition and fielding.

Completion of FDA Class II clinical trials would enable the CCS to integrate fully as a component of the new MHS Genesis EMR. The benefits to the DoD Healthcare system are significant. Using the new EMR through CCS would greatly reduce the learning curve for access to and understanding of medical information, resulting in lower training costs, and greatly reduce any time clinicians might need to learn the new system. CCS's advanced communications and scheduling capabilities would provide a common operating picture across DoD healthcare and save individual hospitals from purchasing their own locally supported software to perform these functions. The CCS' integrated ML-based decision support would enable even the most inexperienced clinicians to benefit from the expertise of the entire clinical network, reducing the potential for error, and the frequency of unnecessary or redundant tests.

The current version of MHS Genesis that is planned for deployment does not fulfill all of the requirements in the MHS Genesis Capabilities Development Document. Incorporation of the CCS in Genesis *would* realize the MHS vision.

**12. List of Appendices**

- Appendix A. Book Chapter. Support for ICU Clinician Cognitive Work through CSE.
- Appendix B. Journal Paper. MHSRS Developing a Cognitive and Communications Tool for Burn ICU Clinicians. *Military Medicine*. Society of Federal Health Officials (AMSUS).
- Appendix C. Journal Paper. Revealing ICU Cognitive Work Using NDM Methods. Special Issue on Expanding Naturalistic Decision Making. Journal of Cognitive Engineering and Decision making. *Human Factors and Ergonomics Society.*
- Appendix D. Journal Paper. Improving Burn ICU Clinician Decision and Communication through IT Support. *Critical Care Medicine.*
- Appendix E. Evidence of Usability-Burn ICU Decision Support. IEEE Systems, Man and Cybernetics International Symposium. Budapest.
- Appendix F. Support for Salience: IT to Assist Burn ICU Clinician Decision Making and Communication.
- Appendix G. Abstract: Evaluation Results for a Burn ICU Clinician Decision and Communications Support System. The 46th Critical Care Medicine Congress. Honolulu, HI. (In review)
- Appendix H. Abstract: High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe.Southern Region Burn Conference. Atlanta. (Accepted) and the Critical Care Medicine Congress. Honolulu, HI. (In review)
- Appendix I. Abstract: Getting the Message: Health IT Can Improve Team Communication. Southern Region Burn Conference, Atlanta. (Accepted) and the 46th Critical Care Medicine Congress. Honolulu, HI. (In review)
- Appendix J. Abstract: Supporting Salience: Valid IT Improves Burn ICU Decision Making, Human Systems Division 2017 National Conference, National Defense Industry Association, Sterling, VA.
- Appendix K. Abstract: Evidence of Decision Support for Burn ICU Clinicians. Military Health Systems Research Symposium.
- Appendix L. Abstract: NIH-IEEE Strategic Conference on Point of Care Technologies for Precision Medicine.
- Appendix M. Presentation. High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. *Southern Region Burn Conference.* Atlanta, GA.
- Appendix N. Presentation. Getting the Message: Health IT Can Improve Team Communication. *Southern Region Burn Conference.* Atlanta, GA.
- Appendix O. Presentation. Support for ICU Resilience: A Cognitive Systems Approach (CSE) Approach to Build Adaptive Capacity. Resilience Healthcare Learning Network Teleconference and the IEEE SMC International Symposium, October 2016.
- Appendix P. Poster: Evidence of Decision and Communications Support for Burn ICU Clinicians MHSRS Conference: August 2016.
- Appendix Q. Presentation: Army Institute of Surgical Research Scientific Symposium. Brook Army Medical Center. Joint Base Sam Houston, 6 January 2016.
- Appendix R. Presentation: Evidence of Salience: Burn ICU IT Evaluation Results. HFES Healthcare Symposium. Human Factors and Ergonomics Society. 14 April, 2016. San Diego, CA.
- Appendix S. Presentation: Invited speaker: Adapting to Change and Uncertainty. Pediatric Cardiac Intensive Care Society National Conference. 11 December 2015.
- Appendix T. Presentation: Building Resilience. Texas Children's Hospital. 11 December 2015. Houston, TX.
- Appendix U. Presentation: A Cooperative Communication System for the Advancement of Safe Effective and Efficient Patient Care, JPC1 IPR, Ft. Detrick, MD, 1 December 2015.
- Appendix V. Poster: A Cooperative Communication System. Defense Innovation Summit, Austin, TX. December 2015.
- Appendix W. Presentation: NIH-IEEE Point of Care Conference Presentation 10 Nov 2015: Valid Point of Care IT for Improved Decision Making Precision.
- Appendix X. Presentation: Support for Salience: IT to Assist Burn ICU Clinician Decision Making & Communication. IEEE Systems Man and Cybernetics International Symposium. October 2015. Hong Kong.
- Appendix Y. Resilient Health Care Network Recognition Application.
- Appendix Z. Literature Review on Clinician Decision Making.
- Appendix AA. Initial Requirements Analysis.
- Appendix AB. Usability Memo and Slide Enclosures.
- Appendix AC. Trip Report to AISR Scientific Review Conference (Enclosure).

- Appendix AD. CCS Straw Man Comparison, April 2016.
- Appendix AE. Trip Report to AISR Validation Study, June 2016.
- Appendix AF. CCS Validation Assessment Research Team Field Guide, May 2016.
- Appendix AG. CCS Machine Learning Validation Report.
- Appendix AH. Confirmation of Contract Deliverables Receipt, August 2016.
- Appendix AI. CCS Transition Plan.
- Appendix AJ. Transition: Cooperative Communication System, August 2016.

**Appendix A.** Book Chapter. Support for ICU Clinician Cognitive Work through CSE

# 7

# *Support for ICU Clinician Cognitive Work through CSE*

**Christopher Nemeth, Shilo Anders, Jeffrey Brown, Anna Grome, Beth Crandall, and Jeremy Pamplin**

**CONTENTS**

Introduction ..... 124
Background ..... 124
Research Design and Methods ..... 125
Quality ..... 126
Research Design ..... 126
Research Site ..... 127
Sample ..... 128
Methods ..... 128
Observation ..... 128
Structured Interviews ..... 129
Artifact Analysis ..... 129
Research Process ..... 130
Data Collection ..... 130
Data Analysis ..... 131
Limitations ..... 132
Preliminary Findings ..... 132
Unit Activity ..... 132
Network ..... 133
Information Resources ..... 134
Cognitive Work ..... 137
Challenges ..... 138
Discussion ..... 139
The ICU Work Setting ..... 139
Communication among Care Team Members ..... 141
The Role of CSE ..... 143
CSE in Health Care ..... 143

Able to Adapt to Surprise ..... 145
Summary ..... 145
Acknowledgment ..... 146
References ..... 146

## Introduction

"...operators pursue goals in complex work domains..." - edits OK?

Cognitive systems engineering (CSE) has been proven to be useful in revealing key aspects of operator behavior as operators pursue goals in complex work domains, providing the foundation for the development of solutions that are ecologically valid. Health care work settings, particularly the intensive care unit, present one of the most challenging work domains for a researcher to study. Cognitive engineering methods (Hollnagel and Woods 1983; Woods and Roth 1988; Roth et al. 2002; Militello et al. 2010) can be applied to understand characteristics of complex work domains such as the ICU as well as the behavior of workers including clinicians and their support staff. The use of CSE methods makes it possible to identify key traits of health care work settings, such as decisions clinicians make, obstacles clinicians face, and initiatives they take to overcome these obstacles in their efforts to restore patients to the best possible health. CSE methods also have the potential to enable workers to better understand their unit's performance and more successfully adapt to unforeseen challenges—in other words, to be *resilient*.

This chapter describes a project using CSE methods that is underway at a burn intensive care unit (BICU) in a major military medical center. This project will develop an ecologically valid computer-based cognitive artifact (Hutchins 2002) that will support individual and clinical team decisions and communication.

## Background

The study of health care relies on the use of proven methods by qualified researchers. This is because work at the sharp (operator) end of health care is (among other traits) dense, time-pressured, and complex. Expert workers can find it difficult to be objective observers of their own activities and work settings. Because of this, studying one's own system may yield conclusions that are logical but may also miss deeper issues. Attention in such studies often focuses on a single theme while excluding the many elements that interact with each other to produce a collective result—its context.

For example, *closed claims reviews* that conclude that error elimination will remove "error causes" ignore the complex pressured context that molded each event. It assumes that a claim will contain all of the information that needs to be known about an adverse outcome. It also presumes to know what caused that outcome, that it was caused by an "error," and that its cause can be "eliminated."

*Retrospective records review* relies on historical documentation in order to draw conclusions about care and its related risks. But records hold little of the context, speculation, deliberation, and complex trade-off decisions that typically mold any significant event.

*Voluntary reporting systems* have been touted as tools to incorporate error reporting and analysis into the culture of medicine (Plews-Organ et al. 2004). However, voluntary reporting fails to note how the approach is vulnerable to social and organizational influences.

Clinical discussions of patient safety often review how effective a single diagnostic or therapeutic intervention is without taking other factors into account that would affect outcomes in actual practice. For example, Shojania et al. (2001) tested the use of a single item to prevent infections: a maximum sterile barrier when placing intravenous catheters. Some clinicians attempt to make system analysis easier by bounding the problem through selection and management of a single variable. Kyriacou et al. (1999), for example, sought to measure and reduce the length of stay in the emergency department. Some clinicians have applied methods such as workload assessment to the ED, but they found that the level of effort that is required makes it difficult to routinely use it as a measurement tool (Levin et al. 2006). Others have imported measures from other sectors to measure a single aspect of ED operation. For example, France and Levin (2006) used the notion of "system complexity" to determine safe capacity during care demand surges but conceded that phenomena such as interruptions need to be added.

Research that does not adequately detect or understand these issues diverts valuable resources into low-yield efforts. Research that reveals context will grasp the constraints that shape opportunities and risks in practice, curb the influence of hindsight and outcome bias, and yield valid solutions that gain traction in actual work settings (Woars and Nemoth 2007). A current intensive care unit study provides an illustration of how the use of CSE makes that possible.

## Research Design and Methods

Our research team is completing the first part of a three-year study to develop a computer-based cognitive aid that supports cognitive work and communication. While it is still in its early stages, it can serve as an example

of CSE's value in health care. We discuss the CSE approach in this chapter in the context of our work on a prior project that described quality standards for how to conduct CSE research.

## Quality

Nemeth et al. (2011) described the use of CSE in a Navy-funded project that demonstrated how to use the CSE approach in the context of the Department of Defense acquisition process. The project's results would be used by government staff members and contractors who have no prior CSE training or experience. The approach needs to be used well to produce useful results. How would the new users know what that is? The team conceived of "reasonable scientific criteria" as a way to guide new users through CSE in a manner that is scientifically rigorous and that links design recommendations directly to operator needs. Using steps in the CSE process, the team considered the goals and activities at each stage, case studies from the literature that exemplified each stage, and ways that performance and scientific rigor could be evaluated at each stage. In order to do that, the team considered three questions:

- What reliability/validity criteria are important and reasonable to apply to CTA data?
- What are the standards of practice, and what needs to be done to meet those standards?
- How can a rigorous process be created and followed while also being open to discovery with respect to process and outcome?

Answers to these questions identified a set of quality standards for each stage of the CSE process (Table 7.1) from Nemeth et al. (2011) that can also be applied to research in the health care context.

In the section Research Process, we describe how the first three standards have guided our efforts during the project's first year. The standards for "Application: design" and "Evaluation" will guide our work in the project's second and third years.

## Research Design

Our project's goal is to improve patient care by better support of the judgment of BICU clinicians and teams by developing a cognitive aid that assists in decision making and communication. The project's three phases are scheduled to take roughly a year apiece for foundation research, cognitive aid prototype development, and prototype assessment. The first-year goal was to develop a thorough description of individual and team cognition that will provide the basis for cognitive aid prototype development in the second year as well as criteria for prototype assessment in the third year.

**TABLE 7.1**

Reasonable Scientific Criteria for CSE

| CSE Step | Standards |
|---|---|
| 1. Preparation and framing | Clear statements of<br>• Issue or problem<br>• Framing activities outcome<br>• Method, settings, project participant selection rationale |
| 2. Knowledge elicitation | Use of multiple knowledge elicitation (KE) methods<br>Use of interview and observation guides<br>Purposeful sampling of participants and settings<br>Qualified prepared data collectors<br>Quality control protocols (specified format to document data)<br>Manage the dual requirements for rigor and flexibility |
| 3. Analysis and representation | Systematic, purposeful, and documented analysis process<br>Audit trail to connect data elements to findings to design elements<br>Multiple analysis processes and multiple passes thru the data<br>Qualified analysis team members<br>Validity checks on findings<br>Goal-driven selection of qualitative versus quantitative analysis<br>Use of reliability indices |
| 4. Application: design | Iterative design–build–evaluate process<br>Subject matter experts (SMEs) for credibility checks<br>Audit trail to connect data elements, to findings, to design |
| 5. Evaluation | Clear assessment criteria<br>Review evaluation results systematically and purposefully<br>Evaluation methods reflect key cognitive components, behaviors<br>Outcomes reflect cognitive and behavioral issues critical for cognitive work<br>Verify whether the design/changes improve performance |

"The five member core team members" was changed to "The five core team members". Please check if OK.

The five core team members are experienced in health care field studies using CSE methods and are located remotely from the research site. To manage this, they retained a licensed vocational nurse (LVN) at the site to help with the administrative aspects of research team visits. All data collection and human subject consent were carried out under the jurisdiction of the medical center's Institutional Review Board (IRB), which reviewed and approved the research protocol. In advance of the team's first trip to the site, the Co-PI and LVN obtained the consent of health care team members working in the BICU who were willing to participate in the study. Those who declined to participate were excluded from observations and interviews.

## Research Site

The research site is a BICU located in a new wing of a federally funded 450-bed tertiary care military academic medical center. The 16-bed unit is widely considered to be one of the best of its kind in the country. Two of the ICU beds are reserved to serve as a postanesthesia care unit (PACU), and another is dedicated to support the center's extracorporeal membrane

oxygenation (ECMO) program. Other nearby units support the ICU, including a step-down unit, dedicated burn operating room, and an outpatient clinic. The typical census averages around 8 patients but has risen to as high as 13 during our study period. This unit's role as a regional tertiary care unit attracts patients who have the most severe affliction from thermal, chemical, mechanical, or electrical burns. It treats patients with burn-like diseases of the skin such as toxic epidermal necrolysis, Stevens–Johnson syndrome, and the autoimmune disorder pemphigus vulgaris. The unit also treats patients with infections or trauma that causes extensive soft tissue damage or loss, such as necrotizing fasciitis, severe degloving injuries, and some war-related trauma. Patient length of stay ranges from days to more than 12 months.

### Sample

All clinicians, patients, and patients' friends and family members are potential participants in the study. By the end of the study, we anticipate that over 150 clinicians will be included in the sample. Subjects are recruited through word of mouth in coordination with the BICU medical director and head nurse. Patients in the BICU (or their legal representative) are asked at the start of an observation period to complete a Health Insurance Portability and Accountability Act release before observation or interview. No clinical information collection or recordings are made in the presence of any patient who declines to complete the release. Patient medical data that are necessary to clinical decision making are collected without protected health information and are used only as examples of information that clinicians need to do their work.

### Methods

The study of human behavior requires repeated samples to capture its richness, complexity, and variation. No method by itself can account for this complexity. As a result, multiple methods need to be used in order to ensure that the account is valid and as accurate as possible. The research design for this project relies on multiple methods to triangulate data collection and analysis: observation, interviews, and artifact analysis. Comparison of data among all of these sources minimizes the potential bias that a single method may induce.

#### *Observation*

In-person observation makes it possible for the research team to witness the phenomena of patient care and team collaboration *in situ*. Informal probe questions enable the researchers to request background and clarifying information in the context of the situation. Observations can be used to study the ways that practitioners perform diagnoses and prepare, launch, monitor,

adjust, and complete patient care. The research team performs observations at various times throughout the day and evening to include a range of circumstances and clinicians' responses. Conditions can range from quiet routine to rapid changes. These can happen during the admission or discharge of multiple patients, emergent conditions such as treating rare emergencies like cardiac arrest or burn shock, and common emergencies such as treating postoperative hemodynamic instability.

Observation also includes informal interviews with clinicians as they work in order to learn the bases for their decisions or apparent indecision, motivations, expectations, and preferences that observation alone cannot reveal. Field notes that researchers make during observation provide data for analysis to reveal patterns among and across clinicians. Observations make it possible to describe the ways that individuals and groups cope with complexity and uncertainty. Research team members pay particular attention to heuristics (rules of thumb), and clinicians have developed their expertise and knowledge about individual and system performance, how they use systems such as the electronic health record, mental simulations they perform, and how they assess outcomes. The research team also watches for how the unit members resolve discrepancies and conflicts, negotiate trade-off, evaluate the credibility of data and information from others outside of the unit, and mentor and coach junior members.

During the first visit, team members visited the unit for five weekdays during the day shift (0800–1600). The team scheduled regular observations on the ICU to avoid interfering with clinical work. Subsequent visits to the site also covered evening and night shifts.

### *Structured Interviews*

Cognitive task analysis (CTA) interviews are used to elicit knowledge from clinicians on their background to learn point of view, work activities, information sources on which they rely, and reflections on the challenges they face (Crandall et al. 2006).

### *Artifact Analysis*

Clinicians use cognitive artifacts to capture and share information (Hutchins 2000). These include hard-copy printouts such as sign-out sheets, white marker status boards, and diagnostic and therapeutic equipment displays. They also include personal notes and related items that individuals find helpful, which are not part of the formal information ecology. The research team is collecting de-identified examples of these artifacts that are maintained by and for the group, as well as artifacts that individuals create and use in their work. Both formal and informal artifacts help to understand the inventory of information that the unit develops and uses, which will suggest the content and flow of information that this project's prototype will help to manage.

### Research Process

Note that there is no entry in Table 7.1 with the italic font. Please check.

The team began its work by conducting orientation interviews with selected clinicians at the research site. Quality standards described in Table 7.1 that guided our work are shown in italics. The interviews sought information about the BICU in order to develop an interview guide that would be used to organize data collection efforts during field visits. This enabled the team to develop clear statements of the issues and challenges and the outcome of framing activities. Using these, the team could create the rationale for method, settings, and selection of project participants at the research site. Four one-week data collection visits were conducted at the research site every other month, relying on quality control protocols to document interviews and observations, and cross-check the content of data records. Purposeful sampling of participants and settings ensured validity and reliability of the data that were collected during each visit. Each observation period lasted one week and was followed by a refractory period, during which the investigators reviewed notes, recordings, and artifacts. Data analysis results were also used to revise plans and interview guides for later data collection efforts.

#### *Data Collection*

A team of four qualified, prepared data collectors traveled to the site for the first data collection visit. They conferred with the Associate PI (located at the research site) on ICU census and plans for clinical activity. Using multiple KE methods to support findings consistency and comprehensiveness, they conducted CTA interviews to account for each role in the clinical care team. They accompanied the clinical team on daily rounds each morning, which were typically held outside of each patient room. During the trip, the team managed the dual requirements for rigor and flexibility by following interview guides, yet taking the opportunity to shadow participants and ask probe questions when the occasion presented itself. The team collected data firsthand by observing the phenomena that occurred while clinicians provided care in the ICU, using the CSE approach to describe the ICU as a work domain and to account for individual and team cognitive activities. They also collected de-identified examples of computer-based and hard-copy artifacts that the staff use in their daily work.

Rounds were recorded using a handheld video camera to capture team interaction and artifact use and were de-identified using a video-editing software. Recordings were made for future reference on how team members use and share information, including reference to artifacts such as sign-out sheets and task lists. When clinicians interacted directly with the patient, the team used audio recordings to capture how information was shared. No video was taken of the patients. When clinicians had time available, two team members conducted a CTA interview following the interview guide that was developed in the initial six months of the project. If the clinicians were not

available during the scheduled team visit, the on-site research nurse would help to organize the interview, and the core team members would participate remotely.

### *Data Analysis*

Data are evaluated using goal-driven selection of qualitative vs. quantitative analysis to extract patterns and themes. The research team gathers for data analysis meetings roughly a month after each data collection visit. The team has experience to detect and elicit patterns through a systematic, purposeful, and documented analysis process. Analysis sessions make possible the insight into what matters in the research setting and why it matters by performing checks on findings credibility, consistency, comprehensiveness, and centrality.

"Analysis sessions make possible the insight into what matters in the research setting..." – edits OK?

Team members prepare by reviewing the data collected from the most recent visit to ensure that each member has a current accurate recollection. This may also include organizing the data and checking to make sure that they are complete and ready to be analyzed. Members assemble as a group in 2–3 day-long sessions over a week to discover what the data mean by looking for central questions, issues, and themes. For example, the interview guide sought information on how team members manage work flow. Data analysis discussion explored observation notes and interview responses for items related to workflow.

The analysis sessions are intense sense-making exercises that use multiple analysis processes and make multiple passes through the data. Qualified team members use interview notes, observation notes, and artifacts to find patterns and themes in the collected data using reliability indices such as intercoder reliability (when and if they are appropriate). The team also looks for related themes, such as whether there is evidence among the data that show how the clinicians identify and reconcile goal conflicts or resolve agendas that do not agree. Team members suggest themes or patterns that seem to occur in the data. Others challenge, modify, or add to the discussion to ensure validity checks on findings. Team members create diagrams, tables, timelines, and storyboards and use other visualization methods to pose, assemble, and reassemble relationships in order to recognize possible patterns among and across data. During these free-flowing exchanges, new insights rapidly evolve and take the team to a new level of understanding.

Keeping track of the logic trail during these sessions can be a challenge. Maintaining the logical connection from data through analyses matters, because each of the requirements that the analyses eventually produce must have a deliberate link to the data from which they were derived. To keep track of these relationships, the team keeps notes that maintain an audit trail to connect data elements to findings to design elements. Without this structure, it is easy to disregard the data, producing a result that is not a set of findings but rather a collective team impression.

By the end of the analysis sessions, the team has deepened their understanding of what they know about the work setting and what occurs there. They also have a clearer sense of what isn't known yet and needs to be included in the plan for the next site visit. Later in the year, further analysis work will code and analyze all interview and observation data to detect themes and barriers and produce requirements for the prototype.

### Limitations

Modest project funding made it necessary to study one site, which limits its reliability. The research team was not available on the unit continuously during the study, making it difficult to observe momentary changes in unit activity such as clinician responses to codes. To mitigate that limitation, the research nurse was available at the research site to collect data in the periods between research team visits.

## Preliminary Findings

While the project has only been underway for a brief time, the first data collection and analysis sessions made it possible to describe initial findings that include unit activity, the network of care providers, and information sources on which the clinicians rely. These elements amount to an initial inventory of the work setting that the team can build on during subsequent site visits.

### Unit Activity

While many activities occur on the unit through 24 h, Table 7.2 shows the essential events that occur regularly each day. Those who are involved in these activities and the information resources they use to perform them start to flesh out a description of the unit.

Through the evening, the bedside nurse and resident both monitor and occasionally provide medication to the patient assigned to their care. From 6:30 to 8:00 a.m., the residents and medical students examine the patients and prepare for formal multidisciplinary rounds. The Assistant Chief Nurse and oncoming bedside nurses hold a safety huddle. Off-going and oncoming bedside nurses review their patient's condition and conduct a handoff. The ICU Chief Nurse reviews the unit population and resource needs, and the unit dietician reviews patient nutrition plans. At 8:00 a.m., the general rounds begin and can last up to two or more hours depending on a number of factors including unit census, patients' condition, and time pressure. From 8:00 a.m. to 2:00 p.m., patients are showered, receive care for their wounds, or are taken to the nearby operating room procedures such as tissue debridement, skin grafting,

**TABLE 7.2**

BICU Schematic Timeline—Weekdays

| Time | Activity | Participants | Information Resource |
|---|---|---|---|
| 0000–0645 | Patient monitoring, occasional medication | Bedside nurse; resident | Patient monitors |
| 0630–0800 | Patient exam, rounds preparation | Resident, medical student | Sign-out sheet; patient health record (PHR), wound flow, radiology images, patient monitors; bedside nurse, off-going resident |
| 0645–0700 | Safety huddle | Assistant Chief Nurse, oncoming bedside nurses | Personal notes |
| 0700–0800 | Bedside report and physical assessment | Off-going bedside nurse, oncoming bedside nurse | Patient monitors |
| 0700 | ICU audit | Assistant Chief Nurse | Personal notes |
| 0700–0730 | Metabolic assessment | Dietitian | Excel file; PHR |
| 0800 | Patient rounds | Intensivist, burn surgeon, fellow, resident, bedside nurse, charge nurse, medical student, respiratory therapist, occupational therapist, social worker, dietician, psychiatrist | PHR |
| 0800–1400 | Shower, wound care | Bedside nurse, wound care team: RN and LVN | Wound flow |
| 0800–1400 | Medications | Bedside nurse | |
| 0800–1400 | Surgeries | Burn surgeon, OR team | Shadow charts |
| ~1400 | Patient exam | Resident | |
| 1200–1300 | Lecture | Staff physician, surgical and medical residents, medical students | |
| ~1500 | Afternoon rounds | | |
| 1530 | Plan for wound care the next day | Charge nurse, wound care coordinator | 4T assignments sheet |

and reconstructive surgery. The remainder of the day includes a lecture for residents/medical students, the resident examination of his/her patient, brief afternoon rounds to review what has been completed from tasks assigned during morning rounds, and an informal discussion between the wound care team leader and the charge nurse to decide patient plans for the next day.

### Network

Patients on this BICU typically need care by a variety of specialists, requiring exceptional planning, coordination, and ability to work together. Table 73

**TABLE 7.3**

BICU Patient and Patient Care Staff Roles

| Patient | Bedside Nurse | Patient Family | Attending Intensivist | Burn Surgeon | Licensed Social Worker |
|---|---|---|---|---|---|
| Head nurse | Occupational therapist | Respiratory therapist | Resident | Medical student | Clinical nurse specialist |
| ICU nurse | Psychiatric nurse | Unit clerk | ICU director | Charge nurse | Pharmacist |
| Staff psychiatric nurse practitioner | | | | | |

depicts many of the roles that need to collaborate to create and manage a feasible plan for patient care across multiple shifts through the week and the weekend. The roles range from the bedside nurse, who serves as a primary care provider and kind of the gatekeeper for patient care by others, to primary care physicians such as the intensivist and burn surgeon, and care specialists such as the respiratory and occupational therapists, those who care for members of the health care team such as the psychiatric nurse practitioner, managers who assist with planning and oversight, and hospital employees off the BICU such as the pharmacist. In a unit that involves as many team members and specialties as this BICU, it can help to focus on a single most important element of the work domain. In this unit, the bedside nurse is closest to the patient and can serve as a focus of attention for the researcher to understand crucial working relationships. Figure 7.1 represents the 31 working relationships in our data that the bedside nurse maintains in daily practice. Among all of these roles, the bedside nurse interacts most with others on the nursing staff, the patients' family and friends, physicians (including physicians of different levels of training and of different specialties), rehabilitation/occupational therapy technicians, and the clinical lab and blood bank.

### Information Resources

Prior work by researchers including Xiao et al. (2001), Wears et al. (2007), Nemeth et al. (2006), and Bisantz et al. (2010) has described the role of cognitive artifacts (Hutchins 2000) in the health care setting. These artifacts include physical items that are either personal (e.g., a sign-out sheet or note on a scrap of paper) or informal and used by a group (e.g., marker board), as well as electronic information displays that are local (e.g., equipment information display) or distributed (e.g., information system display; electronic medical record). Figure 7.2 depicts many of the artifacts that the staff relies on to perform individual and team cognitive work each day.

Databases and interfaces to manage them include the PHR, outpatient record, blood glucose management, laboratory culture, nurse scheduling, and radiology images. While used in concert, many of these systems are

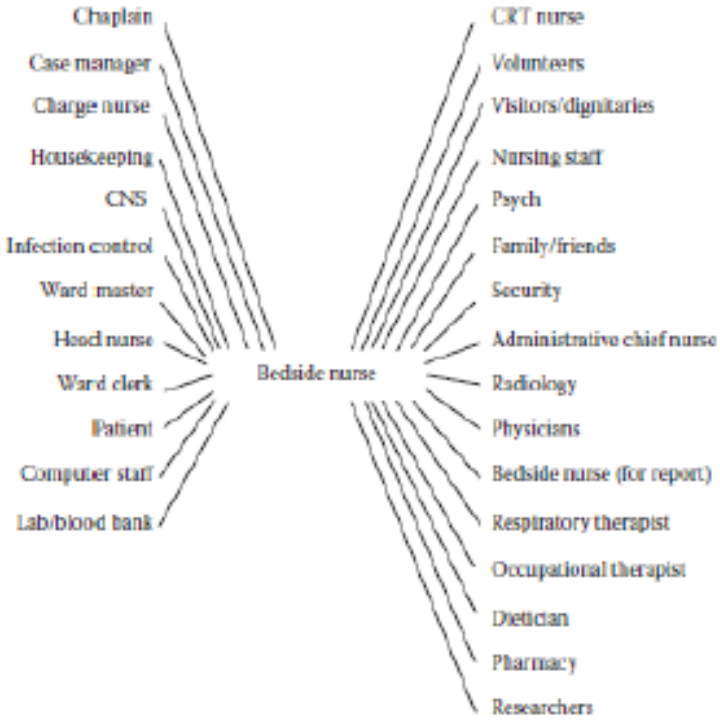



**FIGURE 7.1**
Initial representation of bedside nurse work relationships. (Copyright © 2013 Applied Research Associates, Inc.)

actually separate. This separation requires care team members to take extra steps and make temporary hard-copy notes to use and transfer information among systems. Other information resources beyond databases include white boards, a daily wound care plan, vital signs flow list, email/cell phone roster, landline phone roster, resident sign-out sheet, and a charge nurse checklist. The strong emphasis on research at the project site has made it possible for clinicians to develop their own formal electronic information sources in addition to the hard-copy artifacts that may be found at other health care locations. The Wound Flow software program makes it possible to identify the location and condition of tissue injury and skin grafts. An Excel file that the unit dietitian has developed makes it possible to accurately track the quality and amount of nutrition that is crucial for burn patient recovery. The Burn Resuscitation Decision Support software enables the staff to accurately manage fluid resuscitation during the critical 48 h following a significant burn injury. The solution that this project creates will need to bring these various parts of this information ecology (Nemeth et al. 2008) together in order to form a cohesive whole for the unit to use. We expect

The entry "Nemeth et al. 2008" is not included in the reference list. Please provide missing information in the reference.

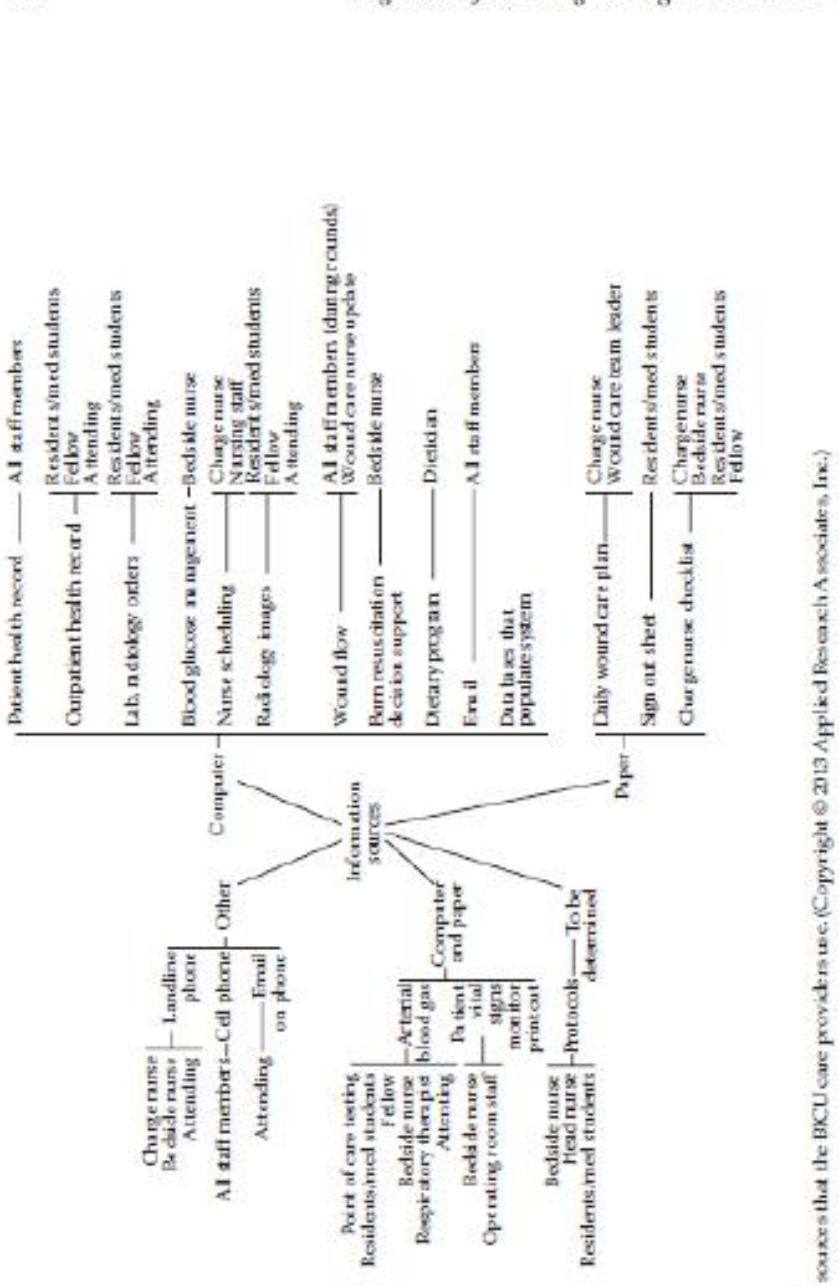



**FIGURE 7.2**
Information sources that the BICU care providers use. (Copyright © 2013 Applied Research Associates, Inc.)

that using the cognitive aid will enable the unit staff to work together more effectively and efficiently and, as a result, improve patient care effectiveness and outcomes.

### Cognitive Work

An initial review of the data indicates that individuals and teams perform a number of macrocognitive (Crandall et al. 2006) activities, which are summarized in Table 7.4. The staff performs *rework* through bridging and work-around strategies to link systems that don't talk to each other in an effort to ensure *information continuity*. For example, the ABG unit is not connected to the database for the electronic PHR. (See Chapter 6 for additional examples, and a proposed model, for tracking ways that information is maintained throughout health care systems.) The dynamic activities on the unit require *negotiation* hourly/by shift/daily among individuals, specialties, and those who have different levels of expertise. *Allocation of resources requires planning and replanning* among and across patients and specialties in *anticipation* of the patient status and needs, and how to meet them through preparation and participation in events.

"Allocation of resources requires planning and replanning among and across patients and specialties in anticipation of the patient status and needs, and how to meet them through preparation and participation in events." - adds CIO?

**TABLE 7.4**

Emergent Themes for Cognitive Work of Burn ICU

| Theme | Definition |
|---|---|
| Rework | Bridging and work-around strategies to link systems that don't talk to each other. |
| Information continuity | Arterial blood gas (ABG) does/doesn't connect to electronic PHR. An additional volume needs to be created for a very long term care patient. |
| Negotiation | Among individuals and care specialties, team member levels of knowledge and expertise are dynamic, which requires negotiation by the hour, shift, and day. |
| Scheduling | Planning and replanning among and across specialties. |
| Anticipation | Patient status, needs, and how to meet them; preparation and participation in events. |
| Coordination | Collaboration requires expression of expectations, prioritization, agreement, and recruitment/transfers. |
| Clarification | Inquiry, sense making, common grounding, to drive down levels of uncertainty and reach an acceptable level of confidence. |
| Resources | Access, availability, permission, provision, preparation, authority, certification, and use related to equipment, medications, and supplies. |
| Tasking | Assignment of ICT team members to best match patient needs; based on individual abilities and experience and team needs. |
| Cross-checking | Identify, confirm, and correct information; problem detection, which may create drag in completing care activities. |
| Tracking | Account for what needs to be done, whether it has been completed, and what remains to be done. |
| Gaps | The ability some more experienced team members have to suspect something that is needed is missing. |

*Collaboration* requires the expression of expectations, prioritization, and agreement for staff member recruitment and patient transfers. In order to reach threshold of confidence with which they are comfortable, staff members *clarify* through inquiry, sense making, and seeking common care by reducing uncertainty. Use of *resources* such as equipment depends on its availability as well as permission, provision, preparation, authority, and any required certification to use them. These traits fit what Cook and Woods (2002) have described as the "technical work" in the context of health care. *Tasking* assigns ICU staff members to best match individual abilities/experience and team needs to meet patient needs. Through *cross-checking*, the staff detects problems and identifies, confirms, and corrects information. Their *tracking* efforts account for what needs to be done, whether it has been completed, and what remains to be done. Staff members with the greatest expertise are able to see "gaps," which are, in effect, "what isn't there" but should be.

## Challenges

A number of work domain issues shown in Table 7.5 can detract from the time and effort that could be devoted to patient care. Our project team considers each issue from the viewpoint of whether the cognitive aid could help to either mitigate or eliminate them. Nurses fill gaps in the *limited orientation* that residents and float (off unit) nurses receive, which takes time from patient care. Due to *lags in information* timing of information on labs and blood cultures, staff members need to rely on verbal orders (referred to as "on the sly") that are not fully socialized or shared and can result in care delays. *Bedside nurses reconcile conflicts between* patient care needs and technology protocols, guidelines, policy, and regulations. *Procedural drag* results from the need for transcription and work-arounds due to system organizational gaps. The need for clinician *reliance on memory* provides the researcher with a marker for failure, as technology fails to support the needed work. *The long-term story of the patient/big picture is lost*, because trend information and understanding are lost or degraded over a long term of care. *Reliance on verbal exchanges* makes the flow of information porous, brittle, erratically shared, and less reliable. The *authority gradient* between junior and more senior staff members encourages passivity with regard to concerns and impedes sharing. *Common grounding accuracy* suffers from underspecification, requiring confirmation, verification, and clarification. It is not always clear *who has the "Con?"* (has the lead) among specialists during procedures when care quality is high, but no individual takes accountability to assure results. *Timing* issues can result in poor coordination and stale information, such as when a procedure was performed. Without *salience* to bring it to the clinician's attention, important patient information such as "stat" orders is lost in homogenous information displays. Software *usability/access/usefulness* issues result in difficulties in being able to use it, having the knowledge it

**TABLE 7.5**

Emergent Themes of Barriers and Challenges to Effective Care

| Issue | Definition |
|---|---|
| Limited orientation | Residents and float RNs receive limited orientation to the unit. RNs provide orientation, which takes time from patient care. |
| Lags in information, medications, labs, and blood | Reliance on verbal orders "on the sly" (informally) that are not fully socialized or shared; creates consistent care delays. |
| Bedside nurse reconciles conflicts | Technology protocol, guidelines, policy, regulations, and patient care needs require choices to be made. |
| Procedural drag | The need to create work-arounds and bridging tactics to fill the gap between incompatible systems slows down work efficiency. |
| Reliance on memory as a failure marker | Technology fails to support necessary work, causing clinicians to rely on memory for continuity (e.g., action items not completed by afternoon rounds not carried through to the next day). |
| Story of the patient/ big picture is lost | Incremental views of patient status are not synthesized into a whole picture; particular concern for patients in BICU for extended periods. |
| Reliance on verbal exchanges | Information flow is porous, brittle, not shared, or reliable. |
| Authority gradient | Encourages passivity with respect to expressing concerns. |
| Common grounding accuracy | Under specification, needs for confirmation, verification, clarification all affect ability of clinicians to develop consensus. |
| Action/who has the "Con?" | Numerous well-qualified clinical specialties collaborate but lack of clarity regarding who is leading a particular procedure (e.g., ECMO). |
| Timing | Lack of synchrony can result in stale information (e.g., when the procedure was performed). |
| Salience | Great deal of information that is presented homogenously. Information that is most relevant is difficult to find (e.g., "Stat" orders are not evident). |
| Usability/access/ usefulness | Systems cannot be used without requisite operator knowledge, certain access requirements. |
| Organizational issues = drag | Compliance with administrative reminders detracts from patient care. |

requires to use it, and being able to enter data accurately. Compliance with *organizational issues* such as administrative reminders creates drag for clinician efficiency.

## Discussion

### The ICU Work Setting

ICU patients present clinical teams with unique challenges and complex combinations of life-threatening injuries and illnesses. Care for this patient

population is necessarily multidisciplinary and includes many specialties. Care providers across these clinical areas must collaborate to develop treatment plans, assess progress, and refine or change treatment plans and modes.

Clinician decisions are only as good as the information that is available when they are made. The daily work on the unit requires representations that serve as a map of the ever-changing environment of work that must be successfully navigated. Clinical teams that care for ICU patients in the military health care system encounter these challenges as they make diagnostic and therapeutic decisions and share them with colleagues. Decision-making difficulty increases as the number of patients and the severity of their conditions increase. Complexity grows as the number of care providers seeks to make their own unique contribution to a patient's care.

Patient care activities rely on the acquisition, portrayal, and analysis of therapeutic and diagnostic information from many sources. This creates a complex work setting that is composed of multiple independent agents. All interact in various ways according to inconsistent rules in an attempt to adapt to changing conditions. Because of this, the organization's outcomes are unpredictable, but they often follow predictable patterns (Plsek and Greenhalgh 2001).

Other ethnographic studies also revealed insights into acute care settings. For example, Fackler et al. (2009) used CTA to identify cognitive aspects of critical care practice in two academic ICUs and identified broad categories of cognitive activity: pattern recognition; uncertainty management; strategic vs. tactical thinking; team coordination and maintenance of common ground; and creation and transfer of meaning through stories. Anders et al. (2012) used a simulator-based experiment to evaluate ICU nurses' ability to detect patient changes using an integrated graphical information display (IGID) compared with a conventional electronic chart-style ICU patient information display. The study found that the 32 ICU nurse samples reported more important physiological information with the novel IGID compared with the tabular display and concluded that information displays should accommodate the diversity of those who are intended to use it.

Novak et al. (2012) found that medication administration intersects with other organizational routines, and IT-enabled changes to one routine lead to unintended consequences in its intersection with others. Introducing IT can be improved by nurses who provide technology-use mediation before and after the rollout of a new health IT system. Their efforts can help others to better understand the relationship between IT introduction and changes in routines.

In addition to operational complexity, our research into reporting health care adverse events using CSE methods (Nemeth et al. 2006) has also revealed technical, social, political, and legal forces. Each influences acute care settings such as the ICU, which are typically uncertain, interrupt driven, saturated, and contingent.

*Uncertain*: Clinicians must treat widely varying patient populations. Time pressure can force clinicians to make decisions based on information that can be insufficient or ambiguous. Field studies using CSE methods can discover initiatives that clinicians have developed to minimize uncertainty.

*Interrupt driven*: Interruptions create breaks in clinicians' task-oriented work (Chisholm et al. 2000), and when they occur during diagnosis and treatment, they can degrade or defeat attempts to treat patients. Work domain study using CSE methods can identify gaps in care continuity, detect how clinicians allocate limited attention reserves, and produce tools such as cognitive artifacts that maximize patient care opportunities.

*Saturated*: Facilities and staffs typically run at or near capacity. With little margin of time or resources to spare, clinicians have to develop strategies to cope with variations in care demand. Work domain studies using CSE can reveal discontinuities that exist in the match between resources and demand, such as late shifts, and unexpected surges in care demand.

*Contingent*: The process of care depends on the patient, including presenting symptoms, documentation of history, response to therapy, expected trajectory of treatment, compliance, and more. CSE methods can be used to discover how care providers create, monitor, and adjust multiple contingencies in order to achieve as satisfactory and expedient an outcome as possible for patients.

In addition, distraction, complexity, remote influences, and consideration make health care human subjects research a particular challenge.

*Distraction*: Many activities are performed by a variety of clinicians in the vicinity of each other. This makes it easy to be distracted by phenomena that are not necessarily key features of the work domain.

*Complexity*: Acute care settings have many complex activities that occur at the same time. This is particularly true in an ICU.

*Remote influences*: Care team members can be distributed across various locations and across time. Not all activity that matters occurs within view or in the immediate recall of those whom the researcher interviews.

*Consideration*: Patients in the BICU are typically fragile as a result of some trauma. This calls for the researcher to have an adequate sensitivity to care providers, patients, and the patient's family members.

All of these influences form the context in which clinicians perform their cognitive work. The CSE approach makes it possible to describe the domain and individual and team activity in it to transform findings into requirements that serve as the basis for a prototype cognitive aid.

### Communication among Care Team Members

Team communication creates, and is created by, the work context. CSE can be used to reveal the context and worker behaviors that lead to understanding communication needs and how to support them. This contrasts with the more traditional information engineering approach that assumes that

understanding comes simply from the faithful uninterrupted transmission of data (Feldman and March 1981; Stohl and Redding 1987). Care provider expectations differ on communication content, form, relevance, and value of its completeness.

Interventions based on CSE methods can benefit team communication. For example, Grome et al. (2009) found that co-creative development workshop helped surgical team representatives to create and adapt preoperative briefing content and structure, as well as measures to assess the briefing's effect on teamwork, communication, and patient safety.

The entry "Nemeth and Cook (2013)" is not included in the reference list. Please provide missing information in the reference.

Nemeth and Cook (2013) used CSE to identify barriers that can erode the quality and reliability of health care communication that this project addresses.

*Difficulties in communication.* Health care and the information that is needed to provide it are typically complex and demand accuracy in order to avoid misinterpretation.

*Confusion of responsibility.* Interwoven relationships among care providers, units, departments, and institutions can result in confusion over who is responsible for a patient's care.

*Lack of, or variable availability of, good information resources.* Even with sophisticated information technology available, system failure or incompatibility can result in images and reports being mislabeled, misunderstood, swapped, late, misidentified, or unavailable.

*Work environment pressures.* Care provider efforts to cope with workload demands and time pressure can result in a kind of "shorthand" that edits information in order to be efficient.

*Lack of standards or training.* Clinical specialties and institutions can vary in the way they go about practices such as handoffs, resulting in the potential for misperception.

*Aptitude.* Patients and family members may find it hard to understand the information that is conveyed through written, verbal, and graphic health care communication.

*Attention.* Understanding and context are essential to effective communication. Simple transmission (e.g., a "data dump") does not guarantee that others understand what is provided or can correctly put it into context.

*Attitude.* Clinician empathy may yield a number of benefits, including patients reporting more about their symptoms and concerns, increased physician diagnostic accuracy, patients receiving more illness-specific information, increased patient participation and education, increased patient compliance and satisfaction, greater patient enablement, and reduced patient emotional distress.

Reader et al. (2008) found that team structure and individual roles and stature have significant effect on ICU communication, and a difference in status appears to influence how communication is perceived. The "authority gradient" barrier mentioned in Table 7.5 may be related to this issue.

Through the use of CSE, the cognitive aid that this project produces will need to help the ICU staff to overcome these potential barriers.

## The Role of CSE

The use of CSE methods makes it possible for the researcher to "get in" at the right level of detail. Too general a study will miss the nuances and refinements that clinicians create in order to make their work possible. Too detailed a study may collect great amounts of data but will also miss the broader patterns that make insight possible. Studies of such a complex domain require repeated visits in order to reveal the deeper aspects of what occurs. These are what have been referred to as the "messy details" of technical work (Nemeth et al. 2004). The researcher needs to learn about real-world settings that involve the organized activities of daily life (Garfinkel 1967). Real-world settings are stubborn, though, and do not easily reveal themselves (Blumer 1969).

Research can be basic (a search for general principles), applied (adapting general findings to classes of problems), or clinical (related to specific cases). Most design research is clinical because time and budget allow for little else (Friedman 2000). CSE methods can be used to negotiate the gap between applied and clinical research.

## CSE in Health Care

Recent work on collaboration has produced distributed cognition and joint cognitive system models that can be used to better understand health care as a collective enterprise. The use of CSE to identify and describe all ICU elements, including clinicians, information, and artifacts, can identify system gaps. Addressing gaps can lead to authentic improvement in performance and outcomes. For this reason, CSE is particularly well suited to the discovery of phenomena in complex real-world settings.

The entry "Hutchins 1995" is not included in the reference list. Please provide missing information in the references.

Distributed cognition (Hutchins 1995) is the interaction of individuals, artifacts, and the environment. Practitioners must rely on this to prevent the formation of gaps in the continuity of care (Cook et al. 2000). This includes transfers between departments, work-cycle shift changes, and information exchanges among professionals from different fields of practice. Clinicians in an ICU comprise a joint cognitive system that can modify its behavior and decision making on the basis of experience in order to maintain order (Hollnagel and Woods 1983). The daily work of the clinician requires representations that serve as a map of the ever-changing environment of work that must be successfully navigated (Rasmussen et al. 1994). Individual elements of information vary enormously in the length of time that they are reliable, and their value depends on their context. What is represented and how it is represented should depend on the cognitive work it is intended to

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support. Furthermore, the partial and overlapping interaction among clinical specialties in the ICU lends itself to additional gaps in care continuity and the misadventures that can result.

### Validity

Nemeth et al. (2011) recommended four ways to verify whether results from qualitative studies such as this ICU research project are valid. Findings must be credible, consistent, comprehensive, and central.

*Credible.* Do findings "ring true" to SMEs and others who work in the domain?

*Consistent.* Do findings replicate across interviews and across incidents?

*Comprehensive.* How general are the findings? To what range of tasks and settings do they apply? Can boundaries be identified, and can those limitations be stated?

*Central.* Do findings speak to cognitive issues that *matter* for performance based on SME judgments, research literature, and other sources?

Studies that meet these criteria are more likely to pass validity tests when solutions are evaluated.

## Aspects of Resilience

Knowledge gained through the use of CSE about the nature of work as it is actually done can help to contribute to the system's ability to adapt when confronted with unforeseen challenges—to be more *resilient* (Hollnagel et al. 2006). Recent writing in resilience engineering has identified a number of system characteristics that contribute to system resilience. This knowledge can improve their ability to operate despite significant challenges such as changes in the type, rate, and volume of care. Three characteristics that CSE can assist include being self-aware, the ability to identify and apply resources, and the ability to adapt to surprise.

### Self-Aware

The "cottage industry structure of the national healthcare delivery system" results in "disconnected silos of function and specialization."(Reid et al. 2005, pp. 12–13) Acute and ambulatory care patients require coordinated care that is provided by multiple distributed care providers. Their care also calls for the coordination and integration of many functions and specialized areas of knowledge over time. Yet connectivity, integrated care, and coordination are inadequate nationwide at all stages of illness treatment. An estimated 60 million patients in the United States suffer from two or more chronic

The entry "Reid et al. 2005" is not included in the reference list. Please provide missing information in the references.

conditions and are particularly affected by the disconnection among clinical care specialties. The ability to reveal the nature of work domains by using CSE can start to mitigate this significant and widespread issue.

### Able to Identify and Apply Resources

Skills, supplies, equipment, and facilities are routinely assembled to perform each procedure. CSE can be used to document work processes and what influences them. That can lead to insight into how these configurations are developed and managed, what goes well, and where misadventures can occur.

### Able to Adapt to Surprise

We have shown in prior publications (Nemeth et al. 2007; Cook and Nemeth 2010) how health care organizations respond to events, particularly misadventures. More often than not, the response attempts to isolate the cause and declare that it will not happen again. These efforts stop the exposure to risk. However, they also stop the learning that can inform us how systems have difficulty adapting. The use of CSE makes understanding what goes right, and what occasionally does not, a routine learning process that can improve the ability to adapt.

## Summary

We need to learn what people actually do in health care teams and how to design work processes and systems based on that knowledge. This calls for an approach that reveals the true nature of work as it is actually done, not as it is intended to be done. CSE serves that purpose well.

Early data collection and analysis activity in our BICU research have identified the network of those who care for patients, the information sources they use, and the flow of patient care activity. Continued visits are expected to deepen the understanding of interrelationships among clinicians, how they address and resolve conflicts such as different agendas, the information sources and their use, and cognitive activities for each of the clinical specialties and roles. Results from this first year of study will be used to develop requirements for decisions that clinicians make. Requirements and use cases will provide the basis for a prototype to be developed and evaluated in the project's second and third years.

The well-designed valid cognitive artifact that results from our use of CSE is intended to support individual and team cognitive work, which is expected to improve the reliability and efficiency of clinical care for patients.

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**Appendix B.** MHSRS Developing a Cognitive and Communications Tool for Burn ICU Clinicians. *Military Medicine*. Society of Federal Health Officials (AMSUS).

MILITARY MEDICINE, 181, 5:205, 2016

# Developing a Cognitive and Communications Tool for Burn Intensive Care Unit Clinicians

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**ABSTRACT** Background: Burn Intensive Care Unit (BICU) work is necessarily complex and depends on clinician actions, resources, and variable patient responses to interventions. Clinicians use large volumes of data that are condensed in time, but separated across resources, to care for patients. Correctly designed health information technology (IT) systems may help clinicians to treat these patients more efficiently, accurately, and reliably. We report on a 3-year project to design and develop an ecologically valid IT system for use in a military BICU. Methods: We use a mixed methods Cognitive Systems Engineering approach for research and development. Observations, interviews, artifact analysis, survey, and thematic analysis methods were used to reveal underlying factors that mold the work environment and affect clinician decisions that may affect patient outcomes. Participatory design and prototyping methods have been used to develop solutions. Results: We developed 39 requirements for the IT system and used them to create three use cases to help developers better understand how the system might support clinician work to develop interface prototypes. We also incorporated data mining functions that offer the potential to aid clinicians by recognizing patterns recognition of clinically significant events, such as incipient sepsis. The gaps between information sources and accurate, reliable, and efficient clinical decision that we have identified will enable us to create scenarios to evaluate prototype systems with BICU clinicians, to develop increasingly improved designs, and to measure outcomes. Conclusion: The link from data to analyses, requirements, prototypes, and their evaluation ensures that the solution will reflect and support work in the BICU as it actually occurs, improving staff efficiency and patient care quality.

## BACKGROUND

Patients who are admitted to the Burn Intensive Care Unit (BICU) present health care teams with unique challenges as a result of their fragile and often unstable condition. Their complex combinations of life-threatening injuries and illnesses make trauma and surgical care for these patients necessarily complex. Clinicians from 15 specialties must work together to make effective decisions, develop treatment plans, assess patient progress, and refine care management over time. This team must also account for limited resources and must adjust their course of treatment according to variable patient responses to interventions.

Care also relies on clinician cognitive work, which includes decision-making and related activities such as problem detection, sense making, and building common ground among the care team members. Under time pressure, intensive care unit clinicians must rely on a large volume of data that is separated among multiple sources. The decisions clinicians make are only as good as the information that is available and important (salient) when the decisions are made. Because of this, the Institute of Medicine[1] recommended improving access to accurate, timely information, and making relevant information available at the point of patient care.

Research and development for this project is being conducted by Applied Research Associates, Inc., an 1,100-member science and engineering consulting firm, which is creating a decision and communications support system that will serve a 16-bed military tertiary care BICU. This Cooperative Communication System (CCS) is expected to enable the health care team to remain connected to information about each patient and to each other across time and location as the team delivers care. The CCS will keep providers informed of a patient's status, and of other health care providers' patient care activities, enable the staff to understand goals, objectives and tasks related to each patient, and to reconcile differing points of view. Its decision and communication support and machine learning features will make it possible for clinicians to make more accurate and timely diagnoses, to perform more timely and appropriate tests, and to make better plans to optimize patient care. Use of the CCS is expected to improve the availability of information and the synchronization of care among BICU team members, which in turn are expected to improve patient outcomes.

This article describes rigorous field study, analysis, requirements, and information design and programming to design and develop an ecologically valid information technology (IT) system.

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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. In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

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## METHODS

The CCS research team is using a mixed methods Cognitive Systems Engineering[2,3] (CSE) approach for this study. The CSE approach includes methods that are particularly well suited to both learn about behavior and cognition as humans confront complexity in work settings such as the BICU and to develop tools to support their cognitive work. The approach translates knowledge about human cognitive performance to develop solutions, including information system interface design.[4] In this study, knowledge that clinicians need includes vital signs and laboratory values that one would expect would matter in trauma and surgical care decision-making. Knowledge also includes unexpected data patterns that matter, but are difficult to detect.

As a "systems engineering" methodology, the CSE approach includes all of the agents that can act in the work setting: clinician and support staff, tasks, information sources, the facility, and more. Figure 1 illustrates five phases in the approach and how the activities in each phase relate to phases of this project. As Figure 1 shows, CSE phases include data collection, data analysis, and solution development. Integration of these five phases ensures that the solution the CSE process produces is inherently valid by being grounded in worker and work setting data. Each element in the solution that the CSE approach produces can be traced back through requirements, through analyses, to the original data. The ability to identify each element among workers, work setting, and tools can also help designers to anticipate shifts and unintended consequences that can happen when new IT such as the CCS is introduced.[5] The CSE approach has been proven to successfully study cognitive activity in complex field settings in high-hazard sectors such as defense, national security, nuclear power plants, and law enforcement. The project team has recently used CSE to perform work on behalf of the Department of the Army,[6,7] Chief of Naval Operations (Nemeth C, Wiggins S, Crandall B, et al: C2 Upgrade for NECC Branch [OPNAV N857]. Contract N00024-10-C-6309. Washington, DC: Department of the Navy. 2011), Office of Naval Research (Anderson KR, Crandall B, Grome A, Nemeth C: Environmental and ship motion forecasting cognitive aid investigation: Decision and information requirments development. Contract N00014-11-C-0360. Washington, DC: Office of Naval Research. 2014), and Department of Homeland Security (Nemeth C, Grome A, Laufersweiler D, Crandall B, Strouse R: A research roadmap to improve screening performance through cognitive systems engineering. Contract GS-10F-0298K. Washington, DC: Department of Homeland Security, 2013).

Our project team studied clinicians who work in a 16-bed, American Burn Association accredited regional referral burn center that is a part of a 450 bed, academic, military, level I trauma center. The team obtained approval for human subject research from the funder and research site institutional review board and obtained informed consent from all participants.

In Year 1, the research team used data collection methods (observations, interviews, surveys, and artifact analysis) to go beyond surface descriptions (phenotypes) that revealed underlying patterns (genotypes) of systemic factors that mold the work environment and affect clinician decisions.

### *Data Collection*

A team of 2 to 4 researchers made 4 week-long data collection visits to the research site, and coordinated additional collection with an on-site research nurse between visits.

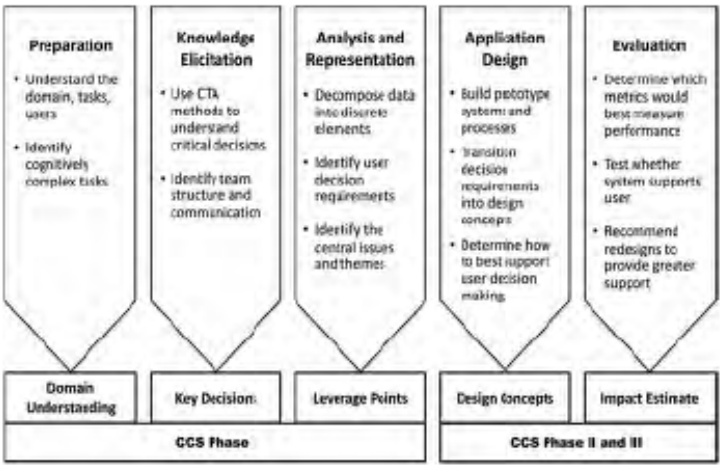


**FIGURE 1.** Five phases of cognitive systems engineering.

During these visits, they performed the following data collection methods:

Observation of clinical teams as they provided patient care and managed the unit. Team members conducted 31 observations with the BICU staff, including bedside, charge and wound care nurses, residents, attending physicians, and physical, occupational, and respiratory therapists. These sessions involved shadowing a single person and asking them to talk aloud as they completed their work. Use of probe questions enabled researchers to request background and clarifying information in context to better understand motivations, information use, and decision-making.

Forty-nine semi-structured cognitive task analysis (CTA)[8] interviews lasting between 30 to 90 minutes each with members of the BICU clinical staff elicited knowledge about their background, perspectives, work activity, information sources, and challenges they face.

Artifact analysis of computer-based and hard copy information sources that clinicians use in their work, including sign-out sheets, personal notes, status boards, and information system and equipment displays.

Brief surveys to identify patterns, such as work team relationships (usually conducted by the on-site research nurse in-between research team visits).

### Data Analysis

The research team analyzed data collected from four week-long site visits and research nurse support at the site between visits. Through the following eight steps (Fig. 2), their analyses identified clinician goals and barriers to goal achievement. After the first site visit, the team performed an initial data review and extraction of emerging themes to review and analyze interview and observation notes. Following the second site visit, the team conducted a systematic data review and coding to reveal thematic categories developed during working sessions, and code interview sections to relate them to each theme. After the third visit, they reviewed and interpreted coded data, synthesized and merged findings, and reflected on newly collected data. Each of the steps used analyzed cognitive work to provide the basis for analyzing the cognitive work requirements of BICU clinical teams and distil a descriptive model, as well as artifact analysis of the forms and documents that the BICU clinical teams use, to more fully understand the kinds of information they seek, use, and share with one another. After developing initial requirements for the CCS, team members made another visit to present the challenges/barriers and initial requirements to a select set of BICU clinicians to obtain an initial appraisal of the findings by verifying accuracy and identifying possible gaps. The team used results from the data analysis to identify barriers to cognitive work, and develop final requirements for the CCS that would enable BICU staff to overcome those barriers.

### Participatory Design

Research, software development, and machine learning team members met with the clinical co- principal investigator (JP) for a 2-day data analysis and design session to refine and revise design requirements. The team also held a similar design session a few weeks later at the research site to capture clinician insights. In these sessions, representatives from all of the clinician groups that work in the BICU proposed system design ideas that might facilitate timely, effective, and efficient patient care. The sessions provided the interface designer with beginning concepts for further development and refinement. The research team also updated and

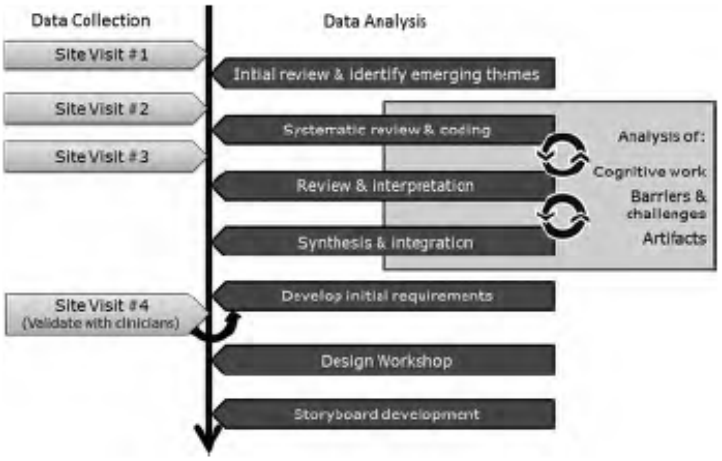


**FIGURE 2.** Data collection and analysis process.

refined the use cases that the software development team would need.

## RESULTS

One hundred fifty-one BICU clinicians and staff members representing all unit roles consented to participate in this research and many were subjectes of interviews and observation. Roles included attending physician (surgeon, intensivist), fellow, resident, physician assistant, respiratory therapist, occupational/rehabilitation therapist, wound care specialist, dietician, bedside nurse (registered nurse, licensed vocational nurse), unit nurse (e.g., infection control), care manager, ward clerk, chaplain, volunteer, other physician (e.g., anesthesiologist, consulting physician), ancillary services, and student (medical, nursing). Members of this sample and each of the roles also participated in design workshops.

Year 1 results showed that the IT solutions that are currently available to BICU clinicians are not sufficient for clinician information needs. This is because current solutions do not help clinicians to efficiently drive down uncertainty at the individual and the team level. This compels clinicians to exert cognitive effort find and model information that is stored within and across multiple health IT systems to make decisions. To counter this, we identified 21 barriers to effective clinical care and recommending 39 requirements for the CCS prototype (see Table I). These requirements were further developed into rough, then increasingly refined, information displays through creative design workgroups and repeated interviews and surveys. Data analysis identified problems that current health IT solutions present, 21 barriers to cognitive work on the BICU, and developed 39 CCS requirements.

### *The Problem*

The following examples demonstrate difficulties using current health care IT, such as finding important (salient) information that the CCS is intended to address:

Example 1

*Patient on insulin drip (which is tracked on the medication flow sheet and the in/out flow sheet) but the patient was not getting hourly blood glucose measurements (which are tracked on the labs and vital signs flow sheets). Small example, but the patient's blood glucose on re-check after six hours was <30.*

Example 2

*Ok, I'm trying to identify what possible new medication might have caused a patient's liver to start to fail (this same scenario could apply to any system). There is NO way for me to organize the data in such a way that I can see: Vital signs, Labs, Medication at the SAME time. I must do this manually. This is true in [commercial IT system] too. We should be able to do this, especially if we can assign a medication to a system, and potentially unassigned it.*

Example 3

*Ordered a right upper quadrant ultrasound yesterday. Turns out, the patient had several of these in the past, not necessarily in the last month (last was in July), all with similar results—difficult to see the gallbladder. [We] (d)id a different study today. Probably would have saved at least the cost of the procedure yesterday had I know this . . .*

### *Barriers and Requirements*

Each of the barriers that the team discovered presents an opportunity to learn how the CCS can support better care coordination. Using the barriers, the team created requirements for the CCS that would enable clinicians to overcome them (Table I). The first barrier provides an example:

*No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*

The requirement states how the CCS solution can help to overcome the barrier.

*System shall provide access to a plan of patient care, visible to all caregivers responsible for that patient, that includes:*

*(a). Current patient status and top-level assessment.*
*(b). Goals and priorities for those goals.*
*(c). Changes/updates, such as indication that plan is being updated when one caregiver is working on it.*
*(d). Schedule of activities and any changes, timeline.*
*(e). Orders and their status.*
*(f). Identity and contact information for patient's care team.*

The collection of requirements supports development of a number of use cases. They also guide the interface designer's configuration of display content and layout, and software developers planning for interactive features.

### *Use Case*

A use case is a narrative description that suggests how a system might be used. By assembling requirements into a description, software developers can get a sense of how the system will operate to support cognitive work on the unit. The first paragraph of a use case for access to a patient care plan that was described above, describes how each of these features (shown in bold type) would serve clinician needs.

At 6:30 a.m., a bedside nurse has started his preparation for the day shift by reviewing information on the patient he is responsible for. Opening CCS, he can see a **roster of patients on the unit,** chooses his patient's **"at-a-glance" view** that shows **recent vital signs, current orders, medications, care plan, and notes from the night shift.** He checks the patient's standing **care plan** and **treatment goals** (from the electronic health care record), and **reviews orders** (from

**TABLE I.** Barriers and Requirements

| Problem/Barrier | Needs/Requirements |
|---|---|
| No effective means to synchronize and adapt different aspects of patient care over the course of a shift (e.g., among RN, OT/PT, wound care) | Need to determine optimal timing and sequence of activities |
| Lack of awareness around activities/events that are tightly coupled | Need awareness of planned/scheduled patient care activities (e.g., wound care, rehab, line changes, etc.) |
| No efficient communication of patient status change across disciplines | Means to share the plan<br>Means to adapt the plan in real time and share changes across the team.<br>Bedside nurse needs to shift the goals and priorities<br>Means to know how changes in orders affect/change planned activities<br>Means to know what planned events are and who needs to be there<br>Practitioners need to understand what's going on with their group of patients across the shift (whatever their group happens to be) |
| Updated information is available but not readily accessible or visible to clinicians (e.g., cultures) | Clinicians need to be aware that updated information is available, particularly regarding laboratory cultures |
| Orders late, missing, or overtaken/replaced by other orders | Need efficient, accurate way to specify meds, procedures |
| Reliance on verbal orders and no standardized way to share orders | Physicians need access to orders from charge nurse's checklist<br>Physicians need prompts to enter orders<br>Need indicator of status of order entry (has it been placed or not?)<br>Need indicator of status of order (in process, completed)<br>Physicians need to be aware when entering order that it's the same as or different from previously entered orders<br>Changes to orders need to be disseminated to wider team so that team has common ground. Changes in orders need to be apparent to whole team |
| Documentation requires significant time from key members of the clinical team (RNs, Residents, RTs etc.) and is often redundant | Information Management tools and processes built around efficient use of staff time and effort<br>Minimize staff time required to capture information by reducing redundant information gathering and entry<br>Minimize staff time spent as the "system integrators" who move data from one system to another<br>Need "user-friendly" interfaces/systems |
| Lags in information updates means information in system is sometimes stale/inaccurate | Means to indicate if patient is highly unstable (because information for unstable patients can become inaccurate in short time frame)<br>Means to know whether information in system is up-to-date (e.g., is this an accurate reflection of the patient's status right now?)<br>Means to know whether orders are in process but results not entered into system yet (e.g., cultures, laboratory results)<br>Means to know recency of information updates<br>Means to capture and disseminate changes to orders that occur verbally within subteams |
| Trends are important information, but cannot get them from Essentris or other IT | Clinicians need trend information |
| No ability to keep track of patient status over time > 24 hours | Need view of patient that is more than just this shift. Both macro level view of indicators and over longer time spans |
| How many clinical staff are currently on the unit? | Need to know who is available, and where to find them<br>Need access to nurse assignments by shift, by patient<br>Means to access assistance, guidance, decision makers<br>Need to know which specialty is assigned to each patient (e.g., RT) and patient acuity |
| Is patient ready for upcoming surgical procedure | Need means to know whether patient is prepared for procedure (have they gotten blood products, antibiotics, consent, pregnancy test) |
| OR RN does not know enough about upcoming procedure to prepare surgical suite properly | OR nurse needs procedure specific description (need to know more about specific information needs) |
| Bedside RN does not know enough about surgery as it is being performed to prepare properly for patient's return | Bedside Nurse needs means to know what to expect re patient needs following procedure (e.g., what was worked on, how much blood given or lost, sedation?) |
| Rounding Checklist not readily available/accessible to all members of clinical team | Means to construct checklist in real time (during Rounds) or immediately after |
| Impact of dropped tasks, gaps, and lapses not known or tracked | Means to post checklist so all staff have ready/easy access |
| Checklist management is unclear (responsibility for making sure items are completed is unclear). | Means for staff to "check off completed items, makes notes re: hold ups, changes/revisions"<br>• Means for incomplete items to "roll over" to populate next day's check list and to be reviewed at next day Rounds |
| Reliance on clinician to mentally integrate data | • Clinicians need a holistic/macro-view of the patient's trajectory (e.g., are they getting better or getting worse over last 24 hours.?) |

the laboratory test database) that are pending as well as the day's **care activities that the Wound Care team, Respiratory Therapists, and Physical Therapists** have recommended and **what times** they can perform them.

Both software development and machine learning team members are using these requirements and use cases to develop, evaluate, and refine interface prototypes.

After translating analysis findings into concise problem statements and information system requirements, the team developed a number of visual representations to describe BICU cognitive work and key resources that clinicians use (model of cognitive work, care team, and information sources) and prototype information displays.

### Model of Cognitive Work

Complexity can hide underlying systematic patterns of cognitive work that clinicians perform in the BICU. Figure 3 illustrates these patterns that our CSE approach revealed.

The top level of the model (at left) shows the unit's primary role in cognitive work: synchronization of patient care both among clinicians and over time. The next level down includes activities that all unit members perform to accomplish synchronization: clarification, coordination, negotiation, and anticipation. Supporting tasks make each of those activities possible. Each task can be observed in the way that clinicians interact with each other and use information sources to minimize uncertainty. Requirements that the team developed from these tasks indicate possible leverage points, or opportunities, to improve synchronization.

### Patient Care Providers

Knowing what to include and exclude is part of the challenge in the study of a complex system such as the BICU. To do that, the team asked 8 nurses, 5 respiratory therapists, 2 physical therapists/occupational therapists, 1 nutritionist, and 1 physician on the BICU "Who do you communicate with to do your work?" The resulting network is being used to guide development of role-specific screens in the prototype versions of the CCS.

### Information Sources

Artifact analysis developed an inventory of the information sources shown in Figure 4 that clinicians rely on to provide patient care. Sources ranged from physical items (e.g., status boards) to communications (e.g., cell phones) to computer databases (e.g., the electronic health record) and paper and electronic sources (e.g., arterial blood gas monitor). Disconnection among most of these sources was one of the barriers the team's inquiry revealed. The need for clinicians to transcribe and reenter data from one system to another detracts from time to care for patients, and also presents the opportunity for inaccurate transcriptions.

### Information Displays

Based on the participatory design sessions, the design team developed several versions of the interface design. This resulted in an information design prototype that was based on Year 1 findings and requirements with views organized according to clinician needs.

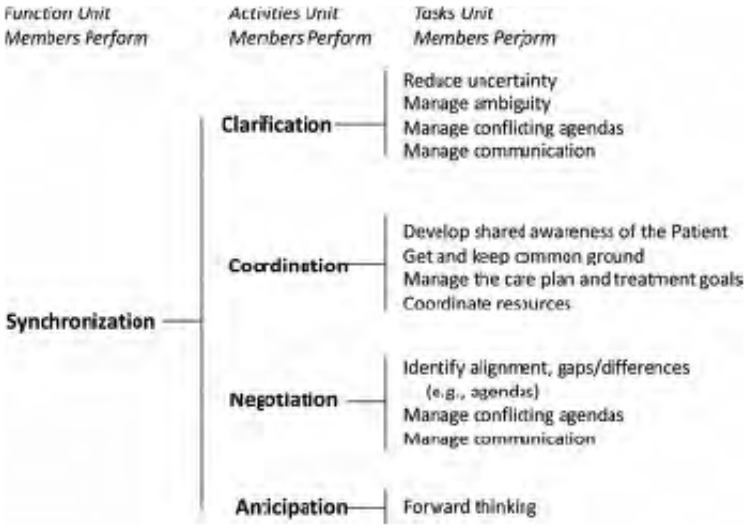


**FIGURE 3.** Descriptive model of Burn Intensive Care Unit cognitive work.

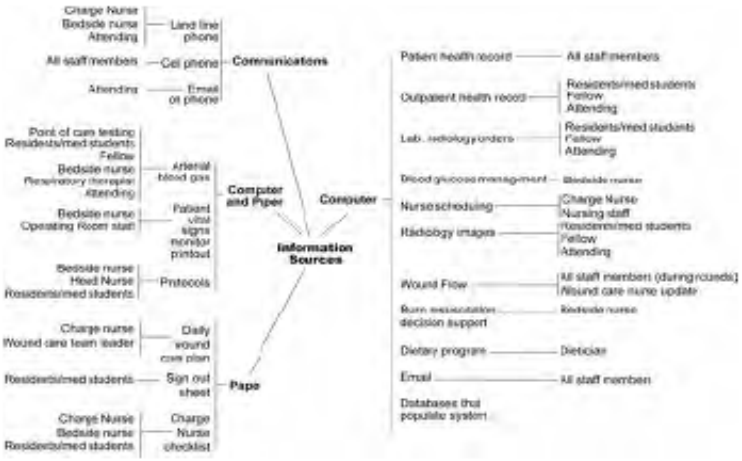


**FIGURE 4.** Burn Intensive Care Unit information sources.

*Patient View* (Fig. 5)

Makes salient information evident by showing critical variables for each patient organized by neural, cardiac, respiratory, gastrointestinal, pulmonary, and renal systems. A "parent-child" display tab feature serves as a kind of tab reference to see more detailed material. The view also includes a Wound Flow analysis of the patient's skin and graft condition (developed by the research site), as well as the patient's schedule for the day.

*Multidisciplinary Rounds View*

Provides a means for the charge nurse to document key details of the daily interdisciplinary rounds that are conducted each morning starting at 8:00 a.m. Entry of goals, medications, and orders captures patient care decisions, put them in motion, and makes it possible to track their progress through the day.

*Unit Level View*

Indicates the location and condition of each patient in the 16-bed unit, and the two operating rooms nearby. Provides a message window to share information that affects the whole unit, and staff members on the unit that shift.

## DISCUSSION

Health care IT systems must reflect actual clinical practice to provide information that will effectively support decision-making and related cognitive work of patient care. We have shown how the CSE research approach can be used to identify barriers to decision-making, and develop potential solutions to overcome them.

Despite years of effort in medical informatics, a gap remains between the complexities of the clinical work setting and the information systems that are intended to support clinician cognitive work.[9] This is true of the electronic health record (EHR) as well as other health care IT such as Computer Physician Order Entry.[10] The difference has implications for clinician performance and, ultimately, patient care. The examples in the Problem section of this article demonstrate how a clinician's inability to find salient information affects clinical decision-making. We contend that the reason for this is a failure to accurately reflect the work domain and behavior in the clinical setting.

During this research we have studied individual and team clinician work in actual and controlled settings. Among the findings mentioned above, we have also found issues with health care IT displays, including the EHR. The EHR is intended to serve as the central information source for clinicians to use while making patient care decisions. EHRs are often linked with other systems, including clinical decision support, and computerized physician order entry. Applications such as dispensing medications can also include interaction with other systems such as bar coding at medication dispensing, robot for medication dispensing, and automated dispensing machines. Administrative applications include electronic medication administration records and bar coding at medication administration.[11] These interrelationships can have a widespread effect on the work that clinicians perform.

Clinician patient care decisions are based on information that is provided by various means, which increasingly include the EHR. While providing some benefits, the EHR's rapid development has created "... digital piles grown so gigantic, unwieldy, and unreadable that sometimes we wind up working with no information at all."[12] Among all of these

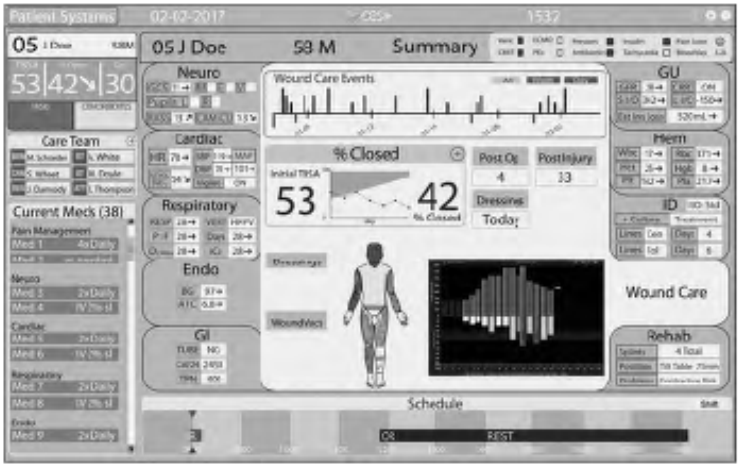


**FIGURE 5.** Cooperative Communication System Patient View prototype.

data, where does the clinician look for what matters when assessing trends and making diagnostic and therapeutic decisions? Do data that matter stand out, or are they obscured by other elements? And how can system developers know what matters? What data matter most to a patient and clinician at the moment they are being considered? Machine learning features, we are including in the CCS can be used sort through the "digital" piles to make useful information salient (stands out or is prominent).

Automation has traditionally been employed in high-hazard settings to replace individuals in the performance of work that is considered to be inappropriate for humans. Rather than replace humans, though, automation needs to aid humans as they work to solve problems. The way that a problem is presented can improve or degrade the performance of cognitive work[13] and aiding has typically been directed at the novice level. In fact, aiding is most needed on difficult problems, which are the type of problems that experts confront. As in other high hazard settings, expertise[14] in health care is the ability to know what is—and what is not—important.

Health care activities rely on the acquisition, portrayal and analysis of therapeutic and diagnostic information as an integral part of individual patient care. The daily work of the clinician requires representations that serve as a map of the ever-changing territory of work that must be successfully navigated.[15] What is represented, and how it is represented, depends on the individual and group cognitive work that it is intended to support? Individual elements of information vary enormously in the length of time that they remain reliable, and their weight depends a great deal on their context. The need for accurate, timely information also exists at the unit level, such as the operating room and intensive care unit, where the technical work of unit planning and management directs who will get care, what type of care will be provided, and when it will be provided.

Progress in improving health care IT to support patient care relies on going beyond the surface descriptions (phenotypes) of work domains to the underlying patterns (genotypes) of systemic factors.[16] Understanding any work domain and the forces that shape it requires methods that are suited to their study. Human factors[17] and CSE research methods within the naturalistic decision making model[18] have proven value in revealing the key aspects of health care work domains such as the BICU in this study to develop valid information displays.

Improvement in IT support for health care cognitive work requires repeated, deep looks into the clinical work setting using methods that are suited to the study of individual and team cognitive work to find what data truly matter. Use of CSE's decision-making approach to understand patient care settings can inform the development of effective IT support. The salience that results can begin to overcome embedded difficulties with records that, left unattended, will continue to impede clinical care for patients.

As a BICU IT system, CCS is a Force Protection resource to provide optimal support for military patients. Through CCS decision support, clinicians can make more accurate and timely diagnoses, perform more timely and appropriate treatments, and provide evidence-based care that reduces the time lag from "bench-to-bedside" care. As a team tool, CCS builds consensus and efficiency that can be expected to shorten patient length of stay and improve outcomes.

As a networked system, the CCS has the potential to extend beyond the fixed walls of a hospital to incorporate prehospital, contingency operations, and theater evacuations during military operations. Improved communication, the CCS affords, also facilitates hand off on arrival at the care facility.

For example, when a soldier gets injured, a networked communication system could immediately start relaying information to a forward surgical team or Combat Support Hospital to keep the receiving health care team apprised of the patient's status so that they can adequately prepare and deliver care.

## CONCLUSION

The findings from our CSE study are being used to create an information display that presents salient information, which will spare clinicians from having to find and synthesize it as they do now. This is expected to improve staff efficiency and patient care quality by improving clinician decision-making and communication. Specific CCS views sort information according to BICU cognitive work, from preparing for and conducting rounds, to individual patient care, to managing the unit as a whole. The link from data to analyses, requirements, prototypes, and evaluation ensures that the CCS solution will reflect and support work in the BICU as it actually occurs.

The research team's prototype, which can also mine data for relevant information, will be tested and validated using criteria from the first year of research. Use of the CCS is eventually expected to help to decrease missteps, lapses, delays in care, and the morbidities from causes such as wrong medication/dose, infections, and unanticipated emergencies such as cardiac arrest.

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CN (the principal investigator, lead author) contributed in data collection/analysis and interface design; JP (the co-principal investigator) is the clinical subject matter expert; SA and AG contributed in data collection/analysis and requirements development; RS contributed in interface design; BC contributed in data analysis, requirements development; JS (the task area manager) contributed in software development standards; EMS (the task area manager) contributed in research standards and is the clinical subject matter expert.

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**Appendix C.** Revealing ICU Cognitive Work Using NDM Methods. Special Issue on Expanding Naturalistic Decision Making. Journal of Cognitive Engineering and Decision Making. Human Factors and Ergonomics Society (2016).

*Special Issue*

# Revealing ICU Cognitive Work Through Naturalistic Decision-Making Methods

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The fragile health of patients who are admitted to a burn intensive care unit (ICU) requires clinicians and clinical teams to perform complex cognitive work that includes time-pressured diagnostic and therapeutic decisions that are based on emergent and interrelated patient information. Barriers to clinician efforts delay patient care and increase care cost, length of stay, and the potential for misadventures. The Cooperative Communication System is a real-time information technology system in its final year of development that is designed to support individual and team cognitive work and communication in the burn ICU. The project has used cognitive systems engineering methods to reveal genotypes: the traits that mold this naturalistic decision-making work setting. Requirements derived from findings guided development of seven core features, configurable displays, and machine learning features that enable clinicians to obtain and use the most important information on individual patients and among and across patients. Recent evaluation data demonstrate the system's usability and value to the clinical staff. More efficient, reliable collaboration among members of the ICU staff who use the Cooperative Communication System is expected to improve patient safety and improve patient outcomes.

**Keywords:** cognitive systems engineering, communication, decision support, domains, health care, macrocognition

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This paper describes the process that our team and client followed to reveal the cognitive work in a burn intensive care unit (BICU) and to support it by developing an ecologically valid, coherent information technology (IT) system to facilitate individual and team decisions and communication. It also describes how the use of naturalistic decision-making (NDM) methods are suited to the study of BICU clinicians and their work setting.

Care for the fragile patients who are admitted to a BICU requires clinicians and clinical teams to perform complex cognitive work: the set of macrocognitive activities (Cacciabue & Hollnagel, 1995; Klein et al., 2003) in which they engage as they perform the myriad tasks of patient care. These include time-pressured diagnostic and therapeutic decisions that are based on emergent and interrelated patient information from multiple sources. Multiple barriers that we identified to that work can delay patient care and increase care cost, length of stay, and the potential for misadventures. To make it possible for the BICU to overcome those barriers, our research and programming teams have developed the Cooperative Communication System (CCS), which is a real-time ecologically valid (Cacciabue & Hollnagel, 1995) computer-based cognitive artifact (Hutchins, 2002) that is designed to support BICU individual and team cognitive work and communication by making important data evident.

Our research team has used a cognitive systems engineering (CSE; Hollnagel & Woods, 1983; Woods & Roth, 1988) approach over the past 3 years. A yearlong field study of this NDM work setting revealed the genotypes of the BICU (Hollnagel, 1993): the factors that mold it as a

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work domain. Requirements that we derived from the field study's findings guided development of seven software system core elements, configurable displays, and a machine learning (ML) feature that identifies patterns in data that would be difficult to detect without it. Each feature enables clinicians to find and use the most important information about individual patients as well as among and across patients, improving decision efficiency, accuracy, and ability to build consensus among care team members. Recent evaluation data demonstrate the system's usability and value to the clinical staff. More efficient, accurate decision making and collaboration among members of the intensive care unit staff who use the CCS is expected to improve patient safety and optimize patient outcomes.

## BACKGROUND

Arthur Elstein and colleagues (Elstein, Schulman, & Sprafka, 1978) displaced the notion of medicine as an art with the notion of medicine as problem solving, based on Newell and Simon's research proposing that human minds might be considered as information-processing systems. Medical action "became equated with scientific action, which came to denote a specific thought process" (Berg, 1997). Rather than being based on a clinician's personal character, individual merit in clinical work came to be understood as the use of a method. To manage the methodical consideration of dense, complex, and contingent information, clinicians came to rely on a distributed cognition (Hutchins, 1995), which is a commonly shared knowledge that benefits a group but cannot be known by any single individual, and which groups use to perform collaborative work. Cognitive artifacts, which are part of this distributed cognition, are information displays that clinicians develop and use or are made to use (Hutchins, 2002). Cognitive artifacts range from checklists to status boards and informal notes and more, and they are used to organize crucial information to support cognitive work.

Recent research into patient safety issues "strongly supports the use of decision support tools to improve human performance" (Cook, Woods, & Miller, 1998). Those tools need to reflect a detailed understanding of the strengths and weak points of current sharp end (operator) knowledge if they are to actually improve work processes. Artifacts shape cognition and collaboration, and the way that a problem is presented can improve or degrade clinicians' cognitive work (Woods, 1988). Clinicians often create, update, and change their mental models of patients and unit activity, particularly in complex care settings such as the BICU. By drawing together complex elements of information for clinicians to consider, representations can make a task easier (Zhang & Norman, 1994). Representations can also integrate multiple kinds of information in a compact, efficient manner (Heiser & Tversky, 2002).

Software programs that were intended in prior years to serve as clinical decision aids have met with limited success because clinical practice has shown that guidelines, models for decisions, and even the clinical data are far more complex than initially thought (Berg, 1997). These rule-based programs tried and failed to transfer decision making to a machine agent. Instead, skillfully crafted representations can assist human expert judgment by portraying domain semantics (a work setting's essential elements) that describe the current state, constraints, goals, and opportunities for action. The prototype that we describe is such a representation and is intended to support, not direct, the judgment of clinical professionals.

Our research site, a 16-bed BICU in a 450-bed tertiary care military academic medical center, is widely considered to be one of the best of its kind in the country. Two of the 16 beds are reserved to serve as a postanesthesia care unit, and one is dedicated for the center's extracorporeal membrane oxygenation program. Nearby facilities that support the intensive care unit include a step-down unit, dedicated burn operating room, and outpatient clinic. The unit's patient census averages around 8 patients but has risen as high as 13 during the project. Patient length of stay ranges from days to months. Patients who are admitted to the unit have the most severe affliction from chemical, mechanical, or electrical burns, as well as burnlike diseases of the skin, such as toxic epidermal necrolysis, Stevens-Johnson syndrome, and the autoimmune disorder pemphigus vulgaris. The unit

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also treats patients with infections or trauma that causes extensive soft tissue damage or loss, such as necrotizing fasciitis, severe degloving injuries, and some war-related trauma.

### NDM Work Setting

NDM evolved under the leadership of pioneers including Jens Rasmussen and Gary Klein to improve on classical decision research by explaining how individuals use expertise to solve real-world problems. The NDM approach is used to describe the decisions made by experienced agents (e.g., clinicians) who work in complex settings (e.g., health care) and who face personal consequences for their actions (Klein, 1997). The NDM approach "addresses the cognitive work that individual operators perform as they confront and resolve conflicts and contradictions that arise between goals and multiple ways to achieve them" (Nemeth, O'Connor, Klock, & Cook, 2006). The approach seeks to understand human cognitive performance by studying how individuals and teams actually make decisions in real-world settings (Klein, 2000). The professional literature has developed three criteria to describe research that counts as NDM study:

- It focuses on expertise.
- It takes place in field settings.
- It reflects the conditions that complicate our lives.

The NDM researcher is interested in sympathetically addressing how individuals or teams and organizations make certain kinds of decisions in natural settings (Nemeth & Klein, 2011). The approach that this paper takes embraces the richness of sharp end work settings through NDM methods, including attention to worker behaviors as well as the tools that they create to perform cognitive work (Nemeth et al., 2011). Our study meets all three criteria, as well as many of the criteria that Weick (2001) set forth for a naturalistic decision setting (in italics). No individual has all of the knowledge that is necessary to coordinate care, and as a result, *information is inadequate* and must be shared. Synchronizing the interactions among many clinicians, patients, and activities within short periods means that *time is pressured*. Roles on the unit range from the burn surgeon to medical intensivist, resident, bedside nurse, respiratory therapist, occupational therapist, nutritionist, wound care, infection control, anesthesiologist, and more. They all pursue varying agendas, which can cause team goals to be *ill-defined* and at times conflicted. *Stakes are high* because outcomes can have a significant effect on patient morbidity and mortality. The expertise that is required to manage complex patient cases means that *practitioners are experienced*. All critical care activity occurs at the sharp end, which is a *rich context*. The fragile state of the unit's patients creates continually *dynamic conditions*. Changes in demand influence resource availability and procedures that are performed. The number, type, and duration of procedures are continually subject to change. Physicians, nurses, technicians, and clerical staff all work together to provide needed care. Staff members, facilities, equipment, procedures, patients, and their families must come together at specific times in a certain state of readiness. *Team coordination is essential* because no single member has firsthand knowledge of what is needed to allocate resources or manage the schedule.

Care for patients in the BICU is necessarily multidisciplinary, which requires attention from multiple clinical specialties. Care providers must collaborate over time to make effective decisions, develop treatment plans, assess patient progress, and refine plans to manage care. Through these daily tasks, they demonstrate the macrocognitive aspects of work that are shown in Table 1.

Decisions about how to manage patient care rely on access to the most important information about the patient when performing the activities in Table 1. This is why the Institute of Medicine (2000) recommended making relevant information available at the point of patient care and improving access to accurate, timely information.

## METHODS

Our project research uses ethnomethodology to investigate rational properties of practical actions that depend on the "ongoing accomplishments of organized artful practices of everyday life" (Garfinkel, 1967, p. 11). These ordinary routine details of daily life are based on a "collection of behavior patterns and beliefs" (Patton, 2002, p. 80). Those behaviors and beliefs provide

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TABLE 1: Macrocognitive Activities

| Macrocognitive Activity | Description |
|---|---|
| Naturalistic decision making | Reliance on experience to identify a plausible course of action and use of mental simulation to evaluate it |
| Sense making/situation assessment | Diagnosis of how a current state came about and anticipation of how it will develop |
| Planning | Changing action to transform a current state into a desired state |
| Adaptation/replanning | Modification, adjustment, or replacement of a plan already implemented |
| Problem detection | Ability to notice potential problems at an early stage |
| Coordination | How team members sequence actions to perform a task |
| Developing mental models | Mental imagery and event comprehension based on abstract knowledge and domain concepts and principles |
| Mental simulation and storyboarding | Use of mental models to consider the future, enact a series of events, and ponder them as they lead to possible futures |
| Maintaining common ground | Ongoing maintenance and repair of a calibrated understanding among team members |
| Managing uncertainty and risk | Coping with a state or feeling in which something is unknown or not understood |
| Turning leverage points into courses of action | Ability to identify opportunities and turn them into courses of action |
| Managing attention | Use of perceptual filters to determine the information that a person will seek and notice |

*Note.* Adapted from Crandall, Klein, and Hoffman (2006).

standards for decisions on what is, what can be, how one feels about it, what to do about it, and how to do it (Goodenough, 1971).

Care providers, cognitive artifacts, and information systems in this BICU work setting make up a joint cognitive system (Woods & Hollnagel, 2006) that can be studied and modeled through the use of scientific methods such as CSE. The CSE approach is used to design technology, training, and processes that help people to manage cognitive complexity in sociotechnical systems (Militello, Dominguez, Lintern, & Klein, 2010). Using CSE methods, we developed an in-depth understanding of the people, tasks, and work contexts (including the information technologies) that are designed to support electronic documentation, order entry and management, and clinical decision making. Integration of five CSE phases—preparation, knowledge elicitation, analysis and representation, application design, and evaluation—produces a solution that is ecologically valid: based on data drawn directly from rigorous systematic study of the clinicians and BICU work setting. Research team members were experienced in field studies and located remote from the research site. We added a research nurse at the site to help plan research team visits and collect data (e.g., brief surveys) when the team was not present.

The research team obtained approval for human subject research from the institutional review boards of both the funder and the research site. Data collection and human subject consent were conducted under the jurisdiction of the medical center institutional review board, which reviewed and approved the research protocol. Before the research team came to the site, the co–principal investigator and research nurse obtained consent

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of 151 BICU clinicians who were willing to participate in the study.

### Research Design

The project consisted of three phases, roughly a year apiece: foundation research, prototype development, and evaluation. As Figure 1 shows, we used a triangulated methodology to get at the actual nature of worker behaviors and the work setting, as no single method is sufficient to understand the complexity of human behavior.

In the first year, we developed a descriptive model of individual and team cognition, which provided the basis for prototype development in the second year and the criteria for prototype assessment in the third year. The research team followed a process shown in Figure 2 during the first year, which included three CSE phases: preparation, knowledge elicitation, and analysis and representation. While waiting for institutional review board approval, the research team prepared for field studies by interviewing selected clinicians at the research site by phone to learn information about the BICU. This provided the basis to develop an interview guide to organize data collection efforts during field visits.

*Data collection.* The research team collected data by making four weeklong visits to the BICU. The timing of these visits was planned for different periods of the academic training calendar in this teaching facility. During each visit in Year 1, we conducted formal interviews and collected or documented artifacts (e.g., forms, information displays) that participants use to help them accomplish their work.

*Observation.* Research team members conducted 31 observations with the BICU staff members, including nurses (bedside, charge, and wound care), residents, attending physicians, and therapists (physical, occupational, and respiratory). They also circulated through the BICU to observe clinical activities over 8-hour shifts and asked occasional informal questions of those who had consented to participate in the study. The daytime and evening observations contributed to our understanding of the BICU in ways that might otherwise have been overlooked. We also observed and recorded interdisciplinary rounds using a handheld video camera to capture how the clinical team interacted and used artifacts such as sign-out sheets and task lists. Recordings were made for future reference on how clinicians use and share information, including artifacts. Recordings were later de-identified using video-editing software. When clinicians interacted directly with a patient, the research team used audio recordings to capture how information was shared.

*Interviews.* The research team conducted 49 semistructured cognitive task analysis interviews lasting 30 to 90 minutes with members of the BICU clinical staff following the interview guide that was developed in the first 6 months of the project. Cognitive Task Analysis is "a family of methods used for studying and describing reasoning and knowledge . . . to find out how they think and what they know, how they organize and structure information, and what they seek to understand better" (Crandall, Klein, & Hoffman, 2006, p. 3). As the most common method used to elicit knowledge, the cognitive task analysis interview's structure enables the interviewers to follow a predetermined path to probe deeply into a subject matter expert's tacit knowledge and discover unanticipated insights. Two researchers interviewed each clinician individually. One acted as lead interviewer, and the other took real-time notes on a laptop. Using a Critical Decision Method procedure, we sought to learn how participants experienced an event that pressed them to their limit and what information they had and needed in those circumstances.

*Artifact analysis.* People actively manage the dynamic characteristics of their work setting by drawing on a deep knowledge of their work domain to create and use artifacts. The objects that they create, affirm, change, and discard reflect the nature and changes that occur in the life of a group. Identifying the world of physical, social, or abstract objects that people create makes it possible to understand their actions (Norman, 1993). All research team members collected de-identified information and printouts or pictures of the 20 information sources that the BICU staff used to do their work. These

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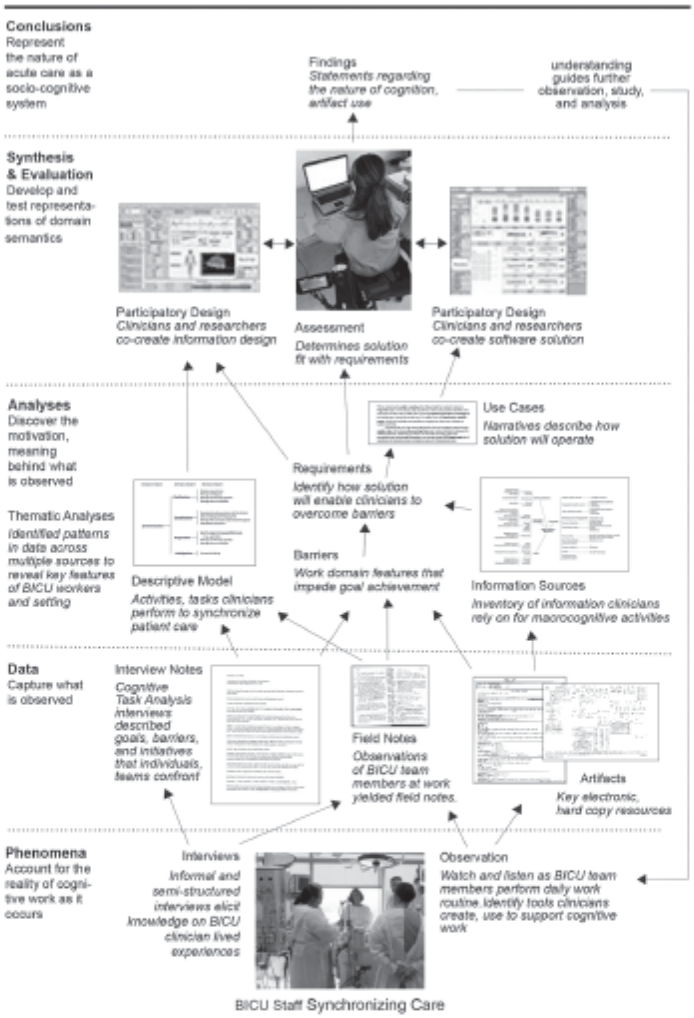


*Figure 1.* Cooperative Communication System: Project research design.
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artifacts included 3 types of communication (land line, cell phone, email on phone), 3 that used a combination of computer and hard copy printout (arterial blood gas analyzer, vital signs monitor printout, and protocols/guidelines), 3 paper artifacts (daily wound care plan, sign-out sheet, and charge nurse checklist), and 11 computer information sources ranging from the patient's existing medical record to his or her outpatient record, orders for laboratory tests and x-rays, blood glucose management software, nurse schedule, x-rays and scans, the unit's wound-tracking software, software designed to manage burn fluid resuscitation, the

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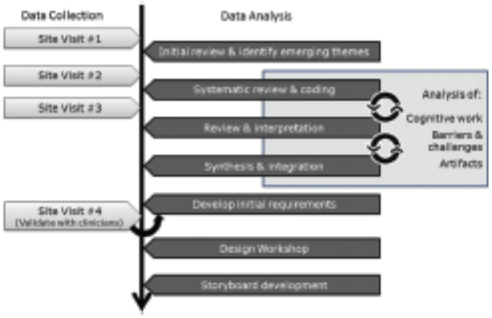


*Figure 2.* Data collection and analysis process.
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nutrition program that the dietician developed, email, and databases that populate the displays.

*Data analysis.* Members of the research team met for multiday sessions after each site visit to analyze the data. The analysis process involved several iterative steps that included multiple passes through the data, group discussion, gap filling, data reduction, and synthesis. Participants took care to link each finding back to specific data elements. The analyses checked on the credibility of findings, consistency, comprehensiveness, and centrality, which made it possible to understand what matters in the research setting and why.

After each data collection trip, research team members reviewed the set of interview and observation notes and held team discussions and work sessions to characterize emerging themes and identify remaining research questions to inform subsequent data collection. Using the thematic categories developed during the group working session, the 3-member analysis team segmented and coded interview sections that were relevant to each theme using Dedoose (www.dedoose.com), a commercially available qualitative data analysis program. The team members first coded a pilot sample of interviews independently and then met to compare use of coding categories, identify consistent and inconsistent application of categories, and discuss discrepancies. The result of these discussions was a refined set of category descriptions that provided guidance for subsequent data coding. After the pilot, the analysis team coded the rest of the data set, which included 49 interviews and 31 observations. In all, 727 data excerpts were coded by thematic category.

The analysis team then posed questions to identify the "main takeaways," such as "What challenges are they facing?" Each member documented the findings from the review and interpretation of the coded data. The team then reviewed the full set of findings developed by individual members and clustered the items based on similarity. The key question guiding this synthesis was as follows: "What is getting in the way of efficient and effective patient care and team coordination?" Following the synthesis activity, the analysis team created initial requirements for the CCS by asking questions about each barrier/challenge:

- What does the clinical team need to overcome that challenge?
- What system or display features could help address that challenge?
- What is the anticipated effect of meeting that requirement on team coordination, efficiency, and patient care?

In addition to holding sessions after each data collection visit, the research and analysis teams met for additional sessions to identify barriers to cognitive work on the unit and derive system requirements to overcome barriers.

During Years 2 and 3, the research team performed two further CSE phases: application design and evaluation.

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### Application Design and Development

*Participatory design.* Research, analysis, programming, and ML team members met for a 2-day data analysis and design workshop in December 2013. The co–principal investigator, who is an MD, participated from the research site using Face Time. During the workshop session, participants developed interface design concepts that would embody the design requirements. They began by asking for preferences about what should be in a clinical information display, then jotted down and shared ideas using Post-It notes that were placed on a white board and grouped into themes and categories. They divided into smaller groups to design rough representations of interfaces based on the notes and then present the concepts to the larger group. Results provided the interface designer with beginning concepts to develop into information design prototypes.

Research, development, and ML team members held a similar design session at the research site in February 2014. Twenty-six clinicians—from nurses to technicians, residents, and attending physicians—used the same approach as the December session to capture insights. A number of those who participated had also been interviewed during Year 1. After that, the designer developed several versions of the interface, resulting in an information design prototype based on Year 1 findings and requirements.

*Agile development.* The programming team developed a flexible architecture for the CCS and organized it into seven essential components. They used JIRA (https://www.atlassian.com/software/jira), a commercially available database software for project tracking, to manage requirements so that results reflected Year 1 research findings. Frequent creation and review of prototypes enabled the research and clinician team members to rapidly review and refine each element.

### Evaluation

*Validation interviews.* Three research team members visited the BICU in March 2014 for a design review and validation of information design display prototypes. Three nurses, two residents, and members of the client team offered comments on the concept representations. None had been interviewed during Year 1. The researchers identified gaps in the interface content and improvements that could be completed before programming began. They also verified the key systems requirements with selected members of the BICU staff.

*Usability assessment.* The research team conducted 45-minute usability assessment sessions (Rubin, 1994) with 43 clinicians (13 physicians, 20 nurses, and 10 respiratory therapists) at the research site in November 2015. All three roles use IT support to make clinical decisions, and only a few had previously participated in the project. Two rooms of the BICU were each outfitted with a laptop that could connect wirelessly to the Federal Information Processing Standards–compliant Amazon Government Cloud server where the CCS prototype was installed. A video camera was set up in each room to look over the shoulder of the participant to record how each used the CCS and to capture comments. The recording could then be referred to in case we had any questions about our written notes. After confirming consent and attending a 5-minute orientation of the display, 12 physicians and 20 nurses were asked to perform two hypothetical yet clinically relevant scenarios—preparation for surgery and new admission—while speaking aloud for Verbal Protocol Analysis. One senior attending physician provided comments on the prototype but did not perform scenario tasks. Ten respiratory technicians performed the new admission scenario. Each participant was asked a number of questions requiring a decision about the patient. In each room, a facilitator and an observer collected quantitative data (e.g., how long it took a participant to answer each question) and subjective responses to issues (e.g., ease of use, trust in the CCS, comparison with the current IT system).

## FINDINGS

### Barriers

We identified 21 key challenges and barriers to safe and effective clinical care on the BICU that are listed in Table 2. Many of them could be addressed by the CCS system. For example, while following a bedside nurse, an observer noticed that the nurse looked in the electronic

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TABLE 2: Burn Intensive Care Unit—Challenges and Barriers to Effective, Efficient Patient Care

| |
|---|
| No effective means to synchronize aspects of patient care. |
| Lack of awareness of activities/events that are tightly coupled. |
| No efficient way to communicate changes in patient status across disciplines. |
| Updated information (e.g., cultures) is available but not accessible/visible. |
| Orders are often late, missing, or overtaken/replaced by other orders. |
| Reliance on verbal orders; no standardized way to share them. |
| Lack of coordination between shifts. |
| Documentation requires significant time from key members of the clinical team: |
| IT issues and work process requirements frequently require redundant and/or repeated information capture and data entry. |
| Documentation also compounds the cognitive workload and attention management issues for clinical staff. |
| Trend data were identified as important but unavailable from the existing electronic medical record or other IT. |
| Tracking patient indicators over time >24 hours is difficult. |
| Cognitive workload: clinicians must mentally integrate data. |
| Delayed information updates means that system information is sometimes stale/inaccurate. |
| Knowledge of resource availability: Who is on unit (e.g., clinical team members, consults)? |
| Coordination between burn intensive care unit and operating room: |
| Do not know if patient is ready for procedure. |
| Do not know enough about procedure to prepare effectively. |
| Rounds checklist not readily available/accessible to all members of clinical team. |
| Dropped tasks, gaps, and lapses not tracked; impact not known. |
| Responsibility for management/completion of checklist items is unclear. |
| Substantial staff time spent tracking down in-process items (medicine, laboratory results). |
| Reliance on nurses to track and fix information gaps. |
| Resources and needs are poorly matched. |
| Errors (e.g., wrong orders) require the unit members to correct, redirect, back up, clarify. |

*Note.* Nemeth, Anders, Dominguez, Crandall, and Grome (2014). IT = information technology.

health record to figure out the medications that the patient required. The nurse wrote them down on a piece of scratch paper and walked to the nurse's station to find another nurse to co-sign into the Pyxis dispensing unit; then, both walked to the Pyxis unit to get the medications. Only then was she able to go back to the patient's room and administer the medications. Use of the CCS would spare these work-arounds, as it draws data from multiple sources into a unified picture of patient and unit data.

### Requirements

The research and analysis teams reviewed the information needs that we had identified as barriers to cognitive work (Table 2) and used them to develop a series of 39 requirements for the CCS. Requirements describe what the CCS would do to make it possible for care providers to overcome the barriers. For example, the barrier "cognitive workload: clinicians must mentally integrate data" evokes a need: "Clinicians need a holistic/macroview of the patient's trajectory (e.g., has the patient gotten better or worse over last 24 hours?)." To overcome the barrier, the CCS would need to provide "trend data and key indicators (e.g., for each of the main bodily systems)" and "trends on vitals, wound healing, medication dosing, infections" with the anticipated benefit of a "clinician

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TABLE 3: Translation of Barrier Into Requirements and System Features

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Effects |
|---|---|---|---|
| No effective means to synchronize and adapt different aspects of patient care over the course of a shift (e.g., among RN, OT/PT, wound care nurse)<br>Lack of awareness around activities/events that are tightly coupled<br>No efficient communication of patient status change across disciplines | Need to determine optimal timing and sequence of activities<br>Need awareness of planned/scheduled patient care activities (e.g., wound care, rehabilitation, line changes)<br>Means to share the plan<br>Means to adapt the plan in real time and share changes across the team.<br>Bedside nurse needs to shift the goals and priorities<br>Means to know how changes in orders affect/change planned activities<br>Means to know what planned events are and who needs to be there<br>Practitioners need to understand what is going on with their group of patients across the shift (whatever their group happens to be) | Visualization of patient schedule for shift (Patient × Time), shareable across team<br>Ability to sequence or overlap patient care activities<br>Configurable patient groupings<br>Prepackaged text to indicate changes to schedule (e.g., there is a half-hour delay in PT)<br>Sequence, time of planned activities<br>Provide reason for delay and remedy (using prepackaged text)<br>Overview through time for unit management<br>Visually connect interdependent events<br>Prompt/notify appropriate person when change affects their activity (e.g., when wound care affects PT/OT and RT) | Patients get needed care with fewer delays<br>Efficient use of staff time<br>Reduces unmet treatment plans and intentions<br>Supports replanning—helps staff identify windows of opportunity |

*Note.* Nemeth, Anders, Dominguez, Crandall, and Grome (2014). OT = occupational therapist; PT = physical therapist; RN = registered nurse; RT = respiratory therapist.

better able to focus on problem detection, anticipate need for changes in treatment plans, and optimize decision making around patient care." Table 3 provides another example of how system features can satisfy multiple requirements, rather than mapping one-to-one. The analysis team translated a number of barriers into requirements that then guided system features intended to improve patient care by supporting decision making and communication.

The research and analysis teams followed a similar process, shown in Table 4, to develop a model of cognitive work that guided the CCS development. Aspects of clinician cognitive work that we had discovered through data collection and analysis meshed effectively with the kinds of macrocognitive activity shown in Table 1. These enabled us to determine what the unit needed to support cognitive work and what kind of activity it was. For example, we frequently observed clinician efforts to reduce the uncertainty and manage the ambiguity that is inherent in highly dynamic environments such as the BICU. Clinicians had to efficiently get the particular, current, and accurate information that they needed "right then." This was an activity of

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TABLE 4: Translation of Observed Cognitive Work Into Activity

| Aspects of Cognitive Work | What Helps/Supports Team Cognitive Work? | Analysis Category |
|---|---|---|
| Reduce uncertainty | Timely, accurate information | Clarification |
| Manage the ambiguity that is inherent in highly dynamic environments such as the burn intensive care unit | Ability to efficiently get to the particular information needed "right then" | Orders |
| | IT that effectively highlights gaps and indicates when updates are available | |
| | Good interface design | |

Note. Nemeth, Anders, Dominguez, Crandall, and Grome (2014). IT = information technology.

*Figure 3.* Descriptive model of burn intensive care unit cognitive work.
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cognitive work that we termed *clarification*. A decision support system that effectively highlights gaps and indicates when updates are available would make that clarification possible through good interface design.

Complexity in the clinical setting can hide these underlying patterns in cognitive work that occur in this NDM work setting. By creating the descriptive model of cognitive work (Figure 3), we represented how BICU clinicians synchronize care through tasks and activities. The unit's main function is shown at the model's top level (far left): synchronization is the coordination of care among clinicians over time. Clarification, coordination, negotiation, and anticipation are the activities that unit members perform to synchronize care. Tasks that make up each activity, shown at right, can be observed in the way that clinicians interact and use information sources to minimize uncertainty. These are the mission, activities, and tasks that the CCS is designed to improve.

During our fieldwork, we kept track of the information sources that the clinicians mentioned, which are shown in Figure 4. This helped us to know what information clinicians rely on, where the information can be found, the various clinical roles that use them, and the range of locations that individuals had to go to perform their work. As important as these sources are, none of them are connected. To use information, care team members must find, collect, transcribe and assemble it. The CCS architecture would need to include these elements to integrate them into the system prototype.

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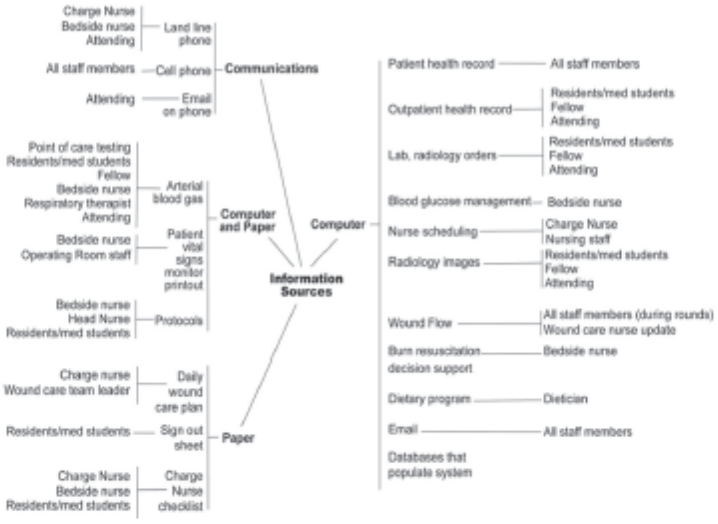


*Figure 4.* Burn intensive care unit information sources.
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The research and analysis teams developed use cases to translate the requirements into narrative descriptions of how the system would support clinician cognitive work. These descriptions enable the research team and designers/developers to conduct an informed conversation on how the solution would function in the BICU context. The following excerpt shows how the CCS would address one of the barriers: the need to track orders, such as laboratory tests that are processed off the unit. System capabilities that might help clinicians to overcome the issue are shown in bold text:

> When checking the **orders status** (from the existing electronic medical record), the resident notices a **tripwire cue** on the display indicating that results for a blood culture taken at 0400 were due back from the lab by 0600. She sends a **prepackaged text message** to the laboratory to learn where the results are. The order line in the **patient's status page**, which the bedside nurse and burn surgeon can also see, indicates that a query is pending.
>
> Curious as to why that routine lab test is late, the burn surgeon opens a more **molar view** that shows **all pending labs** and notices that the test is delayed for all BICU patients. Checking by phone with the laboratory, he finds that a failed equipment part has slowed throughput, and he sends a brief **CCS text note** to all residents and bedside nurses to **expect a delay** for that particular test.

*Information design prototypes.* Both the 39 requirements and the participatory design session results guided the creation of information design prototypes. These static illustrations modeled how the large and complex sets of data would best be displayed to match the way that clinicians use it. The patient view prototype (Figure 5) has a "parent-child" tab/window format that enables the user to shift from a glance at key variables for a system (e.g., cardiac in the parent tab) to a larger display (child window) that contains more detailed information for that body system. The research team used the information design prototypes to review the concept

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*Figure 5.* Information design prototype: Patient view.
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with residents, nurses, and technicians before the interactive version was programmed.

*Software prototypes.* The programmers developed a customizable widget-based web layout that presents a real-time view of the electronic health record and incorporates results from ML as they are made available via a relational database. The CCS architecture includes seven elements that were developed in response to the system requirements. Tracking of clinician and interface metadata will make it possible for ML algorithms to better identify user information needs and display preferences. The ML feature has the potential for CCS to improve and refine information displays as tasks and roles evolve.

*Patient identifier.* This graphic element is included in the unit view and patient view and includes patient number, total burn surface area at admission, and an indicator of illness severity and progress based on key trends.

*Unit view.* The unit view serves as the CCS "splash" screen that the user first sees when opening the system, and it is organized according to the BICU floor plan. The view includes a patient identifier for each individual who is being cared for on the unit, which enables the staff to scan among and across patients and recognize care needs at a glance. Selecting one of the identifiers takes the user to the full patient view for the person in that room.

*Patient view.* The patient view prototype shown in Figure 6 displays >320 variables for an individual patient, organized by system, from cardiac and neurological to wound care.

The patient view is configurable, which makes it possible to tailor the display to individual user preferences and preserve the story of the patient through time. Users can either accept a default CCS user interface view or configure which data elements appear and where they are located on the display, by moving each data element to a preferred position on the screen. Data can be viewed as either a table or line graph. A control bar at the top of the screen makes it possible to choose the time frame for the display from the most recent shift to as far back as when the patient was admitted. A change in the time frame simultaneously changes the time range for all data in the interface. Relational information displays can also be created by linking meaningful combinations, such as "cardiovascular," "cardiopulmonary," or "cardiorenal," to help clinicians answer questions about patient condition or treatment effects.

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*Figure 6.* Cooperative Communication System software prototype: Patient view.
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One feature was in development when the usability assessment was performed in 2015, and it is scheduled for validation assessment later in 2016:

*Tasking, messaging, and alerting:* real-time message correspondence enabling care team members to develop and maintain common ground on a patient's history, status, prognosis, and care plan.

Completion of three other features is planned as future work:

*Scheduling:* tracks staff assignments on the unit and to patient care teams, showing available individuals and care specialties.

*Order management:* lists orders from diagnostic tests to treatments, minimizing uncertainty about plans, status, and results.

*Checklists:* an interactive roster of quality measures, making it possible for the clinical team to verify that essential evidence-based care is accomplished.

*Machine learning.* The CCS incorporates ML algorithms, which will make it possible to identify patterns in data that would otherwise be unknown, such as trends, comparable patients and care regimens, and the way that clinicians use the system. The CCS ML capability combines traditional open-source off-the-shelf data-mining tools with new data-mining capabilities. This improves a clinician's ability to quickly identify and view similarities and discrepancies while comparing a current patient's health trajectory with those from a large database of previous patients. The ML feature enables clinicians to leverage knowledge of the treatment plans and results from all available records of previous patients on the unit who had comparable conditions and interventions. Comparison with previous similar patient care regimens enables a clinician to better consider decisions about the current patient. The ML feature will also enable the CCS to identify what information is salient for a particular clinician or clinical role and to offer options that are better suited to user preferences.

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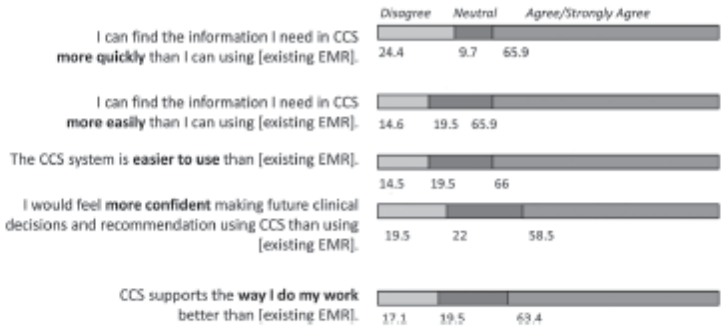


*Figure 7.* Responses to comparison questions.
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### Evaluation

The evaluation phase of CSE estimates how the solution affects the work that it was intended to support. The phase determines how to best measure performance; it tests whether the system supports the user; and it recommends redesigns to improve (Crandall et al., 2006). We sought to determine how well the CCS supported individual decision making and team collaboration in clinical work.

In November 2015, our usability assessment evaluated how well the CCS supported individual clinician needs to find and use key patient data. We conducted sessions on the BICU with clinicians assigned there, to ensure the highest fidelity to the actual work setting. The assessment did not include team collaboration features, such as communication through the messaging feature, which will be evaluated in 2016. Results of the assessment included responses to questions comparing the CCS with the electronic health care record that has been used at the site for years. Figure 7 shows responses to five comparison statements according to the percentage of those who responded *strongly agree* or *agree*, *neutral*, or *disagree*. The degree of positive acceptance is noteworthy in light of the short length of time that the sample had used the CCS prototype. Many responses to open-ended questions complimented features that the research team had learned early in the CSE process: simultaneous display of salient data, shared mental model of patient status, and sparing clinicians from work that the system can handle:

- *Respiratory therapist:* "Having the information right there makes you think, when you can see the trends. It helps to pull the information together in one place."
- *Nurse:* "I like that CCS may bring us together and on the same page. All members on the team may see things the same way."
- *Attending physician:* "Nice to have actual and ideal or adjusted body weight to dose drugs."

Improvements that the usability assessment revealed included preference among nurses for a view that included all laboratory values for a patient and respiratory therapists' desire for a view that summarized all of a patient's ventilator settings.

## DISCUSSION

Our efforts over the 3 years of the project have produced the following key results.

### Key Results

*Descriptive model of BICU cognitive work.* The research team's activity in Year 1 confirmed that clinicians use multiple processes that are captured in the macrocognitive activities mentioned earlier. We identified information that is useful to clinicians, obstacles that they confront, and initiatives that they undertake to accomplish their patient care goals. On the basis of our

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observations, we grouped the tasks that are important to the performance of cognitive work, identified the major activities that are needed to synchronize the unit, and represented them in the descriptive model of cognitive work (Figure 3). The model and requirements formed the basis for the CCS information design.

*Barriers to cognitive work on the BICU.* Repeated, deep looks into unit activities through observation and informal queries, as triangulated with interviews and artifact analyses, revealed impediments to the unit's mission of care synchronization.

*Requirements for CCS.* A description of what the CCS would be and do flowed directly from barriers to cognitive work that the research and analysis teams identified.

*Seven key elements.* The CCS site architecture is flexible in its configuration, making it possible for the system to evolve as the unit does. Each of the seven elements meets a particular need to synchronize care among and across patients. The patient views can be organized according to individual preferences. Important data are organized and presented according to the way that clinicians work, which spares them the effort of data collection and integration.

*Valid prototype.* We developed a series of information design prototypes and use cases to model and verify how to fulfill system requirements. We spent over a year translating the concepts into interactive displays of critical patient data with trend information, and we tested them for usability among actual clinical staff. As a "platform agnostic" software system, the CCS is independent from proprietary requirements. That makes it possible for the CCS to integrate data from the electronic medical record and various other sources into a unified view.

Health care IT systems must reflect actual clinical practice to provide information that will effectively support decision making and related cognitive work of patient care. Up to now, the rapid development of the electronic health record—from a billing record to a repository for all items meticulously documenting the care that a patient has received—has created "digital piles grown so gigantic, unwieldy and unreadable that sometimes we wind up working with no information at all" (Zuger, 2014). In a similar vein, one senior clinician estimates that 95% of the material in an electronic health record is of no value, yet it requires a clinician to search through it to find the small percentage of patient information that actually matters at the moment that a decision is being made (M. O'Connor, personal communication, June 20, 2013; The University of Chicago Medical Center, Chicago, IL). This failure of health care IT to accurately reflect the work domain and behavior creates significant difficulties (as Table 2 illustrated) for clinicians who care for patients.

Patient point of care relies on support for health care cognitive work through methods that are proven in the study of individual and team cognitive work to find and present salient data. This project demonstrates how the NDM approach makes it possible to develop health care IT that reflects and improves actual clinical practice. It also serves as an example of the benefits of close research team and clinician collaboration from the outset.

The CCS architecture, layout, and operation are based on understanding the BICU as a complex, emergent, contingent, high-stakes care setting. The NDM approach is suited to this process because "the NDM orientation is to be inclusive and curious about different aspects of cognition that will affect the way people handle the conditions such as limited time, uncertainty, high stakes, vague goals, and instability" (Orasanu & Connolly, 1993). The research team's grounding in NDM enabled members to reveal the nature of this setting (as the Findings section shows) and create solution prototypes that are readily accepted (as evaluation results show). In contrast to other traditions, such as heuristic and biases, "the NDM mindset helps researchers to conduct effective observations and interviews. It enables them to capture the way people use their experience to handle uncertainty and vague goals and high stakes" (Nemeth & Klein, 2011).

Use of the CSE approach to understand patient care cognitive work and settings produces an IT system that is ecologically valid. The NDM approach reveals clinician goals and

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needs and guides the development of tools to support them. The resulting configurable displays enable clinicians to tailor them according to individual preferences. Its ML features can be used to sort through the "digital piles" to make important data evident.

### Limitations

Clinicians who participated in the study were assigned to the unit and worked around regular work requirements. This meant that their time was limited, but it also gave us the advantage that all our work was done in the context of actual clinical practice. The research team could not remain on the unit continuously and instead scheduled multiple weeklong visits. To manage that limitation, we retained a research nurse to collect data in between visits. The project was performed at one site due to modest funding, which limited its generalizability. We have proposed further research at other sites in a follow-on project. Information assurance limitations on our use of patient data required programmers and the client team to work in a development environment that is separate from any other system. Funding requirements meant that not all of the features that we identified could be completed during this project. We have included those features in a proposal for follow-on work.

### Further Work

The validation assessment planned for 2016 will verify how well the CCS supports collaboration among team members, using a similar scenario design as the usability assessment and adding the messaging and ML features. Criteria drawn from Year 1 research include the following:

- *Efficiency*—time to complete decision tasks.
- *Accuracy*—fidelity to preferred decisions according to clinical guidelines.
- *Reliability*—whether multiple team members make the same decision, arrive at the same conclusion, or support the same action.
- *Salience*—ease with which needed information can be found.
- *Communication effectiveness*—efficiency, reliability, and accuracy of communication.
- *Trust*—confidence in the system and decisions made using the system.

The project's transition plan will identify the development requirements and final steps to complete the CCS prototype. These include completion of features such as scheduling, application in a care setting other than a BICU, and alignment with approval requirements for defense and civilian health care systems.

## CONCLUSION

Using an NDM approach, we examined BICU clinician decision making and other aspects of cognitive work, including sense making, developing and maintaining common ground, and adaptation and replanning. With this understanding of clinicians' cognitive work, we designed information representations that support their information needs. We developed a cognitive model of information flow, communication, and decision making in the BICU based on the detailed descriptions of clinician communication and cognitive work. Findings to date provide the basis of ecological validity for the CCS decision support and communications system. Matching decision and communication support to the work domain and clinician can improve point-of-care individual and team cognitive work. We expect use of the CCS to increase clinician efficiency, reduce the potential for misadventures, and, as a result, improve patient outcomes.

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Jose Salinas, PhD, is the program manager for the Comprehensive Intensive Care Research program at the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX. The program is currently focused on development of clinical solutions to improve outcomes of military combat casualties arriving at different treatment facilities and echelons of care. This includes the development of novel information technology and engineering solutions that provide users with new approaches to communicate and/or automate different diagnoses and treatments that are normally performed through manual means. Additionally, the program includes research and development projects in the use of information technology for enhanced information dashboards, medical decision support systems, automated technologies, and open/closed-loop devices for field use. As part of these efforts, Dr. Salinas guides research into development of improved digital signal processing algorithms for enhanced diagnosis of combat casualties, including the use of advanced machine learning techniques for better physiologic models of trauma injuries. His current program currently includes more than 20 full-time intramural researchers working at the institute, in addition to multiple extramural efforts with universities and medical devices companies.

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**Appendix D.** Improving Burn ICU Clinician Decision and Communication through IT Support (2016)

Title: Improving Clinician Decision and Communication in Critical Care Using Novel Information Technology

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DRAFT

***Abstract***

Objective: We sought to improve individual and team clinical decision making in the Burn Intensive Care Unit (BICU) using a novel health information technology (IT) that provides real-time decision and communication support, presenting clinicians with salient information that may reduce misadventures.

Design: Our usability assessment measured clinician performance of 3 common ICU tasks in 2 scenarios: preparation for surgery and new ICU admission. A validation assessment compared BICU team performance during two 6-hour simulated patient care scenarios; one with and one without the novel IT system. Observation and thematic coding of field notes measured pre-specified task elapsed time and completion.

Setting: Simulated care scenarios conducted in real BICU.

Participants: BICU clinicians: physicians, nurses, therapists, and physician trainees.

Intervention: A novel IT system that supports decisions by displaying salient information, and improves situational awareness through integrated communication software.

Measurement: Primary outcome measure was time to complete pre-defined tasks. Secondary outcome measures were participant perceptions of ease of use and communication effectiveness.

Main Results: Paper summarizes findings from two assessments of the novel system. In the usability assessment, clinicians using the novel system performed several tasks faster and reported it was easier to use than the legacy EMR system. Using the novel system in the validation assessment, first year resident arrived at an accurate sepsis diagnosis the same time as a senior resident with 4 years' more experience, and the senior resident arrived at an accurate

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ARDS therapeutic decision 2 hours earlier than the first year resident. Teams strongly favored the novel IT system for communication compared to using pager and phone.

Conclusions: The novel IT system demonstrated robust face validity as measured by clinician preferences, appears to reduce time to complete complex tasks including pre-rounding, and improved the efficiency of clinical decision making by novice and more experienced clinicians.

Key words: Intensive care, burn care, health IT, decision making, communication, teamwork

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## 1. Introduction

Care for Burn Intensive Care Unit (BICU) patients is complex and requires a team of highly trained, experienced clinicians to synchronize efforts in order to achieve optimal outcomes. Care is complicated by risks posed by information overload (1), alarm fatigue (2), workload saturation (3), task interruptions (4), and communication challenges born from differences in clinical perceptions, care priorities, and professional identities (5). Individual and team medical decisions are best made with current, accurate information. Effective presentation of the most important, or *salient*, information (6) promises to improve clinical decision making (7).

The electronic medical record (EMR) has evolved as the presumed means to support clinician decisions by documenting and retrieving needed patient information. Some have shown the EMR improves patient care (8), or supports compliance (9). Others (9-13) question the effectiveness of such systems on patient outcomes, or indicate that results using the EMR and clinical decision support are mixed (14-17).

Research on decision aids suggests that the way a problem is presented can improve, or degrade, clinicians' cognitive work (18). Cook, Woods, and Miller (19) reported that patient safety research "strongly supports the use of decision support tools to improve human performance." Cognitive artifacts (e.g., information systems, checklists) that clinicians use to perform cognitive work shape decision making and collaboration (20). Well-designed representations can make a task easier by integrating multiple kinds of information in a compact, efficient manner (21, 22). Combined with machine learning engines that reveal implicit patterns within the data, patient and unit level displays could improve clinical judgment and decision making (23).

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Our research team developed a novel IT system for a 16 bed Burn ICU using Cognitive Systems Engineering (24) methods. The unit is co-located in a 450 bed military Level 1 trauma and academic medical center. Our research (25, 26, 27) identified twenty-one barriers to cognitive work, which yielded thirty-nine software requirements, and seven key modules (See supplementary material Tables S1-S3, available with this paper) that could improve team decisions, enhance patient safety, and patient outcomes. The novel IT prototype incorporated over 320 elements of information in a Patient View (Figure 1) and also included text messaging (Figure 2) to support team collaboration in real time. Designed to incorporate multiple data sources into a single interface, the novel system "sits on-top" of an EMR and can extract the most important information from the EMR database in order to display it according to clinical practice, produce multi-modal alerts, and support clinician awareness of a patient's condition. By using metadata and machine learning engines, the novel system can track how users seek information and evolve in response to an individual user's needs, new scientific evidence, and changes to clinical practice.

**2. Methods**

This paper reports on two assessments we conducted to evaluate a prototype of the novel IT system that our team developed. We evaluated the how using the novel IT system affected clinicians individual and team performance in a Burn ICU. We conducted a usability assessment and a validation assessment of this prototype in an typical BICU patient room (Figure 3). Both assessments were performed under protocols approved by the local institutional review board and the Department of

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Defense Human Research Protection Organization Finally, the novel information system was connected to historical, deceased patient data in a protected IT development environment to evaluate it with real patient data.

*Usability Assessment*

We evaluated how well the novel IT system supported individual clinicians using observations, task time comparisons, and subjective ratings. We observed clinicians as they completed several clinically relevant, information-seeking and decision making tasks. We also compared how well the legacy system supported work on the same tasks. .

We recruited 41 BICU clinicians who routinely rely on IT to make decisions to participate in the usability assessment: credentialed and in-training physicians, nurses, and respiratory therapists. Each participant was given a 5-minute, standardized orientation to the novel system and then asked to complete two typical clinical scenarios, each involving several tasks, (See supplementary materials Figure S1) using the novel IT system. We recorded time to complete tasks (efficiency) and compared it to an expert user of the legacy system. We compared participant decisions to anticipated responses in order to determine efficiency, reliability, and accuracy of their cognitive work using the novel system. Video recordings during the assessment ensured the observer notes were accurate. After completing all tasks with the novel system, each participant rated their effort to find information, the ease of use, and their confidence in their decisions using the novel system as compared to the legacy system (See supplementary materials Figure S2).

*Validation Assessment*

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The second assessment was a case study with two teams completing two 4-6 hour simulation scenarios using either the novel or legacy system, counterbalanced (Table 1). We used an approach based on Rubin's (27) evaluation methods and McGrath's (28) model of group process (Figure 4) to discover how either the novel or legacy IT system affected individual, group, and environmental factors to satisfy outcome measures. The novel system interface and messaging feature used the legacy system as a data source.

Two 3-clinician teams cared for simulated patients using a SimMan 3G high fidelity manikin (Laerdal Medical, http://www.laerdal.com/us/SimMan3G) in an actual BICU patient room. Performing the simulation in a real patient room spared the need to orient participants to an unfamiliar work setting and made it possible to include environmental factors and cues that a simulation center lacks. Teams included a burn surgeon credentialed in critical care (the "attending"), a bedside nurse with critical care nursing certification (CCRN), and a physician in training (the "resident"). If the teams requested consultation or action, research team members performed as additional clinicians from respiratory therapist(s), to rehabilitation specialist(s), nutritionist, pharmacist(s), family member(s), and subspecialty consultants. We simulated these additional team members to avoid distracting the BICU clinical staff from real patient care duties. On the day before the first simulation, we oriented participants to the study (See supplementary material Figure S3), demonstrated the novel IT system including how to tailor the display and use the messaging services, and briefed them on the high-fidelity simulator.

Each simulated care scenario unfolded according to semi-scripted scenarios of newly admitted patients who subsequently developed clinically challenging and complex diagnoses: either the acute respiratory distress syndrome (ARDS) or intra-abdominal sepsis. We chose these scenarios because decisions about their therapeutic interventions are controversial. They are also

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challenging to implement, potentially risky, and typically require teams to make the decisions together. Experienced burn care providers (JCP, MSM, and SJM) validated each scenario script twice in practice sessions. The scenarios were "semi-scripted," because the participant teams could potentially deviate from anticipated care. We foresaw many of these deviations during scenario testing and developed corresponding scripts for many of them. As a result, the teams were asked to interpret available information and to manage the simulated patient accordingly.

Each simulation began at 6:45 AM, the normal time for change of shift. Separate handoffs to the resident and beside nurse from a research team member simulated the "night-shift" team. Teams then had time to prepare for multidisciplinary rounds (i.e. "pre-rounds"), multidisciplinary rounds (MDR), and post-MDR care. The scenario concluded when teams reached key decision points (Table 2; Also see supplementary material Figure S3, S4). Three observers watched as the teams worked, producing sets of observer notes for each of the four scenarios. Observers coded clinical activity of each team based on: a) decisions in the form of orders, b) search for information using the system, c) diagnosis (problem detection) and therapeutic intervention (solution), and d) collaboration and communication via various means including face-to-face, phone, text, and the message feature in the novel IT system. Each observer recorded and time-stamped activity for one of the three team members. At the end of each scenario, participants rated their teams' decision making, communication, and performance and rated both IT systems on a 7-point scale in terms of support for their cognitive work.

We collected data on the time it took to arrive at a key decision, information seeking behaviors, communication and decision-making processes, use of the novel IT system messaging feature, and post-task ratings using a brief survey (See supplementary materials Figure S5). This

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made it possible to examine differences between the novel IT system and the legacy system. Given a small sample of just two teams for this initial validation assessment, our analyses focused on descriptions of the process and examined consistent themes across different data sources.

*Coding Scheme.* Coding focused on cognitive work that was expected to be influenced by IT system use (e.g., searching for information, making decisions, coordinating with the team, detecting problems by perceiving patterns, integrating information to evaluate trends, asking questions, making recommendations). In the weeks before the validation assessment, observers practiced using the coding schemes together in real time and identified, discussed, and resolved coding discrepancies.

*Statistical Analysis and Outcome measures.*

We analyzed quantitative data using a combination of t-tests, one-way analysis-of-variance (ANOVA), and multivariate-analysis-of variance (MANOVA). Qualitative data were analyzed using thematic analysis; a descriptive method.

There were three primary outcome measures: time to reach a key decision in each of the two scenarios, ratings of perceived effort and efficiency using each IT system, and ratings of system support for team communication. We examined the effect of the novel system compared to the legacy system on team decisions, key coordination processes using the systems, and post-task ratings from the teams.

## Results

*Usability assessment*

Forty-one clinical staff members participated: 11 physicians, 20 nurses, and 10 respiratory therapists (RT). Participants were experienced, with 90% of the nurses, 53%

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of the physicians, and 50% of the RTs having more than 7 years of service in the BICU. One senior physician chose to provide comments and did not perform the tasks. All participants who used the novel system were able to complete all tasks successfully. One nurse completed the tasks using the legacy EMR and is shown for comparison with the median time for 20 BICU nurses to complete the tasks using the novel IT system (Table 3). We were only able to complete one legacy system assessment because it included actual patient outcomes, making it difficult to blind subjects to decisions that had actually been made.

After each task, the participant was asked to rate the system on several dimensions of usability. All clinicians rated the overall effort while using the novel IT system to be low compared to the legacy EMR (Table 4). For the admission scenario, there was a main effect of Role on ease of use ratings, $F(1,39)=3.5$, $p=0.039$, and ease of finding information, $F(1,39)=4.24$, $p = 0.042$, with physicians rating the novel system as easier to use than the respiratory therapists. MANOVA of Role on effort revealed that nurses reported marginally significant higher effort ratings than physicians for finding hemodynamic status, $F(1, 30) = 4.03$, $p=0.054$, and finding information to answer a question about the patient's volume status, $F(1, 30) = 4.87$, $p=0.035$.

Clinicians preferred the novel system over the legacy system (Table 5). Comments by nurses and RT's suggested the novel IT system's organization by body system was better suited to a physician's perspective. In response to their requests we added a summary display of all lab data and all ventilator settings to the prototype before the validation assessment.

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*Validation Assessment*

Table 6 shows years of experience for the participants in the validation assessment. Team 1 averaged more experience in general ($M$=8.3, $SD$=2.6 vs. $M$=6.3, $SD$ = 4.2), but team experience was equivalent in the BICU ($M$=4.3, $SD$ 4.4). Supplementary materials Figures S4 and S5 show decisions and the time it took to reach them. Pre-defined important decisions that indicate an accurate decision are shown in bold type. In the sepsis scenario, Team 2 identified the diagnosis of intra-abdominal sepsis at the same time as Team 1 using the novel system and in the ARDS scenario, Team 1 arrived at the choice to treat the patient using prone positioning nearly two hours before Team 2. The junior resident using the novel system also explored additional potential diagnoses including deep vein thrombosis and Lyme disease.

Participants rated the novel system as more effective than the legacy system for supporting decision making (Table 5). A MANOVA of System on information integration and decision making revealed clinicians tended to favor the novel IT system. Post-task ratings across the two systems for *identifying trends in the patient's condition*, $F(1,10) = 5.3$, $p = 0.067$, and *easier to use to make decisions*, $F(1,10) = 5.3$, $p = 0.09$, were marginally significant and higher for the novel system compared to the legacy system. In addition, Participants rated team communication facilitated by the system as more effective for the novel IT system than the legacy system. Independent t-tests revealed that Participants rate the novel IT system as *easier to use for communicating with team members* collapsing across both scenarios, $t(10) = 2.7$, $p = 0.021$ and the *communication was more effective with team members* using the novel IT system, $t(10) = 4.3$, $p = 0.01$.

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## 3. Discussion

Our usability and validation assessment data suggest that use of the novel IT system improves decision efficiency without compromising accuracy. Clinicians favor the novel information displays and communications software over a traditional EMR display and traditional means of communication. The system appears to improve clinician confidence in decision making and communication while reducing the effort that is required to find salient information.

More accurate and efficient decisions shorten patient length of stay and reduce the potential for misadventures. The novel IT system supported both teams even though their decision strategies differed. Each team used the IT system to share basic information about the current state of the patient, which is what Endsley (29) refers to as Level 1 situation awareness. The novel IT system supported option evaluation, problem detection, and decision making, which enabled teams to develop a shared understanding of a patient's status (Endsley's level 2 situation awareness) and evaluate plans for future care.

*Decision Support IT*

Our own findings reflect many of the shortcomings Mack and Saldivar (31) consider typical of current EMRs, from requiring users to tab and type information into cells (time consuming and error prone) to scrolling through multiple pre-formatted pages, regardless of patient problem or user needs, and lack of advanced features (e.g., critical event reporting), smart chart clinical decision support, and the ability to control external devices.

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Similar to Patel et al (32) and Pickering et al (33), we conducted field studies of clinicians to develop and refine novel health IT that supports cognitive work in the ICU. Pickering et al (34) developed an interface to manage information overload, while controlled experimentation has shown that some of these new interfaces are effective in error reduction and task load management (1).

Results from our usability assessment demonstrate that our novel IT system meets clinician needs for decision support while improving efficiency without compromising accuracy. The validation assessment results suggest that clinical teams with less experience may perform similarly to teams with more experience (e.g., time to reach sepsis diagnosis) when supported by novel IT while the same system may improve experienced team performance as well (e.g., time to reach decision about use of prone positioning to manage ARDS). Furthermore, participants rated the novel system as more effective than the legacy system for supporting decision making as well as communication.

Effective IT systems support team efforts to develop shared understanding, enabling them to detect problems earlier, evaluate their options and provide better care. In this paper, we provide evidence that the novel IT system, designed using a cognitive system engineering (CSE) approach, was effective. Our novel IT system was designed to support different views of the information, and may be tailored for different tasks, roles, experience, and patients. Its modular design enables a user to customize information display. For example, information displays may be tailored to support a new admission or an emergency inpatient response; two scenarios that require vastly different information to efficiently, reliably, and accurately manage them.

Participants using our novel IT system with minimal training easily completed six information search and decision making tasks and rated the experience favorably compared to

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their experience with a traditional EMR. During simulated patient care, clinicians found the novel system improved their ability to find and share information more effectively and efficiently. This led teams using the novel system to evaluate more alternatives without increasing time to diagnose.

Consistent with naturalistic decision making research on experts (35), the more experienced resident considered fewer options, and then evaluated each option until it could be ruled out. In particular, the resident with 4 fewer years of overall medical experience used the novel IT system to evaluate more potential diagnoses (e.g., deep vein thrombosis), one of which was correct (perforated bowel).

Our results are consistent with conclusions by Patel and Arocha (36) that effective decision making in an ICU needs to be supported to allow all clinicians to gather and share information to best support patient care. One team used the novel IT system to broadcast data in order to maintain fellow team member awareness of patient status, while the other team was more select in their messaging. The novel IT system provided a means for the teams to establish a shared understanding of the patient's status (37), and engage in collective sense making. It also supported all three levels of Endsley's situation awareness model (30).

*Limitations.*. The patient census grew past planned safety limits 2 days before the scheduled sessions. W successfully executed the assessment by shifting to a back-up plan in which research team members filled ancillary roles to assist the 3-member teams. In the validation assessment, the patient's acuity increased relatively rapidly, which led teams to spend more time at bedside (and away fromthe IT systems) than normal. The project was performed at

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one site, and with two teams, and two diagnoses which limited its generalizability. The team has proposed further research at other sites in a follow-on project.

*Future Work*. Those who conduct similar studies to validation assessment should consider a more gradual change in patient condition, and simulating more than one patient. The next phase will transition the novel system from research to development. Three features (data entry, scheduling, and checklists) will be completed that our research identified as essential to clinical work but were beyond the scope of the initial project. Validating the system's machine learning (ML) algorithms will make it possible to identify patterns in data such as trends, comparable patients and care regimens, and the way clinicians use the system. We intend to implement the novel system in another facility to prove its effectiveness beyond the BICU. It will also be paired with other suitable systems (e.g., EMR, medical devices, databases) so that it can serve as a data integrator.

## Conclusions

Use of a Cognitive Systems Engineering approach has resulted in a flexible novel health IT system that effectively supports clinical cognitive work in an ICU and one that clinicians favored over a traditional EMR. The system is designed to be modular and to evolve with science, new technologies, and changes in clinical practice. More efficient and reliable decisions that maintain accuracy and that help to form consensus among team members by using salient information should translate into improved patient outcomes and safety.

## Acknowledgments

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Figure Legends, and Tables

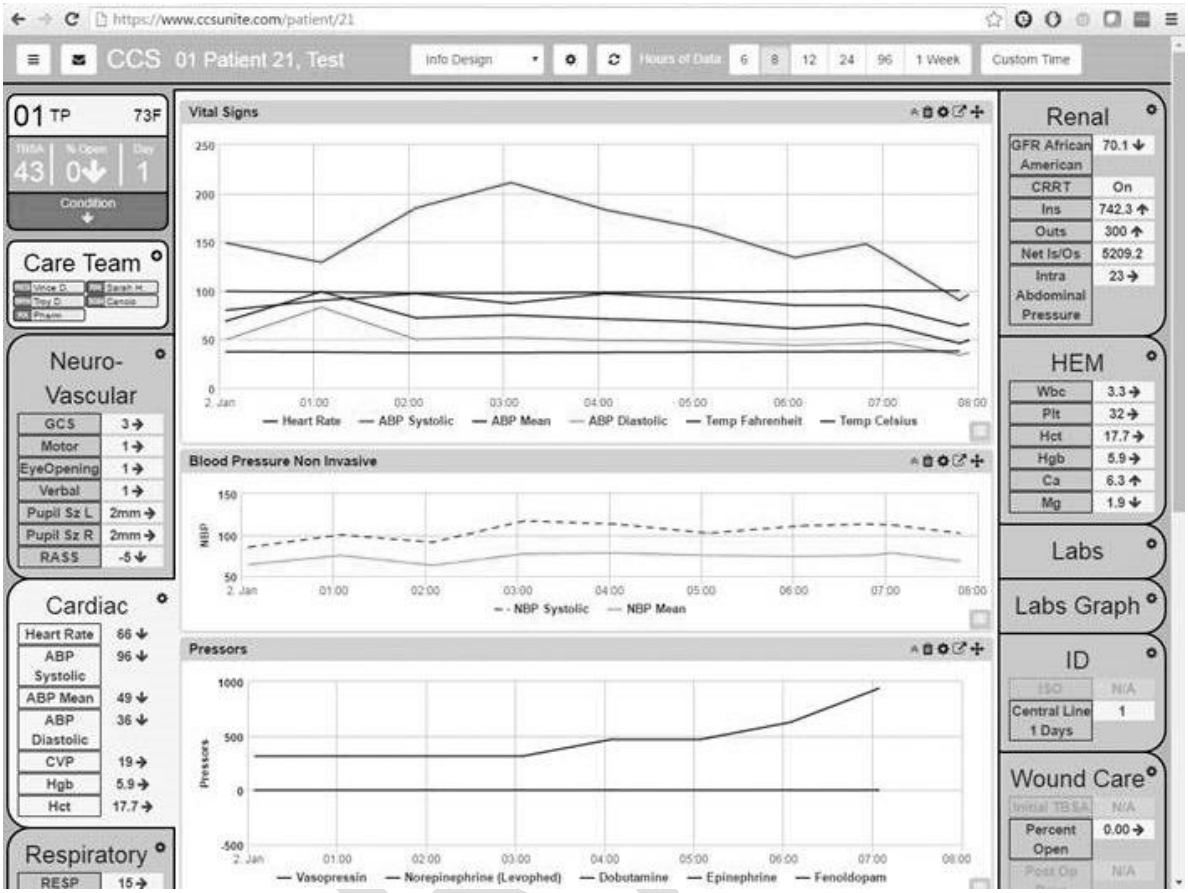


Figure 1: Novel IT System Prototype Patient View

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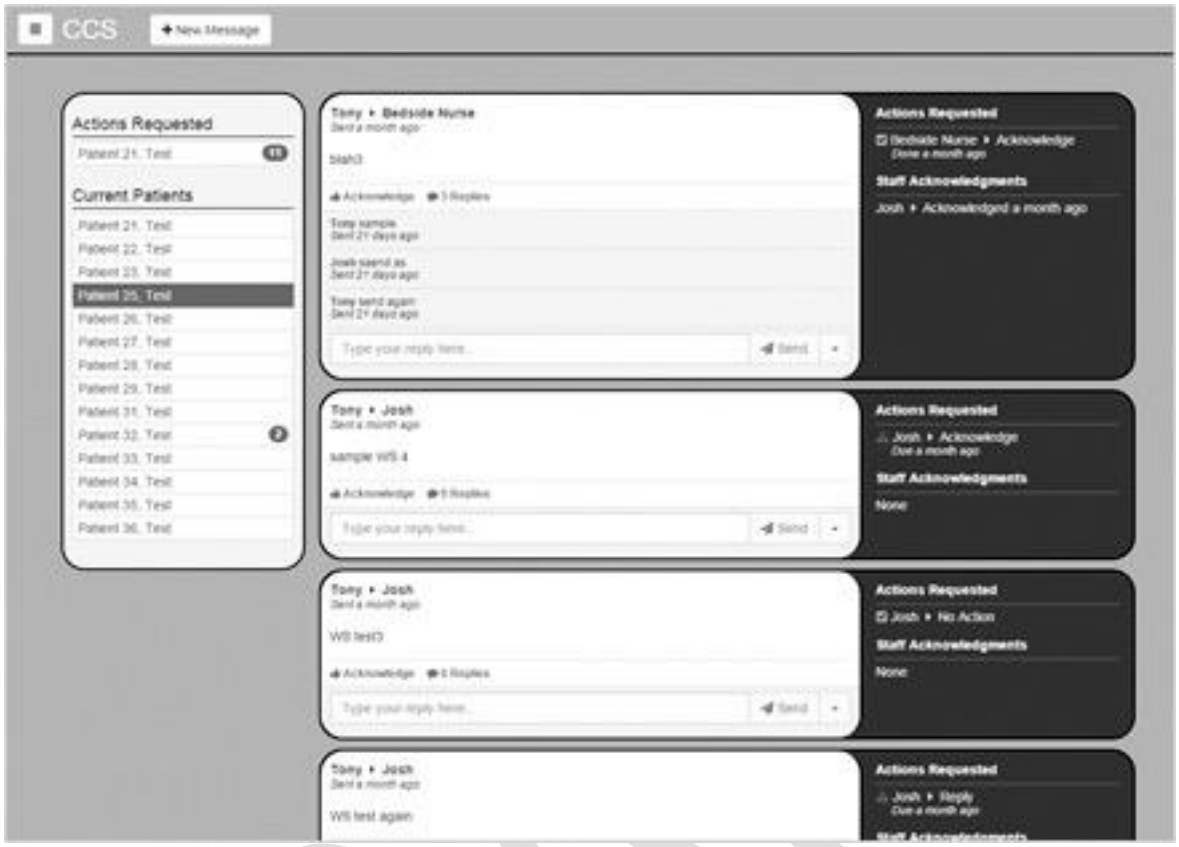


Figure 2: Novel IT System Text Messaging Feature

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Figure 3: Usability and Validation Assessment on the BICU

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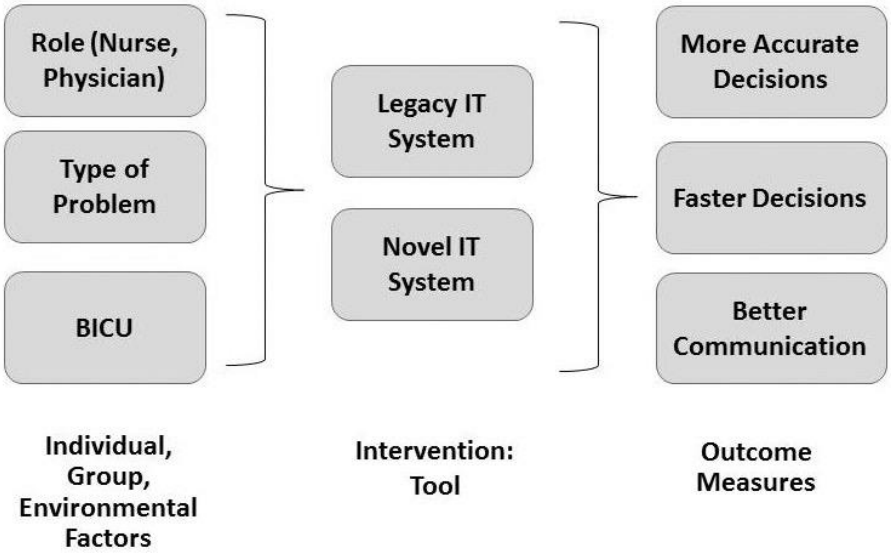


Figure 4. Process Model of Intervention

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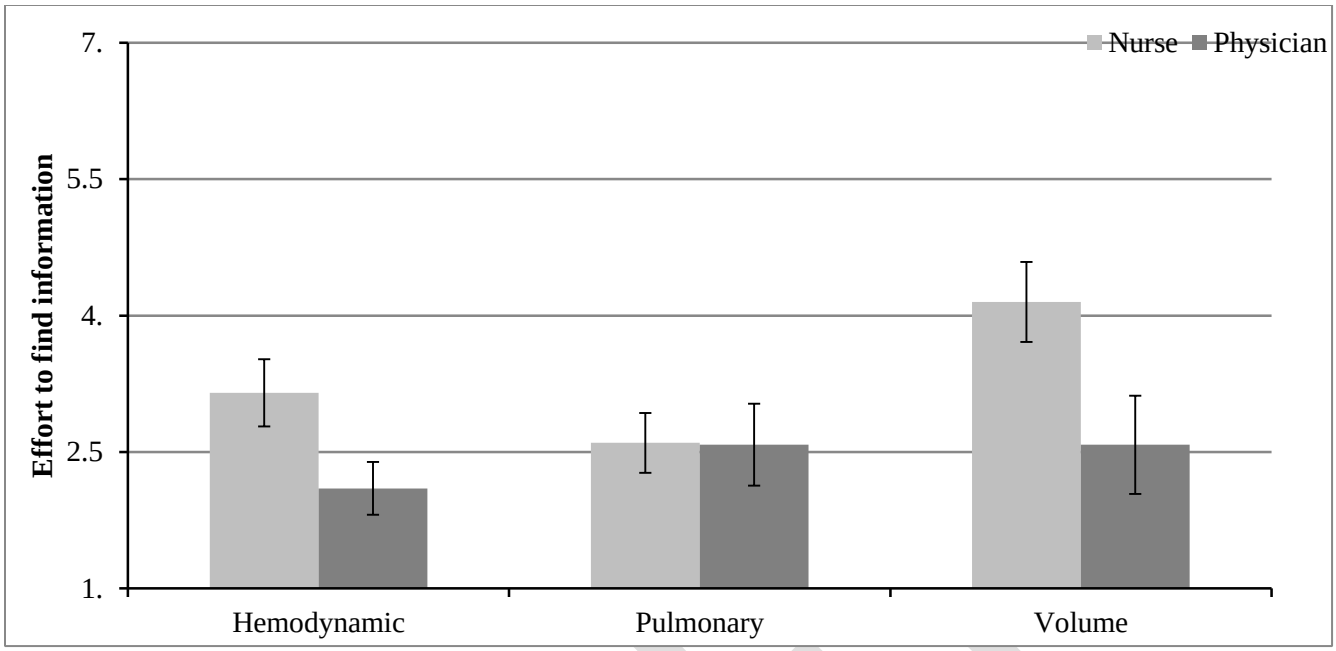


Figure 5. Effort ratings for key tasks by role.

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Table 1: Validation Assessment Study Design

| *Team* | *Day 0* | *Day 1* | *Day 2* |
|---|---|---|---|
| 1 | Orientation | Sepsis Scenario<br>Legacy IT System | ARDS Scenario<br>Novel IT System |
| 2 | Orientation | ARDS Scenario<br>Novel IT System | Sepsis Scenario<br>Legacy IT System |

Table 2: Validation Assessment Scenario Key Decision Points

| | |
|---|---|
| Scenario 1<br>Abdominal Sepsis | • initiation (delivery) of antibiotic therapy,<br>• decision to perform diagnostic procedure (i.e., diagnostic peritoneal lavage or exploratory laparotomy),<br>• decision to perform exploratory laparotomy or transition to palliative care,<br>• communicate with the family/patient's decision maker |
| Scenario 2<br>Severe ARDS | • initiation (delivery) of antibiotic therapy,<br>• paralyze the patient,<br>• order the rotaprone bed,<br>• initiation or decision not to initiate inhaled nitric oxide therapy,<br>• consult the ECMO service, decision to cannulate or forgo cannulation for ECMO<br>• communicate with the family/patient's decision maker |

Table 3: Usability Assessment IT System Comparison by Time (sec) to Complete 6 Tasks

| ***Scenario and Task*** | *Legacy*<br>n=1 | *Novel*<br>n=20 (median) | *SD* |
|---|---|---|---|
| *Scenario 1- Preparation for Surgery* | | | |
| 1--Is the patient's hemodynamic status getting worse? | 164 | 130.5 | 199.91 |
| 2--Is the patient's pulmonary status getting worse? | 395 | 69.5 | 49.69 |
| 3--Is the patient's volume status getting worse? | 255 | 108.5 | 75.51 |

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| *Scenario 2-New Admission* | | | |
|---|---|---|---|
| 1--Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same? | 205 | 87.5 | 84.42 |
| 2--Based on his glucose levels, do you recommend that he be started on an insulin drip? | 53 | 25.5 | 42.87 |
| 3--Based on the patient's lab values, do you think he should be started on CRRT? | 165 | 64.5 | 78.67 |

Table 4: Usability Assessment Subjective Ratings Using Novel IT System

Ratings: 1 (Strongly Disagree) to 7 (Strongly Agree)

| *Scenario 1-Preparing for Surgery* | *Mean* | *SD* |
|---|---|---|
| I am confident in my decision/recommendation. (56.3% Agree/Strongly Agree) | Nurse: 5.2<br>Physician: 5.7 | 1.3<br>1.1 |
| The system was easy to use to make this decision. (48.4% Agree/Strongly Agree) | Nurse: 4.7<br>Physician: 5.6 | 1.7<br>1.1 |
| The system enabled me to quickly find the information I needed. (56.3% Agree/Strongly Agree) | Nurse: 4.9<br>Physician: 5.7 | 1.8<br>1.4 |
| It was straightforward to find the information I needed. (53.1% Agree/Strongly Agree) | Nurse: 4.75<br>Physician: 5.33 | 1.8<br>1.37 |
| *Scenario 2-New Admission* | | |
| I am confident in my decision/recommendation. (70% Agree/Strongly Agree) | Nurse: 5.85<br>Physician: 6.10<br>RT: 5.7 | 0.67<br>0.73<br>0.76 |
| The system was easy to use to make this decision. (57.5% Agree/Strongly Agree) | Nurse: 5.60<br>Physician: 6.10*<br>RT: 4.8 | 1.2<br>0.57<br>1.31 |
| The system enabled me to quickly find the information I needed. (52.5% Agree/Strongly Agree) | Nurse: 5.55<br>Physician: 5.70<br>RT: 4.8 | 1.2<br>1.16<br>1.31 |

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| | | |
|---|---|---|
| It was straightforward to find the information I needed.(55% Agree/Strongly Agree) | Nurse: 5.50<br>Physician: 6.20*<br>RT: 4.9 | 1.05<br>0.92<br>1.37 |

Table 5: Participant Ratings Comparing the Legacy and Novel IT Systems

Ratings: 1 (Strongly Disagree) to 7 (Strongly Agree)

| *Information Search* | *Legacy Better (Ratings 1-3)* | *Neutral (Rating 4)* | *Novel Better (Ratings 5-7)* |
|---|---|---|---|
| I can find the information I need in [the novel IT system] more quickly than I can using [the legacy system] | 24.4% | 9.7% | 65.9% |
| I can find the information I need more *easily* than I can using [the legacy system] | 14.6% | 19.5% | 65.9% |
| *Usability* | | | |
| The [the novel IT system] is easier to use than [the legacy system] | 14.5% | 19.% | 66% |
| I would feel more confident making future clinical decisions and recommendations using [the novel IT system] than using [the legacy system] | 19.5% | 22% | 58.5% |
| [The novel IT system] supports the way I do my work better than [the legacy system] | 17.1% | 19.5% | 63.4% |

Table 6: Validation Assessment Team Experience

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| | Years of Experience | | | Years on BICU | | |
|---|---|---|---|---|---|---|
| | Attending | Resident | Nurse | Attending | Resident | Nurse |
| Team 1 | 10+ | 5 | 10 | 10+ | 1 | 2 |
| Team 2 | 10 | 1 | 8 | 8 | <1 | 2 |

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**Appendix E.** Evidence of Usability-Burn ICU Decision Support.

# Evidence of Usability

*Evaluation of Burn ICU Clinician Decision Support*

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***Abstract*—Burn Intensive Care Unit (BICU) clinicians and clinical teams need to make time-pressured diagnostic and therapeutic decisions as they care for fragile patients. The decisions and related behaviors that we term "cognitive work" rely on complex sets of information that are currently fragmented among multiple databases. The efforts clinicians must make to use them and other information sources pose barriers that delay patient care and increase care cost, length of stay, and the potential for misadventures. We report on the results of a usability assessment to evaluate the decision and communication support prototype that we have developed over the past three years. Initial results indicate the research design, development, as well as close collaboration among researcher, developer and clinician, have resulted in a prototype that clinicians indicate successfully supports their work. We anticipate that better support for decision making and communication among members of the ICU staff who use this Cooperative Communication System (CCS) will improve efficiency and reliability, and as a result, improve patient safety and optimize patient outcomes.**

***Keywords—cognition, macro-cognition, healthcare, decision support, usability***

## I. Introduction

Burn Intensive Care Unit (BICU) patients' fragile condition and complex combination of life-threatening injuries and illnesses pose unique challenges for present those who care for them. Patients who are admitted to the unit that is our research site have the most severe affliction from chemical, mechanical or electrical burns, as well as burn-like diseases of the skin. This unit also treats patients with infections or trauma that cause extensive soft tissue damage or loss such as necrotizing fasciitis, some war-related trauma.

Care for patients in the BICU necessarily requires attention from multiple specialties from burn surgeon to medical intensivist, resident, bedside nurse, dietician, wound care nurse, respiratory therapist, physical and occupational therapist, infectious disease specialist, and more. All of these care providers must all collaborate through time to make effective decisions, develop treatment plans, assess patient progress, and refine plans to manage care. In order to do that, clinicians perform a variety of behaviors termed macro-cognitive activities (in Table 1) [1,2] as they carry out the myriad patient care tasks. These activities can also be seen in the work of operators in other high stakes settings such as defense, emergency response, and aviation.

Table 1: Macro-Cognitive Activities (adapted from [3])

| *Activity* | *Description* |
|---|---|
| Naturalistic decision making | Reliance on experience to identify a plausible course of action and use of mental simulation to evaluate it. |
| Sense making / situation assessment | Diagnosis of how current state came about and anticipation of how it will develop. |
| Planning | Changing action in order to transform a current state into a desired state. |
| Adaptation/ re-planning | Modification, adjustment or replacement of a plan already implemented. |
| Problem detection | Ability to notice potential problems at an early stage. |
| Coordination | How team members sequence actions to perform a task. |
| Developing mental models | Mental imagery and event comprehension, based on abstract knowledge and domain concepts and principles. |
| Mental simulation and storyboarding | Use of mental models to consider the future, enact a series of events, and ponder them as they lead to possible futures. |
| Maintaining common ground | Ongoing maintenance and repair of a calibrated understanding among team members |
| Managing uncertainty and risk | Coping with a state or feeling in which something is unknown or not understood. |
| Turning leverage points into courses of action | Ability to identify opportunities and turn them into courses of action. |
| Managing attention | Use of perceptual filters to determine the information a person will seek and notice. |

Performance of these activities, including decisions about how to manage care, relies on access to the most accurate and *salient*, or important, information about the patient. Electronic health records (EHR) have evolved over time as a kind of repository that is intended to enable clinicians to document and retrieve needed patient information. However, information in the EMR is difficult to find and share and is often unavailable when it is needed most. Mack and Saldivar [4] cite a series of shortcomings that they consider typical of current EMRs:

- Lack interoperability between health care organizations due to no standardized software platform for EMR use
- Lack standardized visual language for EMRs or medical devices, inducing user errors when multiple devices or documentation standards are used in the same place.
- Act as enlarged spreadsheets, requiring users to tab and type information into cells, which is time consuming and prone to errors
- Require users to scroll through multiple pre-formatted pages regardless of patient problem or user needs
- Lack advanced features such as critical event reporting, or smart chart ability for clinical decision support
- Lack the ability to control external devices (e.g., infusion pumps, physiological monitoring)
- Are unable to receive data from remote monitors

Shortcomings such as these force clinicians to develop ways to work around them, which takes them away from the time and energies they could otherwise devote to their patients, and increases the potential for threats to patient safety.

## II. THE COOPERATIVE COMMUNICATION SYSTEM

We have reported in previous SMC symposia [5,6] on our work to develop the Cooperative Communication System (CCS), an information technology (IT) system that is intended to improve individual and team decision making and communication for clinicians at a 16-bed military BICU. Our research team is completing the third year of this 3-year project. Use of the CCS is expected to improve staff efficiency and collaboration, optimizing patient outcomes and improving patient safety.

## III. METHODS

### *A. Human Subject Research Approval*

Our research team obtained approval for human subject research from the funder and research site Institutional Review Boards (IRB). A total of 151 staff members consented to participate.

### *B. Cognitive Systems Engineering*

We have used a Cognitive Systems Engineering (CSE) [7,8] a mixed methods research approach to study cognitive activity in the BICU proven over 30 years as an effective means to reveal essential features that mold complex work settings. The team's close attention to the data and connections among each of the five CSE phases means that the solution this process produces is grounded in data that are drawn from study of the clinicians and BICU work setting (is ecologically valid).

*Preparation.* At the start of the project, the team used the preparation phase to understand the work domain and cognitively complex tasks that they would need to learn about. While waiting for IRB approval, our team conducted a series of interviews with subject matter experts at the Burn ICU and developed an interview guide. The guide provided the structure that would be needed to cover each of the important aspects of the BICU. The guide's structure also made it possible in the analysis phase to recognize common themes across a number of interviews and observations.

*Knowledge Elicitation.* Our activity in the first year included in-person observation, interviews, surveys, and artifact analysis. This phase reveals key decisions that clinicians make that the solution will need to support. Team members conducted 31 observations with bedside, charge and wound care nurses, residents, attending physicians, and physical, occupational and respiratory therapists. Circulating through the BICU to observe clinical activities over 8-hour shifts, team members asked occasional informal questions to learn more about motivation and context. The team performed 49 semi-structured Cognitive Task Analysis (CTA) interviews [3] with members of the BICU clinical staff that lasted from 30 to 90 minutes. One team member acted as lead interviewer and a second took real-time notes, using the Critical Decision Method to learn about occasions when BICU clinicians were pressed to their limits and what information they needed in those circumstances.

Research team members also collected de-identified information and printouts or pictures of the 20 different sources of information that the staff uses to support cognitive work. These included 3 that combined computer and hard copy printout (arterial blood gas analyzer, vital signs monitor printout, and protocols/guidelines), 3 paper artifacts (daily wound care plan, sign out sheet, and Charge Nurse checklist), and 11 computer information sources from the existing patient medical record to the patient's outpatient record.

*Analysis and Representation.* The team rigorously reviewed the observation, interview, and artifact data to identify frequently occurring themes. Figure 1 shows how the team met after each field visit to review data. Using the categories developed during working sessions that were held after each field visit, we segmented and coded interview sections that were relevant to each theme. This identified actual data and connect them to the themes. After a pilot run to confirm they were similar coding in a similar manner, three team members coded 49 interviews and 31 observations, resulting in 727 data excerpts that were coded by thematic category. The process identified 20 key challenges to cognitive work on the BICU, such as "No effective means to synchronize aspects of patient care." The team then developed initial system requirements by asking questions about each challenge such as "what does the clinical team need to overcome that challenge?" and "what system or display features could help

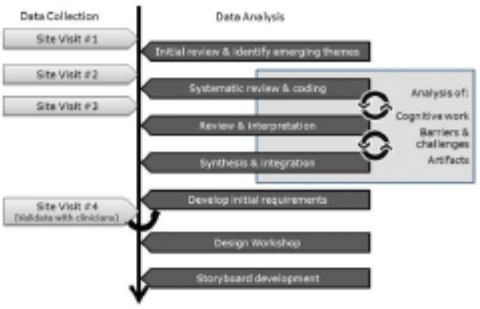


Fig. 1 Data collection and data analysis process
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address that challenge?" The effort produced a series of concise problem statements and 39 information system requirements, such as "Practitioners need to understand what's going on with their group of patients across the shift (whatever their group happens to be)." Feature concepts such as "Visualization of patient schedule for shift (patient x time), shareable across team" described what the system can do to meet the need, along with anticipated benefits such as "Patients get needed care with fewer delays" and "Efficient use of staff time." The team used the features based on system requirements to develop a series of use cases that described how the system is intended to work. A descriptive model of Burn ICU cognitive work (Figure 2) showed how tasks that

Fig 2. Descriptive model of BICU cognitive work
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the clinicians perform include four activities (clarification, coordination, negotiation, and anticipation) in order to accomplish the unit's care synchronization role. Requirements that the team developed from these tasks indicated opportunities, or leverage points, to improve care synchronization.

*Application Design.* Application design produces concepts based on the requirements developed during the knowledge elicitation and analysis and representation phases. Two participatory design workshops that included researchers, developers, and clinicians created rough and increasingly refined notions of what a useful information system would display. The research team information designer translated workshop rough ideas into a prototype we verified in review with a set of residents and nurses as well as client team members. The interface design included seven essential elements to support cognitive work.

*Patient Identifier:* A graphic element that includes patient number, total burn surface area at admission, an indicator of illness severity and progress based on key trends.

*Unit View.* Organized as a BICU floor plan, the view includes an identifier for each patient, status of planned tasks, and facilitates resource allocation and prioritization, care planning and coordination.

*Patient View.* All 320+ variables of critical data are shown for an individual patient (Figure 3), organized by system from cardiac and neurological to wound care and infectious disease using a "parent-child" tab/window format.

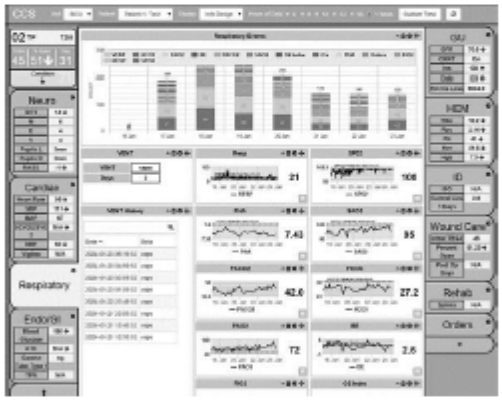


Fig 3. The CCS Patient View software prototype.
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*Scheduling.* Displays staff assignments on the unit and to each patient care team, improving unit efficiency by matching resources to care needs.

*Order Management.* List of all orders from treatments to diagnostic tests that will minimize uncertainty about diagnostic and therapeutic plans, status, and results.

*Checklists.* Lists quality measures that makes it possible for the Charge Nurse to ensure that essential evidence-based care is accomplished.

*Tasking, Messaging, and Alerting.* Real time message correspondence among care team members that supports the

care team's development and maintenance of common ground about each patient's history, status, prognosis, and care plan.

The team programmed the user interface and data mining functions based on findings from the knowledge elicitation and analysis and representation phases. Using the commercially available JIRA (https://www.atlassian.com/software/jira) software project tracking database to keep track of requirements, we used agile software development methods to develop increasingly refined prototypes that we routinely reviewed with BICU clinicians.

*Evaluation*. Assessments make it possible to estimate the effect that using the solution will have on those who are expected to use it, based on requirements that were developed earlier in the project. In November 2015, the team conducted 45-minute long usability assessment sessions with 43 clinicians at the research site. We used usability assessment [9] methods in order to see how well the CCS supported individual clinician needs to find and use key patient data. We were interested to learn: How usable is the CCS system in terms of ease of use, interface, perceived efficiency, and supporting cognitive work? How usable is it compared to the current EMR? Features such as messaging that are designed to support team coordination were not included in this assessment.

Usability is the condition of a product, system or service being suited for human use. Usability assessment can be performed either to determine whether there are difficulties with using a product or to uncover opportunities for improvements. The facilitator describes a scenario the participant is likely to encounter and poses a number of tasks for the participant to perform using the prototype. The participant is asked to "talk aloud" while performing the tasks. This use of Verbal Protocol Analysis can reveal assumptions that a participant brings to a situation. It can show the process that a person follows while attempting to accomplish an objective, and it can detect obstacles that a participant encounters while using the prototype. Results can provide a revealing insight into how those who are intended to use a product actually perceive and use it [10].

In our assessment, the sample of participants included roles that were most likely to rely on information contained in the CCS to make decisions: 12 physicians (residents, physician assistants, and attending physicians), 20 nurses, and 10 respiratory therapists. Two BICU rooms were outfitted with a laptop that could connect via wireless to the Federal Information Processing Standards (FIPS)-compliant Amazon Government Cloud server where the CCS prototype was installed. Each room also had a video camera that was set up to look over the shoulder of the participant, as Figure 4 shows. We used the video to record how each participant used the CCS and also capture comments to make sure that our written notes on the session were accurate. After confirming consent and providing a brief 5-minute orientation to the CCS display, each physician and nurse participant was asked to perform two

Fig 4. Usability assessment workstation
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hypothetical, yet clinically relevant, scenarios while speaking aloud: preparation for surgery, and new admission. Ten respiratory technicians were each asked to perform the new admission scenario. Each participant was asked a number of questions that required a decision about the patient. After each scenario, and at the end of the session, we asked participants to estimate level of effort it took to complete the tasks. In each room, a facilitator and an observer collected quantitative data such as the length of time it took for a participant to answer each question, and subjective responses to issues such as ease of use, trust in the CCS, and a comparison with the current IT system.

## IV. FINDINGS

Results of the usability assessment included two types of qualitative data: usability ratings and responses to open-ended questions. In the first, users rated the usability of the CCS system on several dimensions after completing each scenario, then compared the CCS to their own experience with the legacy system. Users' years of experience with the current EMR ranged from less than 1 year to 10+ years, distributed fairly evenly across the sample, and 76% reported being very comfortable with using it. Table 2 shows responses to five

Table 2: Responses to Comparison Questions

| *Statement* (n=41) | *Disagree* | *Neutral* | *Agree* |
|---|---|---|---|
| I can find the information I need in CCS *more quickly* than I can using [the current EMR] | 24.4 | 9.7 | 65.9 |
| I can find the information I need in CCS *more easily* than I can using [the current EMR] | 14.6 | 19.5 | 65.9 |
| The CCS system is *easier to use* than [the current EMR] | 14.5 | 19.5 | 66 |
| I would feel *more confident* making future clinical decisions and recommendation using CCS than using [the current EMR] | 19.5 | 22 | 58.5 |
| CCS supports the *way I do my work* better than [the current EMR] | 19.5 | 22 | 58.5 |

statements comparing the CCS with the EMR that has been in use at the research site. The degree of positive acceptance of CCS is noteworthy in light of the long experience with the legacy EMR, as well as the short amount of time the participants had used the CCS prototype.

Many comments in response to open-ended questions noted the value of features that the research team had learned from the CSE knowledge elicitation phase: simultaneous display of salient data, shared mental model of patient status, and sparing clinicians from work that the system can handle:

> *"Having the information right there makes you think, when you can see the trends. It helps to pull the information together in one place."* (Respiratory Therapist)

> *"I like that CCS may bring us together and on the same page. All members on the team may see things the same way."* (Nurse)

> *"Nice to have actual and ideal or adjusted body weight to dose drugs."* (Attending physician)

## V. DISCUSSION

Results from the CCS usability assessment demonstrated the value of the CSE methodology to produce ecologically valid decision support software for clinicians in a challenging high stakes work setting.

It also revealed opportunities to improve the CCS. For example, participants found the time scale at the top of the view needed to be larger to read it more easily. Nurses expressed a preference for a tab on the Patient View that summarized all lab values in one place rather than being sorted across body system parent views. Respiratory therapists also expressed an interest in having a tab that summarized all ventilator settings. Some participants found locating information more difficult than we expected. Upon review, we found this was related to the ability to personally configure the central panel (parent view) and the need to scroll to find some of the data widgets. Participants also expressed an interest in changing the manner in which patient fluid intake and output was displayed so they could see net gain/loss at a glance.

Each of the findings from the usability assessment provided guidance for improvements to make before performing a validation assessment planned for later in 2016.

## VI. SUMMARY

Use of CSE informs the development of effective decision and communication support for those who work in complex, high stakes settings such as the BICU. The close collaboration among researchers, design and development professionals, and clinicians creates effective software solutions that reflect clinical practice.

## VII. ACKNOWLEDGMENT

The authors express their gratitude to the clinicians who participated in this effort, LTC Kevin Chung, as well as colleagues Gregory Rule, Chris Argenta, Beth Crandall, Megan Beck, and Nicole Caldwell, RN, for their work on this project.

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**Appendix F.** Support for Salience: IT to Assist Burn ICU Clinician Decision Making & Communication. IEEE Systems Man and Cybernetics International Symposium. October 2015. Hong Kong.

# Support for Salience

## *IT to Assist Burn ICU Clinician Decision Making and Communication*


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***Abstract*—Clinicians need to find and use the most important, or *salient*, information to make optimal patient care decisions. The fragile health of patients who are admitted to a Burn Intensive Care Unit (BICU) requires clinicians and clinical teams to make time-pressured diagnostic and therapeutic decisions based on complex sets of information. Barriers to these decisions, and related behaviors, which we term "cognitive work," delay patient care and increase care cost, length of stay, and the potential for misadventures. We report on the progress of a project to develop a real time IT system to support BICU individual and team cognitive work and communication. Our approach enables clinicians to obtain salient information through three means: role-based data views, ability to personally configure displays, and data mining to reveal trends and patterns. User interface and data mining functions and are now being programmed to develop increasingly refined prototypes that we evaluate with BICU clinicians at each stage through agile software development. Evaluation will verify improvements to decision making that result from clinician use of the CCS. More efficient, reliable collaboration among members of the ICU staff who use this Cooperative Communication System (CCS) will improve patient safety and optimize patient outcomes.**



***Keywords*—cognition, macrocognition, healthcare, decision support, communication**


### I. Introduction

The fragile condition and the complex combination of life-threatening injuries and illnesses that Intensive Care Unit (ICUs) patients face present healthcare teams with unique challenges. One of the most critical challenges that ICU care providers face is the need to perform decision making as well as what Cacciabue and Hollnagel [1] termed "macrocognitive" activities, which are "the cognitive functions that are performed in natural (rather than artificial laboratory) decision-making settings." Klein et al. [2] described macrocognition as "the mental activities that must be successfully accomplished to perform a task or achieve a goal." In addition, cognitive work also entails collaboration among staff members from a number of healthcare disciplines who must work together to perform multiple crucial tasks. These include the need to develop treatment plans, assess patient progress, and refine care management over time. Performing these and other care tasks relies on accurate, current information to be both available and evident when decisions need to be made. For that reason, the Institute of Medicine [3] recommended improving access to accurate, timely information, and to make relevant information available at the point of patient care.

Electronic health records (EHR) have been developed to serve as a kind of patient data repository that was intended to enable clinicians to document and retrieve needed patient information. Figure 1 shows the EHR table format that typically requires

Fig. 1 Example EHR order entry screen (identifying information obscured).

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the clinician to search without providing a way to identify the most important, or *salient*, patient data. As a result, information that is needed to make critical decisions is hard to find, is often unavailable when it is needed most, and is difficult to share. We report on a project to develop a system that makes salient


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patient information evident and supports communication among team members in order to optimize ICU patient care.

## II. THE COOPERATIVE COMMUNICATION SYSTEM

Our research team is in the third year of a 3-year project to develop the Cooperative Communication System (CCS) for a 16-bed military burn intensive care unit (BICU). The CCS is an information technology (IT) system that is intended to improve individual and team decision making and communication in the BICU, which is expected to optimize patient outcomes and improve patient safety

## III. METHODS

### *A. Human Subject Research Approval*

The research team obtained approval for human subject research from the funder and research site Institutional Review Boards. A total of 151 staff members consented to participate.

### *B. Cognitive Systems Engineering*

Understanding any work domain and the forces that shape it requires methods that are suited to its study. The project team is using a Cognitive Systems Engineering (CSE) [4, 5] mixed methods research approach to study cognitive activity in the Burn ICU. The CSE approach (Figure 2) is used to translate

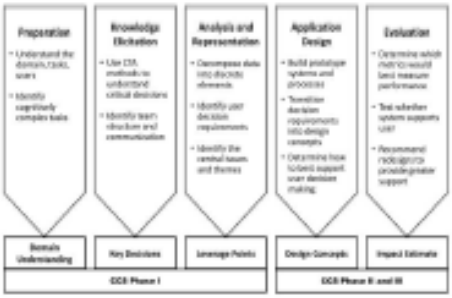


Fig 2. Five phases of Cognitive Systems Engineering. Adapted from [6]

knowledge about human cognitive performance, such as what is needed to attract attention to unexpected data, into principles and techniques to develop solutions including human-computer interface design. [7]. Integration of these five phases ensures that the solution this process produces is grounded in data that are drawn from study of the clinicians and BICU work setting (is ecologically valid). It will also help the team to anticipate shifts and unintended consequences that can happen when new IT such as the CCS is introduced [8].

CSE activity in the first year included preparation and knowledge elicitation through interviews, surveys, and artifact analysis, as well as analysis and representation using table and diagram development and thematic analysis. During the first two years of this project, the team identified 20 key challenges and barriers to cognitive work on the BICU, then translated them into concise problem statements and 39 information system requirements, developed representations to describe the BICU environment and key resources that clinicians use there, formulated a use cases to describe to developers how the system is intended to work, and developed a descriptive model of Burn ICU cognitive work (Figure 3).

Fig 3. Model of BICU cognitive work

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As we reported in Nemeth et al [9] complexity can hide underlying systematic patterns in cognitive work. Figure 3 illustrates these patterns in the BICU. Synchronization of patient care among clinicians and over time is the unit's mission, and is shown at the model's the top level. All of the activities that unit members perform to synchronize care are at the next level: clarification, coordination, negotiation, and anticipation. Supporting tasks from reducing uncertainty to forward thinking comprise the model's activities. Each task can be accounted for in the way that clinicians interact with each other and use information sources to minimize uncertainty. Requirements that the team developed from these tasks indicate opportunities, or leverage points, to improve synchronization.

The team is now programming the user interface and data mining functions based on Year One findings, and is developing increasingly refined prototypes that we evaluate with BICU clinicians at each stage through agile software development methods. Evaluation, including usability assessments, will verify improvements to decision making that result from clinician use of the CCS.

## IV. FINDINGS

Each of the CCS features fulfills one or more of the system requirements. This ensures that each aspect of the CCS will enable clinicians to overcome barriers and uncertainty about patient and team status to make better-informed decisions about diagnoses and treatment. Three aspects of the project are geared to help clinicians find and use salient information:

- Core functions, including data views
- The ability to personally configure displays
- Data mining, to reveal trends and patterns.

*A. Core Functions*

Six basic elements comprise the CCS, which are essential to support the BICU cognitive model (Figure 3).

- *Unit View.* Organized as a BICU floor plan, the view includes an identifier for each patient, status of planned tasks, and facilitates resource allocation and prioritization, care planning and coordination. Each occupied room includes a *Patient Identifier:* a graphic element that includes patient number, total burn surface area at admission, an indicator of illness severity and progress based on key trends. The identifier enables the BICU staff to scan among and across patients and recognize care needs at a glance.
- *Patient View.* Figure 4 depicts the early design for how all critical data are shown for an individual patient, organized by system from cardiac and neurological to wound care and infectious disease using a "parent-child" tab/window format. In contrast with the current EHR shown Figure 1, the Patient View presents all salient, data related to the patient in a single window.

Fig 4. Information design of Patient View. *Copyright © 2015 Applied Research Associates, Inc.*

- *Scheduling.* Staff assignment to the unit, and to each patient care team, improves unit efficiency by making opportunities for care evident. It also saves "missed" opportunities for care such as a chaplain visit, or rehabilitation.
- *Order Management.* The view lists all orders from treatments to diagnostic tests, to minimize uncertainty about diagnostic and therapeutic plans, status, and results. BICU staff members currently spend a significant amount of cognitive and physical energy to coordinate, account for, and adjust medications, therapies, and investigations. The CCS displays information on these items in a manner that makes it easier for care team members to review, question, and modify.
- *Checklists.* An interactive roster of quality measures makes it possible for the unit's Charge Nurse to ensure in real time that essential evidence-based care is accomplished. The checklist view provides a way for the CCS to track quality measures and items may be identified from data in the EHR. For example, possible shortcomings or "faults" can be pushed to clinicians, or items may be displayed as clinical reminders for clinicians to use when making decisions.
- *Tasking, Messaging, and Alerting.* Real time message correspondence among care team members supports the development and maintenance of common ground regarding their patient's history, status, prognosis, and care plan. It will keep the healthcare team connected to important information and to each other. This feature combines rules related to tracking information and clinician activity and providing push notifications ("alerts") according to changes in information or at the request of team members.

*B. Configurable Displays*

The Patient View can be configured, so that a clinician can change what is displayed and how it is shown on the screen. Salient information is available and evident, because views are based on role and task requirements. A configurable display means a resident does not need to review information other than what she/he needs to prepare for morning interdisciplinary rounds. Clinicians who prefer to see certain variables displayed graphically can choose to see them in a stacked line graph. Others who prefer to see the same variables in numeric form can choose to have them displayed in a table. This also makes the creation of relational information displays possible. Such a display shows meaningful combinations such as a "cardiovascular," "cardiopulmonary," or "cardio-renal" that may help clinicians answer questions about patient condition or treatment effects. This ability to choose information and its display is expected to improve clinician understanding of patient trajectory.

*C. Machine Learning*

Machine learning (ML) makes it possible to identify patterns such as trends, comparable patients and care regimens, and metadata on how clinicians use the system. The project's ML effort combines the use of traditional (open-source off-the-shelf) data mining tools with innovative new data mining capabilities. This dramatically improves clinician ability to quickly identify and view similarities/discrepancies between a current patient's health trajectory and those of a large database of previous patients. Clinicians can make more informed decisions about patient care because they can leverage knowledge of the treatment plans and results from all available records of previous patients on the unit who have had comparable conditions and interventions.

We see two major technical challenges for ML:

1) *Irregular Time Series.* Patients have a wide diversity of time-series data which represents a sequence of condition states, medical interventions, and patient responses. Entries in the health records are sparse and uncertain. This complexity makes it necessary to develop a solution that incorporates temporal models that will show progressions of care and sensor readings in context.

2) *Scale and Performance.* The ML operations must provide quick and accurate responses at scale. The system will consider many patients dating back many years and regularly ingest new patient records over time. Some will have records spanning long time periods. The problem's scale requires a solution that will handle this large existing database. It needs to accept, integrate/index, and classify new data from ongoing patient care, quickly identify best matches to support interactive queries from clinicians, and probabilistically project possible future trajectories based on historical precedence.

The CCS project uses eight ML components to analyze clinical records, develop models of patient/clinician interactions, and provide clinicians with decision-support information using the CCS user interface.

- *Data Exploration.* Analyzes the patient database schema and contents and extracts summary metadata and pre-processes key data from historical patient records for cleaning and staging for analytics.
- *Data Access Layer.* Cleans, restructures, stages, and updates data for ML analytics without modifications to the source medical records. Storing cleaned data in our own schemas enables faster data access for analytics.
- *Element Analytics.* Reads in time series patient data and write out aggregations, interpolations, and performs direct data and trend analytic functions (e.g., Sequential Organ Failure Assessment (SOFA) scores).
- *Sequence Analytics.* Uses ML to model temporal sequences where the ordering and relationship of events is critical to interpretation and similarity measures. (e.g., Event Sequence Alignment and Clustering). Identifying sequences of events that are similar between the current and set of historic patients, we identify cohorts and support case-based predictive analysis of possible future events.
- *Similarity Analytics.* Computes correlations within and across multiple factors in the data (including aggregated data) over time windows, and learns models for identifying salient factors for cohort similarity. We use an ensemble of similarity calculations to capture different ways in which temporal values can be similar.
- *Semantic Analytics.* Bridges the semantic meaning of various unstructured data fields to identify domain-knowledge-based similarities where content-only comparisons fail. (e.g., integration of SNOMED CT or ICD-9/10 ontologies) This is useful for identifying key clinical events from notes data in the patient record.
- *Real Time Analytics.* Directly supports interactive features of the UI through analytic capabilities (e.g., moving and windowed averages), and running of models against active patient data (e.g., extracting clinically relevant similarities from cohort recommendations).
- *Metadata Analytics.* Instruments the various components of the CCS system so that we can measure performance, assess usage, identify issues, and better estimate scalability and stability.

The ML function is being developed, and will be evaluated in parallel, with the CCS user interface.

## V. DISCUSSION

Automation has traditionally been used in high risk settings to replace individuals in the performance of work that is considered to be inappropriate for humans. Rather than replace humans, though, automation needs to *aid* humans as they work to solve problems.

The way that a problem is presented can improve or degrade the performance of cognitive work. Expertise in healthcare is the ability to know what is—and what is not— important [10]. Aiding has typically been directed at the novice level [11], but it is actually most needed on *difficult* problems. Difficult problems are the type that experts confront. This is also true in other high risk work settings in addition to healthcare.

Healthcare activities rely on the acquisition, portrayal and analysis of therapeutic and diagnostic information as an integral part of individual patient care. The daily work of the clinician requires representations that serve as a representation of the work that changes continually and must be managed successfully in order to accomplish goals [12]. The information that is represented, and how it is represented, depends on the individual and group cognitive work that it is intended to support. Individual elements of information vary widely in the length of time that they remain reliable. Their salience depends a great deal on their context. The need for accurate, timely information exists at the level of the entire unit as well as at the individual clinician level. The unit level is where the technical work of unit planning and management directs who will get care, what type of care will be provided, and when it will be provided.

Actual improvement to support patient care relies on going beyond the surface descriptions (phenotypes) of work domains to reveal and understand the underlying patterns (genotypes) of systemic factors [13]. Human factors [14] and CSE research methods within the naturalistic decision making model [15] have proven value in revealing the key aspects of healthcare work domains to develop valid IT systems and information displays.

## VI. SUMMARY

In order to succeed, IT support for healthcare cognitive work requires repeated, deep looks into the clinical work setting using methods that are suited to the study of individual and team cognitive work in order to find what data truly matter. Use of CSE's decision-making approach to understand patient care settings can inform the development of effective EHRs. The salient information display that results can begin to overcome embedded difficulties with current health records.

Clinician information needs change according to patient condition, patient problem, clinical task, and clinician role and experience. Through CSE, we have identified seven core functions for the CCS health IT system that will support clinical decision making and communication needs. By matching needed information to diagnostic and therapeutic tasks, the CCS decision and communication support tool is ecologically valid (matches the work domain) and, as a result, is inherently useful.

More efficient, reliable collaboration among members of the ICU staff who use the CCS is expected to improve patient safety and optimize patient outcomes. Readily using salient information will spare clinicians wasted time, uncertainty, and indecision. We expect this will also help to decrease missteps, lapses, delays in car, resulting in shortened length of stay, reduced cost of care, and improved patient safety.

## VII. ACKNOWLEDGMENT

The authors express their gratitude to the clinicians who participated in this effort, LTC Kevin Chung, as well as colleagues: Dianne Lauferswailer, Anna Grome, Beth Crandall, Megan Beck, Greg Rule, Dianne Hancock, LVN, and Nicole Caldwell, RN, for their work on this project.

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**Appendix G.** Abstract: Evaluation Results for a Burn ICU Clinician Decision and Communications Support System. The 46th Critical Care Medicine Congress. Honolulu. (In review)

Authors:

Jeremy C. Pamplin, MD, FCCM, Maria L. Serio-Melvin, MSN, RN, Sarah J. Murray, MSN, RN, Sena R. Veazey, MS, Craig Fenrich, BS, Jose Salinas, PhD, Greg Rule, MS, Christopher Nemeth, PhD,

Abstract Title

**Evaluation Results for a Burn ICU Clinician Decision and Communications Support System**

Structured Abstract

BACKGROUND:

The Cooperative Communication System (CCS) project has developed an ecologically valid decision and communications support IT prototype with machine learning abilities for a military burn intensive care unit (BICU). We evaluated CCS through both a usability and a validation assessment to learn how well it supports individual and team clinical cognitive work.

METHODS:

Usability. We asked 42 BICU clinicians (12 physicians, 20 nurses, and 10 respiratory technicians) to complete two 20-minute scenarios (prep for surgery, new admission). Each was presented with a narrative. We asked questions that required use of the CCS to find the information to make clinical decisions. Each indicated their front-of-mind awareness of their cognitive work y thinking aloud.

Validation. Two teams (resident, nurse, attending) performed in two 4-6 hour scenarios (sepsis, ARDS) on a high fidelity manikin. Teams used a legacy IT system on one scenario, and CCS on the other. We used multiple observer notes, system order entry files, and after action reviews to document team performance.

RESULTS:

Usability. Forty three clinicians (13 physicians, 20 nurses, 10 respiratory therapists) participated. A majority rated the CCS system as good as or better than the legacy EMR along five dimensions. In 5 out of 6 tasks nurse time to complete was over twice as fast using the CCS compared with the legacy EHR.

Validation. Using the CCS in the sepsis scenario, Team 2 performed at the same level as another resident with four more years of experience and explored multiple diagnoses. Using the CCS in the ARDS scenario, Team 1 arrived at the choice to treat the TENS patient by using a rotaprone bed an hour before Team 2.

CONCLUSION:

Clinicians made accurate decisions more efficiently using the CCS. Their preference for the CCS over the existing EHR demonstrates the project's methodology has produced a decision and communication support tool that clinicians find inherently valuable.

**Appendix H.** Abstract: High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. Safe.Southern Region Burn Conference. Atlanta. (Accepted) and the Critical Care Medicine Congress. Honolulu. (In review)

Authors: Maria L. Serio-Melvin, MSN, Sarah J. Murray, MSN, Sena R. Veazey, MS, Craig Fenrich, BS, Jose Salinas, PhD, Greg Rule, MS, Christopher Nemeth, PhD, Jeremy C. Pamplin, MD, FCCM

Abstract Title

High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe

Structured Abstract

Background:

Laboratory simulation reduces realism, forcing clinicians to suspend disbelief while performing in an environment unlike their actual work setting. The Cooperative Communication System (CCS) is a real time health information technology (IT) system we have developed over three years that supports individual and team clinical decision-making and communication in the BICU. We sought to evaluate the CCS in the highest fidelity simulation possible, on the BICU itself, to get the most valid results.

METHODS:

We conducted this IRB-approved, prospective, mixed methods study in a dedicated BICU room. Each of two teams (bedside nurse, resident, attending physician with no patient assignment) performed two clinically accurate scenarios (sepsis, ARDS) over about 6 hours, caring for a high fidelity male SimMan3G(TM) manikin capable of audible heart/lung/bowel/verbal sounds, palpable pulses, and reactive pupils and outfitted with typical BICU lines, dressings, etc. Observers took notes and recorded video to document time to reach key decisions. After each simulation, the team provided comments on the experience and completed a brief survey.

RESULTS:

Teams commented conducting the simulation in the actual BICU enabled them to look beyond role playing and fully immerse themselves in the scenarios. Residents reported that they learned more in 2 days of simulation than they would have working in the BICU caring for actual patients, possibly a result of the compressed timeline, working directly with the attending physician, and having a critically ill patient decompensate rapidly. Teams considered simultaneous care for two critically ill simulated patients would be feasible but they would not include a simulate patient while caring for actual patients. Despite a high census, planning prevented conflicts with current patient care, ensuring no actual patients or unit resources were at risk

CONCLUSION:

Conducting research on an active patient unit offers healthcare research a feasible way to evaluate IT that maximizes fidelity and minimizes risk.

**Appendix I.** Abstract: Getting the Message: Health IT Can Improve Team Communication. Southern Region Burn Conference., Atlanta. (Accepted) and the 46th Critical Care Medicine Congress. Honolulu. (In review)

Authors:

Maria L. Serio-Melvin, MSN, Sarah J. Murray, MSN, Sena R. Veazey, MS, Craig Fenrich, BS, Jose Salinas, PhD, Greg Rule, MS, Christopher Nemeth, PhD, Jeremy C. Pamplin, MD, FCCM

Abstract Title

Getting the Message: Health IT Can Improve Team Communication

Structured Abstract

BACKGROUND:

Our three-year project developed the Cooperative Communication System (CCS), a real time health information technology (IT) system that supports BICU individual and team clinical decision-making and communication and includes its own messaging feature. We sought to learn clinician preference by comparing current (phone, pager, in-person) communication with CCS messaging during a validation assessment in which two BICU care teams (bedside nurse, resident, attending physician) cared for a high fidelity male SimMan3G ™ manikin in two clinically accurate scenarios (sepsis, ARDS) each about 6 hours long.

METHODS:

We conducted a prospective mixed methods study over two and a half days under an approved IRB protocol, collecting qualitative data after each simulation to discover participant perceptions related to decision making, communication, and team performance. Student T-test was used to analyze comparative differences in each question conducted in the survey with statistical significance ($p<0.05$) and confidence interval at 95%.

RESULTS:

Subjects found the CCS system was better at allowing more effective communication ($p<0.02$), that communication was easier (0.001), and the CCS messaging enhanced team communication. Subjects reported integration of messaging in the CCS made it easier to initiate, share and track information among their team members, in contrast to current (phone, pager, in-person) communication. Interestingly, as the acuity of the patient increased, participants spent more time at the bedside and communicated primarily by phone and face-to-face.

CONCLUSION:

BICU clinicians find messaging that is integral to decision and communication support improves clinical team performance.

**Appendix J.** Abstract: Supporting Salience: Valid IT Improves Burn ICU Decision Making, Human Systems Division 2017 National Conference, National Defense Industry Association, Sterling, VA.

Interest Areas: Systems Interface and Cognitive Processing (SI&CP)

Healthcare

Title: Supporting Salience: Valid IT Improves Burn ICU Decision Making

Issue:

The fragile health of patients who are admitted to a Burn Intensive Care Unit (BICU) requires clinicians and clinical teams to make time-pressured diagnostic and therapeutic decisions based on complex, inter-related sets of information. Clinicians need to find and use the most important, or *salient*, information to make optimal patient care decisions which we term "cognitive work." Barriers to these decisions delay patient care and increase care cost, length of stay, and the potential for misadventures.

Objective:

Our goal is to improve individual and team clinical decision making and communication in a BICU using a novel health information technology (IT): the Cooperative Communication System (CCS). The CCS provides real-time decision and communication support, presenting clinicians with salient information, improving cognitive work through enhanced human-machine collaboration, and enhanced assistance for human operators.

Setting:

Our research site is a 16-bed Burn Intensive Care Unit (BICU) located in a 450 bed, military Level 1 trauma and academic medical center. We conducted field research and usability and validation assessment simulated care scenarios on the BICU.

Research Design

Our Cognitive Systems Engineering (CSE) mixed methods approach developed a system that is based on a well-founded understanding of the work domain and operator needs, or *ecologically valid*. CSE activity in the first year included preparation and knowledge elicitation through interviews, surveys, and artifact analysis, as well as thematic analysis and representation using table and diagram development. The project team identified 20 key challenges and barriers to cognitive work on the BICU, then translated them into concise problem statements and 39 information system requirements, developed representations to describe the BICU

environment and key resources that clinicians use there, formulated use cases to describe to developers how the system and evaluated information design prototypes, and programmed and evaluated an interactive software prototype. The final CCS prototype includes a unique identifier for each patient, a unit view, patient view organized according to body system that can be configured to individual preferences, a messaging feature for real-time communication, and data mining to reveal trends and patterns that might otherwise go unnoticed.

Evaluation

We performed two evaluations to verify whether use of the CCS improved individual clinician decision making and team decision making.

A usability assessment evaluated individual clinician performance of 3 common ICU tasks in 2 scenarios: preparation for surgery and new ICU admission. A facilitator and note-taker noted time to complete tasks, and asked participants to report subjective perception of effort for each.

A validation assessment compared performance by 2 3-member BICU teams (physician, nurse, therapists, and physician trainee) during two 6-hour simulated patient care scenarios; one using the BICU legacy IT system, and one using the CCS. Observation and thematic coding of field notes measured elapsed time to arrive at key decision points that had been determined ahead of time.

Measurement:

Primary outcome measure was time to complete pre-defined tasks. Secondary outcome measures were subjective usefulness, and ease of use. In the validation assessment, we also evaluated communication effectiveness.

Assessment Results:

In the usability assessment between equally qualified nurses, time to complete tasks using the CCS was notably shorter than using the legacy system at the same level of accuracy.

In the validation assessment using the CCS prototype, the first year resident arrived at an accurate sepsis diagnosis the same time as a senior resident with 4 years' more experience. Using the CCS prototype, the senior resident arrived at an accurate Acute Respiratory Distress Syndrome (ARDS) therapeutic decision 2 hours earlier than the first year resident. Both teams strongly favored the CCS for communication.

Conclusions:

Measurement of clinician preferences demonstrated the CCS has robust face validity. The system appears to reduce time to complete complex tasks including pre-rounding, and to improve clinical decision making efficiency by novice as well as more experienced clinicians. Use of the CCS is expected to reduce patient length of stay and potential for adverse outcomes.

**Appendix K.** Abstract: Evidence of Decision Support for Burn ICU Clinicians. Military Health Systems Research Symposium.

491 words

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**Building Cognition through Burn Intensive Care Unit Decision and Communications Support**

**Background**: Our research team is in the third year of a 3-year project to design and develop the Cooperative Communication System (CCS), an ecologically valid decision and communications IT system for a military burn intensive care unit (ICU). Our purpose is to improve individual and team decision making to improve patient safety and optimize patient outcomes.

**Methods**: We are using a mixed methods Cognitive Systems Engineering (CSE) approach. Year One CSE methods included observations, interviews, surveys and artifact analysis to develop a distributed cognition model of BICU clinical practice. In Year Two, we developed initial information design and initial software prototypes of the IT system, based on Year One findings. The user interface and data mining functions and are now being programmed to develop increasingly refined prototypes that we evaluate with BICU clinicians at each stage through a mixture of agile and spiral software development methods. Evaluation, including usability assessments, will verify improvements to decision making that result from clinician use of the CCS.

**Results**: Year Two results have translated Year One data and requirements into system features that will enable clinicians to overcome barriers, from uncertainty about patient and team status to decisions about diagnoses and treatment. A Unit View supports resource allocation and prioritization, care planning and coordination. An individual Patient View enables the clinician to increase information salience by choosing what is displayed and how it is shown. This allows for the creation of relational information displays such as a "cardiovascular," "cardiopulmonary," or "cardio-renal" that may help clinicians answer questions about patient condition or treatment effects. Scheduling support improves unit efficiency by making opportunities for care evident, and saving "missed" opportunities for care such as a chaplain visit, or rehabilitation. A Patient Identifier enables the staff to scan among and across patients and recognize care needs at a glance. Order Management minimizes uncertainty on diagnostic and therapeutic plans, status, and results. Smart Checklists track quality measures in real-time to ensure essential evidence-based care is accomplished. Tasking, Messaging, and Alerting support the development and maintenance of common ground among clinicians through real time communication. Each view provides benefits to the clinical team. Task oriented/role based views ensure only salient information is displayed. Clinician configuring of patient displays improves understanding of patient trajectory. Machine learning makes it possible to identify patterns such as trends, comparable patients and care regimens, and metadata on how clinicians use the system.

**Conclusion**: Clinician information needs change according to patient condition, patient problem, clinical task, and clinician role and experience. Through CSE, we have identified seven core functions for our CCS health IT system to support clinical decision making information needs. The CSE approach produces decision support tools that are ecologically valid and inherently useful by matching information to task. More efficient, reliable collaboration among members of the ICU staff who use the CCS is expected to improve patient safety and optimize patient outcomes.

**Appendix L.** Abstract: NIH-IEEE Strategic Conference on Point of Care Technologies for Precision Medicine.

# Valid Point of Care IT for Improved Decision Making Precision

Christopher Nemeth, PhD, Senior Member, IEEE, LTC Jeremy C. Pamplin, MD, Josh Blomberg, Christopher Argenta, Student Member, IEEE, , Maria Serio-Melvin, Jose Salinas, PhD, Member IEEE

***Abstract*—Precision in clinician point of care decisions relies on awareness of and access to the most important, or *salient*, information. Barriers to clinician cognitive work such as poorly-crafted information technology, delay patient care and increase care cost, length of stay, and the potential for misadventures. We report on the Cooperative Communication System (CCS) project using Cognitive Systems Engineering methods to develop a real time IT system to support Burn ICU individual and team cognitive work and communication. More efficient, reliable collaboration among members of the ICU staff who use the CCS is expected to improve patient safety and optimize patient outcomes.**

## I. Cooperative Communication System

Our research team is in the third year of a 3-year project to develop the Cooperative Communication System (CCS) for a 16-bed military burn intensive care unit (BICU). The CCS is an information technology (IT) system that is intended to improve individual and team decision making and communication in the BICU.

## II. Methods

We have used a Cognitive Systems Engineering (CSE) [1] mixed methods research approach to study cognitive work in the BICU. Five phases (preparation, knowledge elicitation, analysis and representation, application design, and evaluation) ensure the solution that the process produces is grounded in data that are drawn from study of the clinicians and BICU work setting. Methods included structured interviews, surveys, artifact analysis, table and diagram development and thematic analysis [2]. The process revealed 20 key challenges and barriers to cognitive work on the BICU, and translated them into concise problem statements and 39 information system requirements. A descriptive model of Burn ICU cognitive work showed how clinicians synchronize care through tasks and activities. Use cases described to developers how the system is intended to work [3]. Machine learning algorithms reveal patterns that would otherwise be undetectable, such as trends, and previous patients on the unit who had similar conditions and treatments. Each formed the basis for an interactive prototype (Figure 1) that is now being evaluated on the BICU.

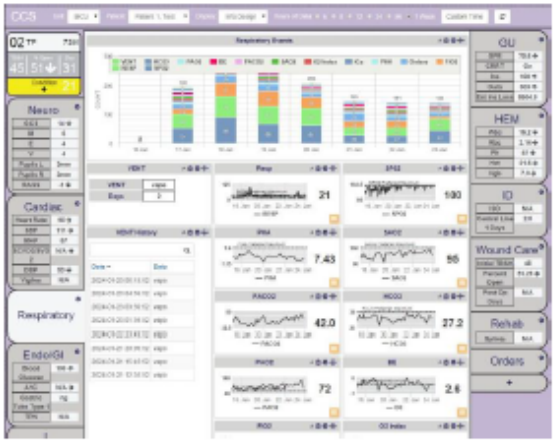

Fig 1. Patient View. *Copyright © 2015 Applied Research Associates, Inc.*

## III. Summary

Precision in patient point of care relies on going beyond the surface descriptions (phenotypes) of work domains to reveal and understand the underlying patterns (genotypes) of factors that mold the domain [4]. Support for healthcare cognitive work requires repeated, deep looks into the clinical work setting using methods that are proven in the study of individual and team cognitive work in order to find and present salient data. Use of the CSE approach to understand patient care cognitive work and settings informs the development of effective IT. The salient information displays that result can improve point of care precision and begin to overcome embedded difficulties with current healthcare IT.

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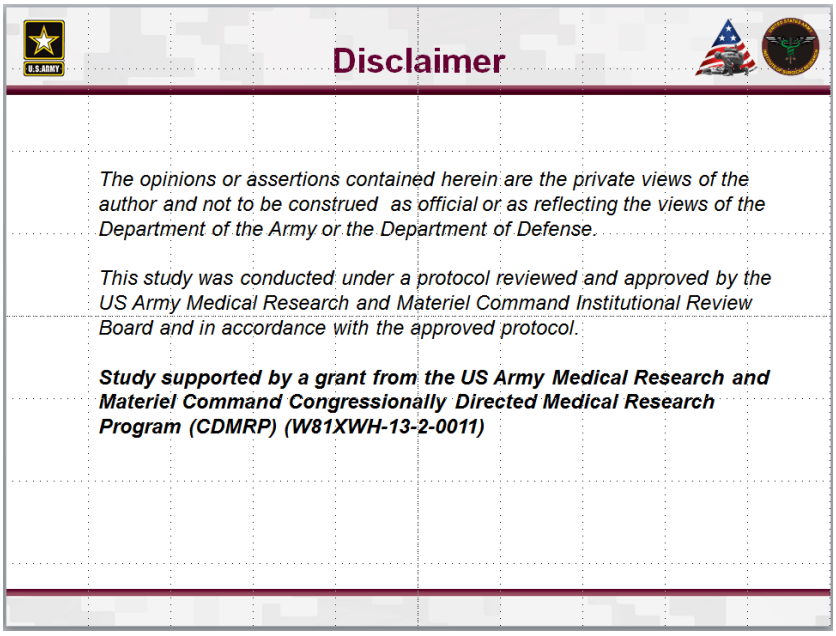
**Appendix M.** Presentation. High Fidelity Simulation in a Clinical Care Unit is Feasible and Safe. *Southern Region Burn Conference.* Atlanta.



## Background

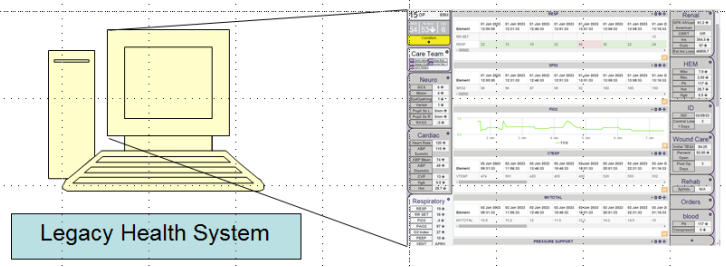
- Simulation (SIM) is a common method for health training
  - Reduces risk to live patients as people learn
  - Must suspend disbelief and perform in an environment that does not reflect the real work domain

## Benefits of Simulation

- Domains of Learning
  - Cognitive
    - Improve critical thinking skills
    - Improve recognition of impending situations
  - Psychomotor
    - Improve dexterity
    - Improve muscle memory
  - Affective
    - Improve emotional response to clinical situations
    - Improve team communication

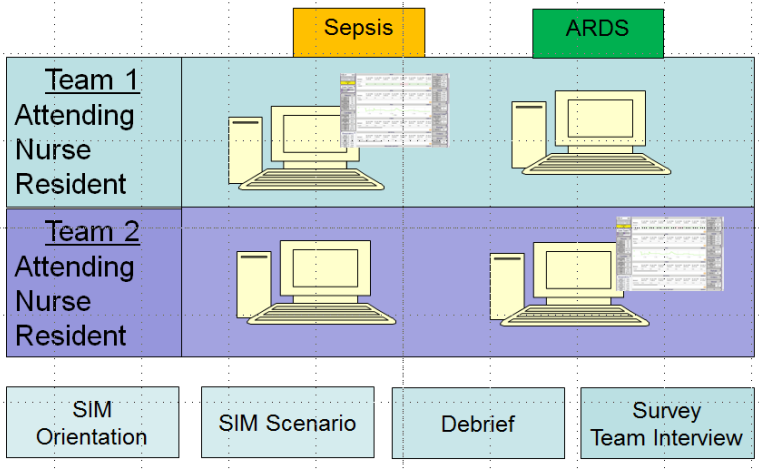
## Background: CCS Research Study

- We used SIM to test a novel health IT program, the Cooperative Communication System (CCS)
  - CCS interfaces with the legacy health system and information matched to clinical mental models, work practices
  - Helps with decision making and team communication



Legacy Health System

## Study Design




SIM Orientation | SIM Scenario | Debrief | Survey Team Interview

## Lab SIM vs Unit SIM

- Potential barriers in the lab setting
  - Environment
  - Equipment
  - Expectations
- These factors may impact fidelity or realism and the ability to suspend disbelief
  - Allow participants to fully engage
- Maximum fidelity and validity with clinical work domain

## Feasibility

- Dedicated research team & consultants: Multiple Roles
  - Clinician Subject Matter Experts (SME)
    - Intensivist (1)
    - Clinical Nurse Specialists (2)
  - Research Team
    - Observers (3)
  - Simulation Experts (2)
    - Medical Doctor
    - Simulation specialist
  - Software Engineer Team (3)
- Time & Cost Estimates
  - Simulation Scenario Development: 6 months (SMEs 20-50% FTE)
  - Simulation Set up/Break Down: 12 hours (SMEs & 1 SIM Specialist 100% FTE)
  - Simulation Run Time: 24 hours over 4 days (SMEs & 1 SIM Specialist 100% FTE)
  - Supplies: Full body dressing; IV bags (1L x 3, 100 ml x 5); tubes/lines/drains; expired kits--REUSED and kept for future SIM

Cost is high up front but reusing the scenario and supplies decreases overall amount.

## Safety

- Safety Rules
  - Real patients take precedence
    - Census safety stop
    - Acuity safety stop
  - Plan B & C
    - B: If safety stops are met—reduce team to 3 dedicated participants
    - C: If no room available on unit—reduce team & move to table top discussion
  - Segregate supplies and simulated medications
    - Keep simulated tools away from real tools
    - Dedicated person to manage equipment

## Methods

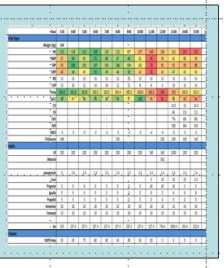
- SimMan3G™
  - Heart sounds
  - Lung sounds
  - Bowel sounds
  - Verbal sounds
  - Palpable pulses
  - Reactive pupils
  - Cardiac Monitor outputs
- All changed in response to the scenario

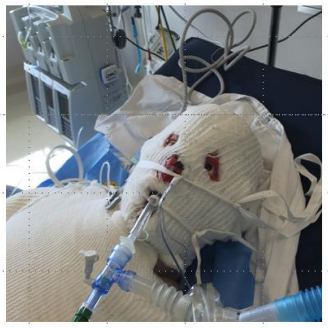
- We simulated
  - Urine
  - Emesis
  - Blood
  - Wounds and Dressings
  - IV Fluids on pump
  - Labs
  - Procedures
  - Ventilator
  - Family
  - Consultants
  - Other personnel

## Patient scenarios

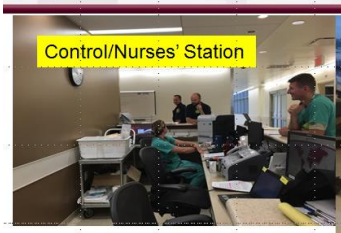
- Realistic to our burn center
  - 34 yo Active Duty E5 with 85% TBSA now post injury day 4
  - 24 yo man with probable TEN
- Similar full body dressings
  - Reused for both scenarios

Each "patient" had a detailed spreadsheet of vital signs, labs, and other elements of care by the hour

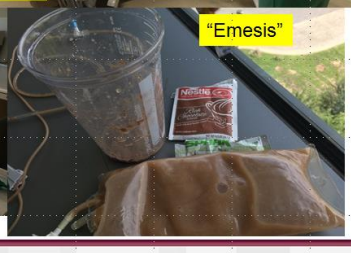




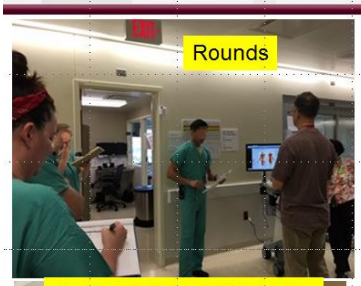
## Methods: Set-up



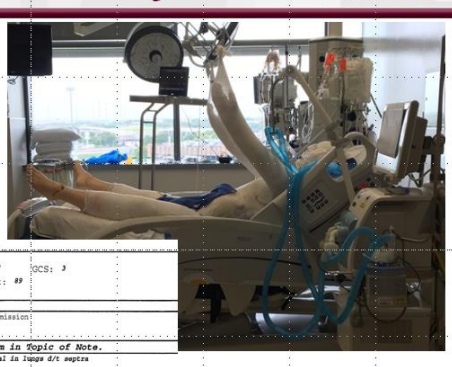
Practice

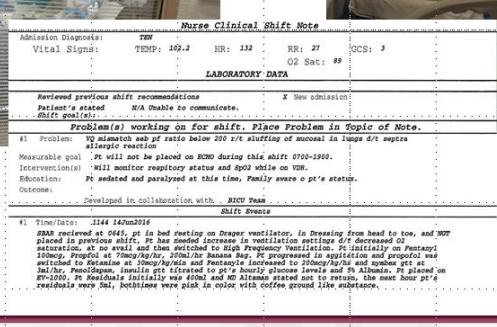


# Methods: Simulation



# Depth of Fidelity





*Nurse Clinical Shift Note*

Admission Diagnosis: *TEN*

Vital Signs: TEMP: *102.2* HR: *132* RR: *27* GCS: *3*

O2 Sat: *89*

*LABORATORY DATA*

*Reviewed previous shift recommendations* *X* New admission

*Patient's stated* *N/A Unable to communicate.*

*Shift goal(s):*

*Problem(s) working on for shift. Place Problem in Topic of Note.*

#1 Problem: *VQ mismatch aeb pf ratio below 200 r/t sluffing of mucosal in lungs d/t septra allergic reaction*

Measurable goal *Pt will not be placed on ECMO during this shift 0700-1900.*

Intervention(s) *Will monitor respitory status and SpO2 while on VDR.*

Education: *Pt sedated and paralyzed at this time, Family aware o pt's status.*

Outcome:

Developed in collaboration with *BICU Team*

*Shift Events*

#1 Time/Date: *1144 14Jun2016*

*SBAR recieved at 0645, pt in bed resting on Drager ventilator, in Dressing from head to toe, and NGT placed in previous shift. Pt has needed increase in ventilation settings d/t decreased O2 saturation, at no avail and then switched to High Frequency Ventilation. Pt initially on Fentanyl 100mcg, Propfol at 70mcg/kg/hr, 200ml/hr Banana Bag. Pt progressed in agitation and propofol was switched to Ketamine at 30mcg/kg/min and Fentanyle increased to 200mcg/kg/hr and nymbex gtt at 1ml/hr, Fenoldapam, insulin gtt titrated to pt's hourly glucose levels and 5% Albumin. Pt placed on EV-1000. Pt Residuals initially was 400ml and MD Altaman stated not to return, the next hour pt's residuals were 5ml, bothtimes were pink in color with coffee ground like substance.*

## Results

- "Most realistic SIM"
- Other staff thought this was a real patient
  - Chaplain visited
  - Social worker asked about the patient
  - Nursing assistant stocked cart
- Enhanced Learning Experience
  - Compressed timeline
  - "learned more in 2 days in SIM than in 2 days caring for real BICU patients"
  - On the unit: all equipment and personnel were real
  - Discussion of using SIM scenarios for clinical training

## Conclusion

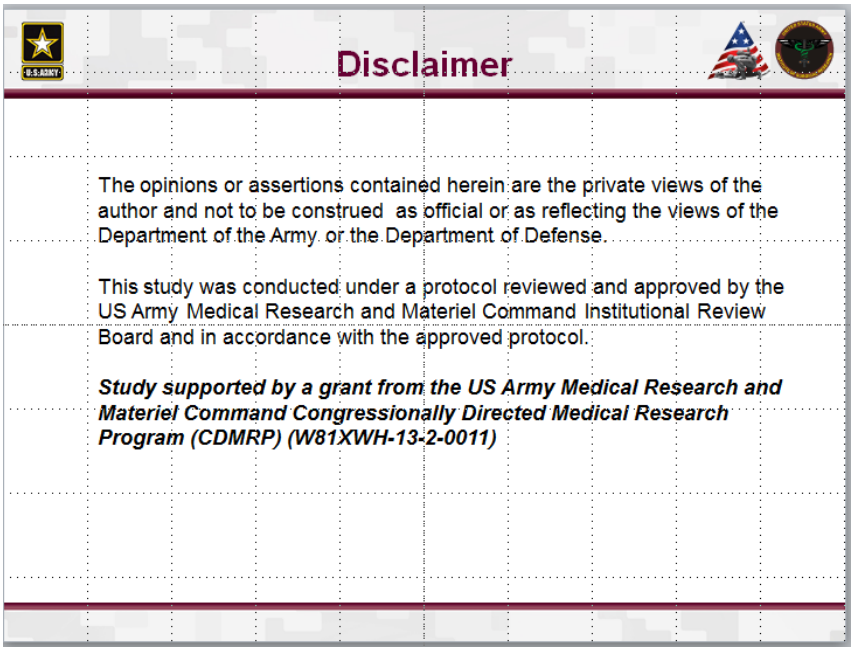
- Simulation taking place in the real work environment provides more fidelity that the lab cannot match
- No real patients were at risk during the SIM proving that conducting research on an active patient unit is feasible for future studies

## Acknowledgements


- The 6 participants who graciously agreed to be participants in our study.
- Burn Center clinical leadership team
- Brooke Army Medical Center Residency directors
- Burn Center clinicians and ancillary staff
- Brooke Army Medical Center Simulation Center
- USAISR Information Management Division
- Ms. Nicole Caldwell, Research coordinator

## Guidance

**Appendix N.** Presentation. Getting the Message: Health IT Can Improve Team Communication. *Southern Region Burn Conference.* Atlanta.



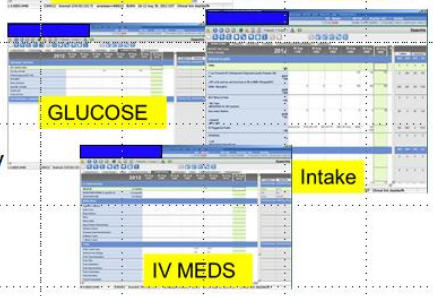
## Background

**Multi-disciplinary Care Team**

Care teams rely on awareness of, and communication about, patient condition

## Background

- Un-prioritized electronic medical record (EMR) data masks what clinicians need to know
- Previous studies have estimated that each patient in the ICU generates 1,300 to over 12,000 data points per day




*Lérou, Dirksen et al. 1988; Gaba 1990; Block 1991; Manor-Shulman, Bevene et al. 2008*

## Background

- Multidisciplinary teams who make time-sensitive decisions need:
  - Real-time communication
  - Well designed displays
- Instead, this is what we must use

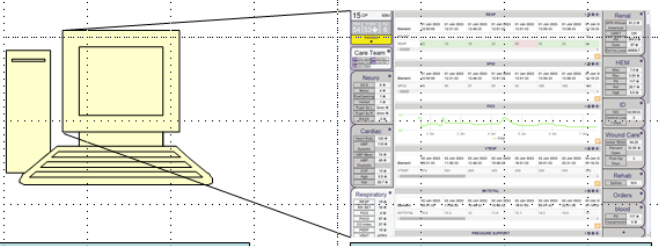
## Click to add title

- Click to add text

**Clinicians and patients deserve better!!!!**

## Cooperative Communication System (CCS)

- We developed a novel, real-time, health information technology (IT) prototype that supports BICU individual and team clinical decision-making and communication
- CCS lays over the EMR and provides information matched to clinical mental models and work practices

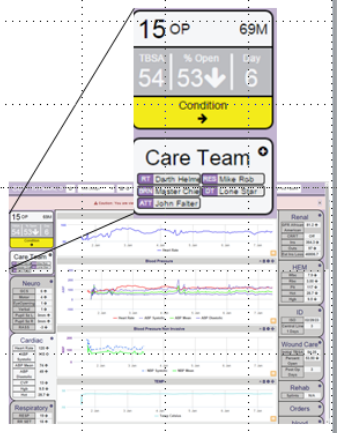


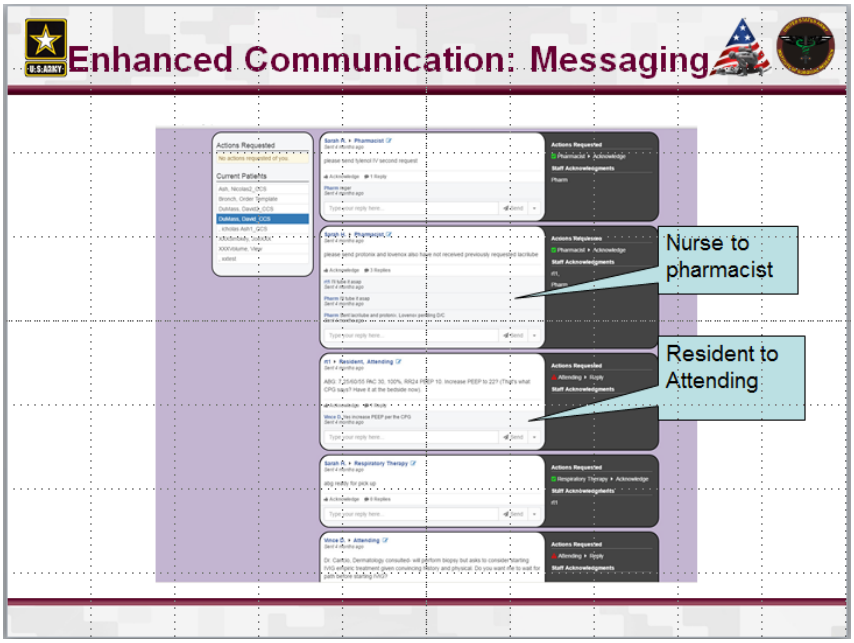
Legacy Health System/ EMR

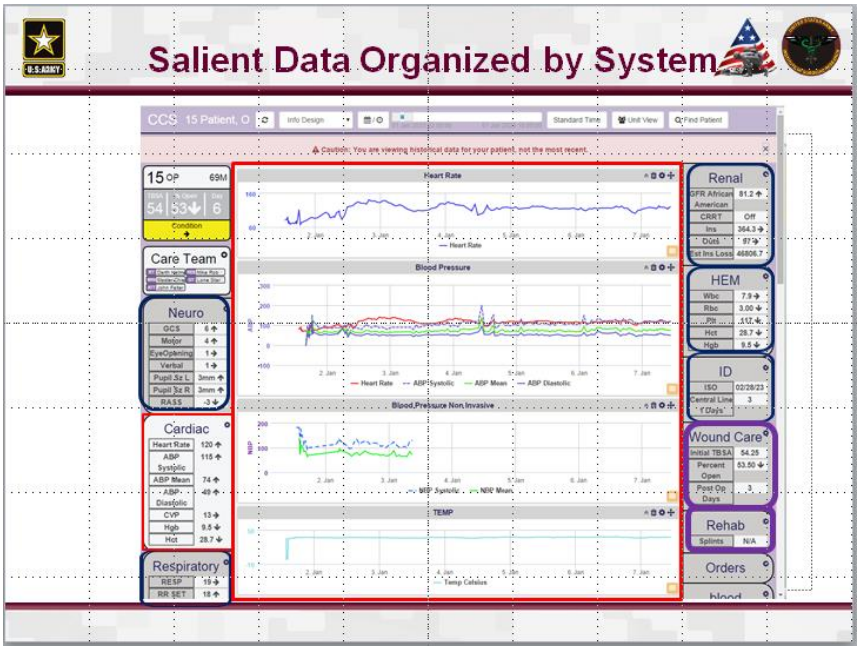
Cooperative Communication System (CCS)

## Cooperative Communication System

- **3 Main Features of the System**
  - **Enhanced communication**
    - Team Assignments
    - Team Messaging
    - Messaging to other services (Lab, Radiology, etc.)
  - **Organization of salient data**
    - Data are organized by system
    - Displays are customizable
    - Includes X-rays and images
  - **Clinical Decision Support**
    - Patients are cohorted by condition
    - Condition and trajectory are displayed

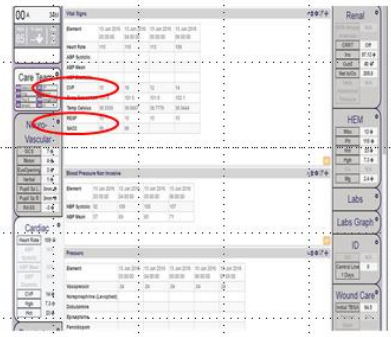



Enhanced Communication: Messaging
Nurse to pharmacist
Resident to Attending

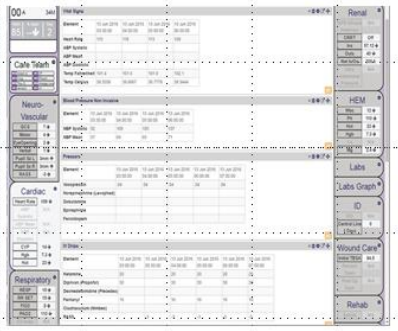

Salient Data Organized by System
Heart Rate
Blood Pressure
Blood.Pressure Non.Invasive
TEMP
Renal
HEM
ID
Wound Care
Rehab
Orders
Care Team
Neuro
Cardiac
Respiratory

# Customizable Displays

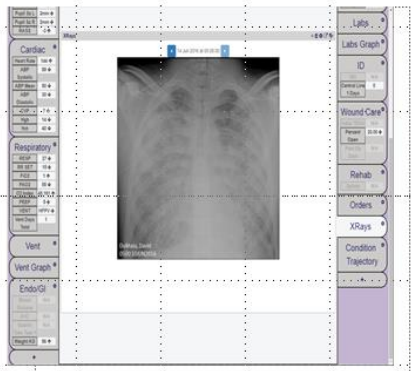
Bedside Nurse 1

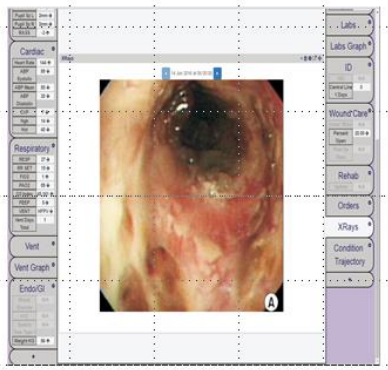


Bedside Nurse 2



# X-rays and Images

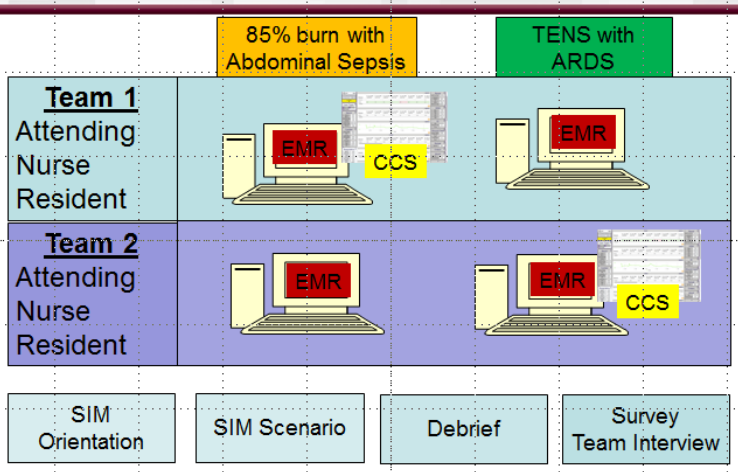




## Methods

- We evaluated the CCS in a simulation room on the Burn ICU to determine how well it supported clinical teams

## Methods: Study Design



# Methods

Survey

| Please circle the number that best reflects your response. | Very Poor | Poor Average | Average | Above Average | Excellent |
|---|---|---|---|---|---|
| I could find the information I needed in the system | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The system was easy to use to make decisions | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Identifying important trends in patient condition was easy using this system | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| I could communicate effectively with other clinicians using this system | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Communication with other clinicians was easy using this system | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| I am confident in my decisions/recommendations using this system | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The scenario was realistic | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **Please circle the number that best reflects your response.** | Very Poor | Poor Average | Average | Above Average | Excellent |
| How would you rate the team's overall performance? | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| How would you rate the team's communication? | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

# Quantitative Results

- Using the CCS in the burn sepsis scenario
  - Resident performed at the same level as another resident with 4 more years experience
  - He explored multiple diagnoses rather than targeting one
- Using the CCS in the TENS/ARDS scenario, Team 1 identified need for a rotoprone bed an hour before Team 2 who used Legacy system alone

## Survey Data: Using the CCS

- Participants reported better ability to find information, make decisions, and identify trends
- CCS was better at allowing individuals to communicate more effectively ($p<0.02$) and communication was easier (0.001)
- Subjects perceived no difference in scenario realism, overall team performance and team communication between the legacy EMR and the CCS

## Qualitative Results: After action interview data

- Nurses (n=2) used IT mostly for data entry, not decision making
  - CCS Lab views "very easy"- could get information quicker
- Residents (n=2) reported the CCS allowed quicker access to imaging, labs and vital sign trends
- Attending physicians (n=2) reported they rarely use IT for decision making:
  - Used CCS to confirm information from verbal reports
  - Grouping of data by organ systems from disparate locations in the medical record appreciated

## Qualitative Results

- Messaging system
  - Effective for non-urgent issues and simple, routine tasks
  - Convenient, did not have to wait on the phone
  - Helped communicate with ancillary services (e.g. pharmacy)
  - Group messaging seen as a benefit
  - Used more in the beginning of scenario and fell off as patient's condition worsened
  - Not appropriate to use for urgent situations

## Conclusion

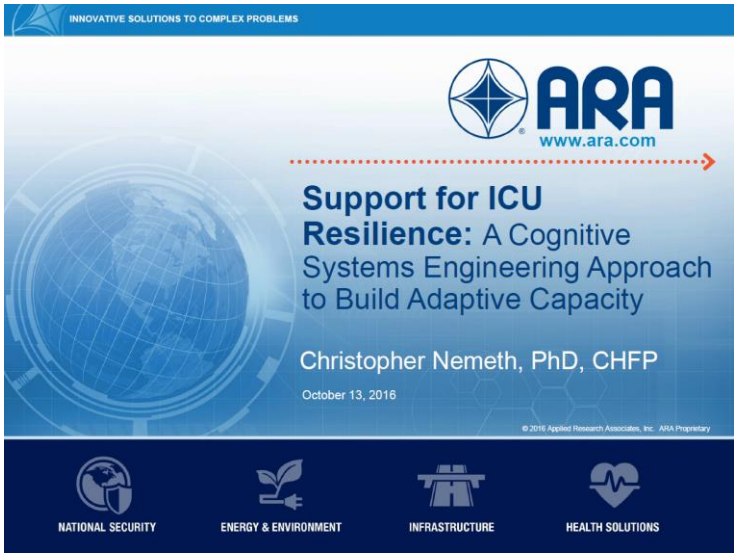
- The team using the CCS arrived at a correct decision sooner.
- CCS helped a novice make decisions at the same time as a more experienced resident
- The integration of messaging made it easier to initiate, share and track information among team members.
- The CCS improved their team's ability to find and use salient information.
- Clinicians do not need IT solutions to assist them when the patient's medical condition becomes unstable.
- Ongoing work: Pursuing transition to development through Defense Health Affairs.

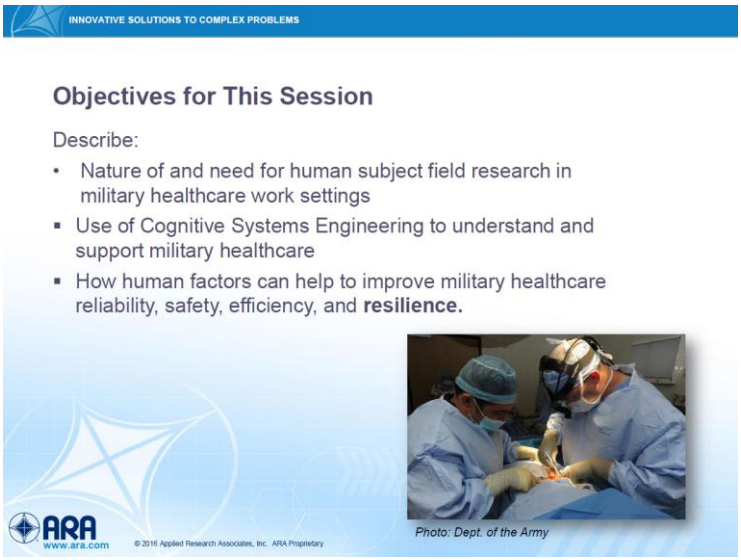
## Acknowledgements


- The 6 participants who graciously agreed to be participants in our study.
- Burn Center clinical leadership team
- Brooke Army Medical Center Residency directors
- Burn Center clinicians and ancillary staff
- Brooke Army Medical Center Simulation Center
- USAISR Information Management Division
- Ms. Nicole Caldwell, Research coordinator

Thank you

**Appendix O**. Support for ICU Resilience: A Cognitive Systems Approach (CSE) Approach to Build Adaptive Capacity. Resilience Healthcare Learning Network Teleconference. 13 October 2016. *(Invited speaker: oral presentation)* and Support for ICU Resilience: A Cognitive Systems Approach (CSE) Approach to Build Adaptive Capacity. Resilience Healthcare Learning Network Teleconference. IEEE SMC International Symposium. Budapest, October 2016. *(oral presentation)*



## Research Site

- Burn ICU in tertiary care medical center,
- 16 beds, 2 reserved to serve as a post-anesthesia care unit (PACU), 1 dedicated to support Extracorporeal Membrane Oxygenation (ECMO).
- Other nearby units support the ICU, including a step down unit, burn operating room, and outpatient clinic.
- Population averages around 8 patients but as high as 13
- Patients have severe affliction from chemical, mechanical or electrical burns, or burn-like afflictions such as toxic epidermal necrolysis (TENS).
- Length of stay ranges from days to months.

*Photo: Dept. of the Army*

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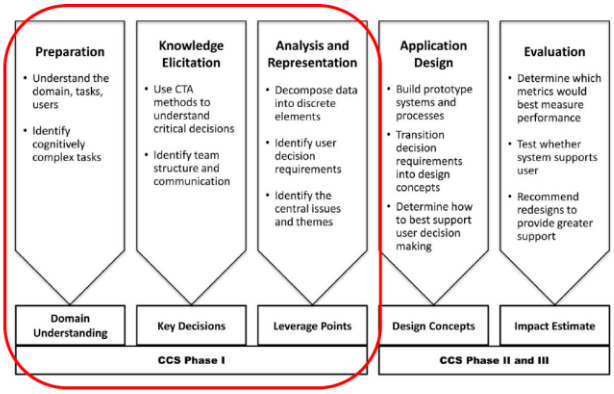
## Cognitive Systems Engineering Phase 1

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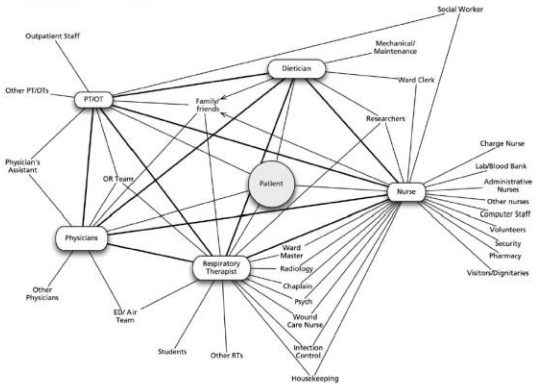
## BICU Patient Team

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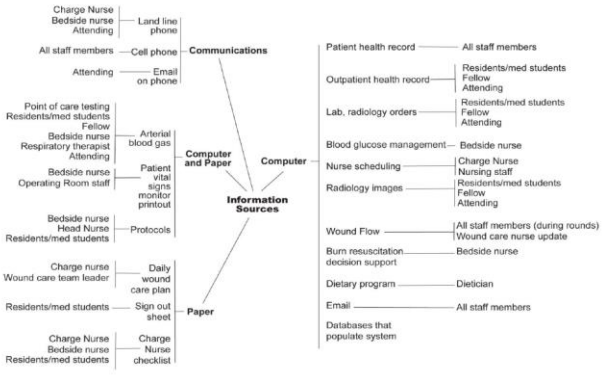
## BICU Information Sources





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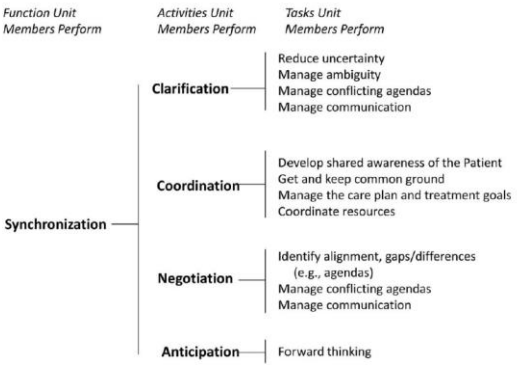
## BICU Cognitive Model





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## Barriers to Effective, Efficient Patient Care

- No effective means to synchronize aspects of patient care.
- Lack of awareness of activities/events that are tightly coupled.
- No efficient way to communicate changes in patient status across disciplines.
- Updated information (e.g., cultures) is available but not accessible/visible.
- Orders are often late, missing, or overtaken/replaced by other orders.
- Reliance on verbal orders; no standardized way to share them.
- Lack of coordination between shifts.
- Documentation requires significant time from key members clinical team,
  - *IT issues and work process requirements frequently require redundant and/or repeated information capture and data entry.*
  - *Compounds cognitive workload, attention management issues for staff.*
- Trend was data identified as important; unavailable from [legacy EMR] or other IT.
- Tracking patient indicators over time > 24 hours difficult.
- Cognitive workload: clinicians must mentally integrate data.


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INNOVATIVE SOLUTIONS TO COMPLEX PROBLEMS

## Barriers to Effective, Efficient Patient Care (cont'd)

- Delayed information updates means system information is sometimes stale/inaccurate.
- Knowledge of resource availability: who is on unit (e.g., clinical team members, consults)?
- Coordination between BICU and OR:
  - *Don't know if patient is ready for procedure.*
  - *Don't know enough about procedure to prepare effectively.*
- Rounds checklist not readily available/accessible to all clinical team members.
- Dropped tasks, gaps, and lapses not tracked; impact not known.
- Responsibility for management/completion of checklist items is unclear.
- Substantial staff time spent tracking down in-process items (meds, labs).
- Reliance on nurses to track and fix information gaps.
- Resources and needs are poorly matched.
- Errors (e.g., wrong orders) require the unit members to correct, redirect, back-up, clarify.


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## Barrier

*No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*

## Requirement

*System shall provide access to a plan of patient care, visible to all care givers responsible for that patient that includes:*

- *Current patient status and top-level assessment*
- *Goals and priorities for those goals*
- *Changes/updates, such as indication that plan is being updated when one caregiver is working on it*
- *Schedule of activities and any changes, timeline*
- *Orders and their status*
- *Identity and contact information for patient's care team*


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## Use Case

*"At 0630, a bedside nurse has started his preparation for the day **shift** by reviewing information on the patient he is responsible for. Opening CCS, he can see a **roster of patients on the unit**, chooses his patient's **"at-a-glance" view** that shows **recent vital signs, current orders, medications, care plan,** and **notes from the night shift**. He checks the patient's standing **care plan** and **treatment goals** (from the electronic healthcare record), and **reviews orders** (from the laboratory test database) that are pending as well as the day's **care activities that the Wound Care team, Respiratory Therapists, and Physical Therapists** have recommended and **what times** they can perform them…"*


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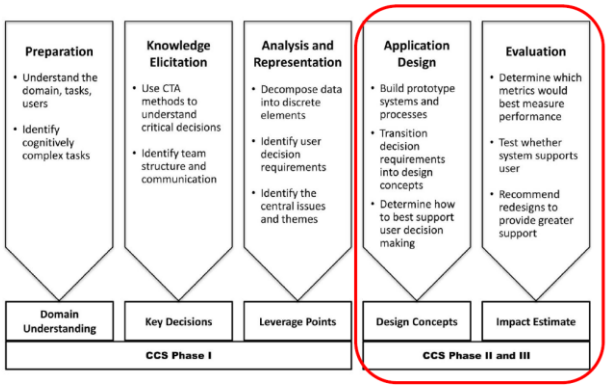
## **Cognitive Systems Engineering** Phases Two, Three

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## **Prototypes** Information Design

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## **Prototype** Key Features

**Patient Identifier** Graphic element that includes patient number, total burn surface area at admission, an indicator of illness severity and progress based on key trends.

**Unit View** Organized as a BICU floor plan, the view includes an identifier for each patient, status of planned tasks, and facilitates resource allocation and prioritization, care planning and coordination.

**Patient View** Critical data are shown for an individual patient, organized by system from cardiac and neurological to wound care and infectious disease using a "parent-child" tab/window format.

**Messaging** Real time message correspondence among care team members supports the development and maintenance of common ground regarding their patient's history, status, prognosis, and care plan

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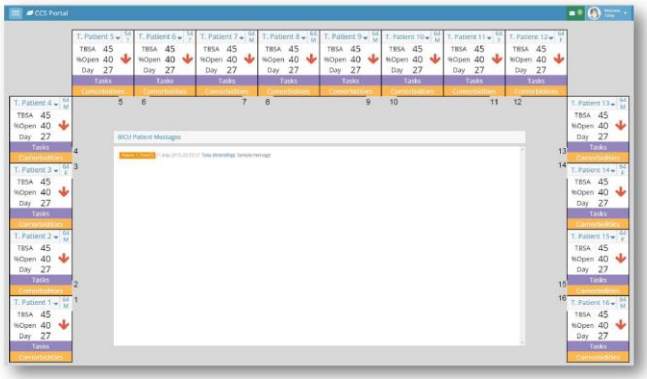
## **Prototype** Software



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## **Prototype** Software

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## **Usability Assessment** November 2015

- 20 BICU nurses used novel IT system to perform decision making tasks
- Two typical scenarios: new admission, preparation for surgery
- Rated ease of use for each task

- Later: asked one experienced BICU nurse to perform same tasks using legacy system, for comparison

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## **Usability Assessment** November 2015

| ***Scenario and Task*** | ***Legacy*** | ***Novel*** |
|---|---|---|
| *Scenario 1- Preparation for Surgery* | | |
| 1--Is the patient's hemodynamic status getting worse? | 2:44 | 2:10 |
| 2--Is the patient's pulmonary status getting worse? | 6:35 | 1:09 |
| 3--Is the patient's volume status getting worse? | 4:15 | 1:48 |
| *Scenario 2-New Admission* | | |
| 1--Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same? | 3:25 | 1:27 |
| 2--Based on his glucose levels, do you recommend that he be started on an insulin drip? | 0:53 | 0:25 |
| 3--Based on the patient's lab values, do you think he should be started on CRRT? | 2:45 | 1:04 |
| | n=1 | n=20 (median) |


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## **Validation Assessment** June 2016

- Two 3-member teams: Resident, attending, bedside nurse
- Two scenarios: Sepsis, Acute Respiratory Distress Syndrome (ARDS)
- Legacy and novel IT systems, counterbalanced
- Performed on BICU, by BICU staff
- Three observers, video recording

| Team | Day 0 | Day 1 | Day 2 |
|---|---|---|---|
| 1 | Orientation | Sepsis Scenario<br>Legacy IT System | ARDS Scenario<br>Novel IT System |
| 2 | Orientation | ARDS Scenario<br>Novel IT System | Sepsis Scenario<br>Legacy IT System |

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## **Validation Assessment** Sepsis

Using novel system, new resident arrives at correct diagnosis at same time as resident who has four more years of experience

**Validation Assessment** Sepsis Scenario Key Decision Points

| **Team One** / Legacy IT | **Team Two** / Novel IT |
|---|---|
| 06:57 Start | 06:45 Start |
| | 08:53 Deep vein thrombosis is common on a long flight |
| | 09:20 Res- I'm looking at Abdominal compartment syndrome |
| | 09:22 R Ruling out pulmonary Embolism |
| | 09:31 R Look for signs of sepsis |
| 09:51 Res>Attend- Brief. Patient infection | |
| **10:41 Res- Abdominal compartment syndrome due to sepsis, unknown source** | **10:43 Res- Suspect sepsis** |
| | **10:45 Res- Perceives septic** |
| | **10:47 Res- Perforated bowel** |
| 10:55 Attend- Ask source of sepsis | |
| | 12:13 Res- Abdominal compartment syndrome |
| | 12:16 Res- May need exploratory laparotomy |

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## **Validation Assessment** ARDS

Using the novel system, the resident decided on use of a rotoprone bed almost two hours before team using legacy system.

**Validation Assessment** ARDS Key Decision Points

| **Team One** / Novel IT | **Team Two** / Legacy IT |
|---|---|
| 06:45 Start | 06:45 Start |
| | 7:48 Res- Suspect antibiotics source of TENS |
| | 8:02 Attend- Let ECMO team know |
| 08:31 R Need to know from derm re: TENS | |
| 08:40 A Not likely TENS | 08:45 Attend- Paralyze him. Have OR ready. |
| | 08:54 Res- Staph infection |
| | 09:16 Res- May be slowly heading to ECMO |
| **09:55 Res- Consider prone. Looking at different courses of action** | 09:51 Attend- If he gets worse we're going to code him |
| 10:39 Res>Attend- Page about ECMO | |
| 11:18 Attend- I'd put him on ECMO now | |
| | **11:52 Res @ done everything to treat him – very critical –..Attend- (D) no ECMO – rotoprone only** |

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## Resilience

Use of CSE in this example can contribute to resilient performance.

- ***Being self-aware***--Disconnection among specialties is aggravated by disconnected information sources.
- ***Able to identify and apply resources***--Scheduling is currently done using hard copy forms and in-person negotiation, which makes it difficult to develop and maintain an optimal plan.
- ***Able to adapt to surprise***--Use of CSE makes understanding what goes right, and what occasionally does not, a routine learning process that can improve the ability to adapt.

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Your comments and correspondence are welcome.

Christopher Nemeth, PhD
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**Appendix P.** Poster: Evidence of Decision and Communications Support for Burn ICU Clinicians MHSRS Conference: August 2016.

# Evidence of Decision and Communications Support for Burn ICU Clinicians


Christopher Nemeth, PhD[1], Dawn Laufersweiler[1], Christopher Argenta[1], Josh Blomberg[1], Tony Hamilton[1], Maria Serio-Melvin, MSN[2], Sarah Murray, MSN[2], Craig Fenrich[2], Jose Salinas, PhD[2], Jeremy Pamplin, MD[2,3]

1. Applied Research Associates, Inc.; 2. United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX; 3. Uniformed Services University of the Health Sciences, Bethesda, MD


## Introduction

The Cooperative Communication System (CCS) project has developed an ecologically valid decision and communications support IT prototype with machine learning abilities for a military burn intensive care unit (BICU). We have used a mixed methods Cognitive Systems Engineering (CSE) approach to develop a descriptive model of BICU cognitive work, which has served as the basis for system requirements, use cases, information designs, and a software prototype. Clinicians can tailor the interface, which assembles salient patient data according to tabs organized by body system that reveal detailed displays including tables and graphs. We report results of usability (individual) assessment and validation (team) assessment to determine how well the CCS supports individual cognitive work.

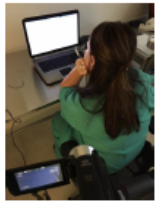
## Aim/Objective

To improve care by supporting clinical decision-making through the design and development of valid computer-based decision support and communication tools.

## Methods

**Usability Assessment**. After a 3 minute orientation to use the CCS, we asked 42 BICU clinicians (12 physicians, 20 nurses, and 10 respiratory technicians) to complete two scenarios (preparing for surgery, new admission) that lasted 15-20 minutes apiece. Each individual was presented with a narrative, then asked a series of questions that required him/her to use the CCS to find the necessary medical information to make clinical decisions. Each was asked to think aloud to indicate their front-of-mind awareness of their cognitive work.

**Validation Assessment**. Two teams performed in two 4-6 hour scenarios (sepsis, ARDS) on a high fidelity manikin. Teams used a legacy IT system on one scenario, and CCS decision and communication support on the other. Teams received a 15-minute orientation on using the CCS. We used multiple observer notes, system order entry files, and after action reviews to document team performance.



An experienced BICU nurse performed 6 clinically relevant tasks using the legacy IT system. Twenty BICU nurses used the CCS to perform the same tasks. The table at right shows time to complete each task using each system.

**Usability Assessment** Individual Decision Making

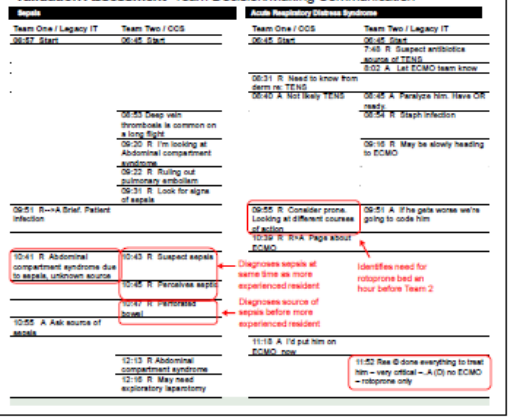
*Legacy and CCS system comparison by time to complete six tasks.*

| Scenario and Task | Legacy | CCS | CCS % faster |
|---|---|---|---|
| Scenario 1- Preparation for Surgery | | | |
| 1--Is the patient's hemodynamic status getting worse? | 2:44 | 2:10 | 20 |
| 2--Is the patient's pulmonary status getting worse? | 6:35 | 1:09 | 82 |
| 3--Is the patient's volume status getting worse? | 4:15 | 1:48 | 67 |
| Scenario 2-New Admission | | | |
| 1--Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same? | 3:25 | 1:27 | 68 |
| 2--Based on his glucose levels, do you recommend that he be started on an insulin drip? | 0:53 | 0:25 | 67 |
| 3--Based on the patient's lab values, do you think he should be started on CRRT? | 2:45 | 1:04 | 61 |
| | n=1 | n=20, median | |

The table at right shows the times that each team reached key decision points during the two scenarios. The team using the CCS arrived at a correct decision sooner than the team using the legacy IT system.

The CCS Patient View organizes data by body systems.

**Validation Assessment** Team Decision/Making Communication




## Results

**Usability Assessment**. The table above compared decision time to complete task using the legacy IT system or the CCS. Nurses using CCS were consistently more efficient. In 5 out of 6 tasks they were over twice as fast using the CCS. We asked subjects to evaluate the CCS along 5 dimensions, with the following percent positive response:

- can find needed information more quickly (65.9%),
- can find needed information more easily (65.9%),
- easier to use (66%),
- feel more confident making future clinical decisions / recommendations (58.5%),
- supports the way I do my work better (63.4%).

Over 80% of participants responded that the CCS would be easily adopted in their work setting from physicians (83%), to nurses (85%), and respiratory therapists (90%). Physician participants (83%) found the layout/look & feel/navigation particularly useful.

**Validation Assessment**. Using the CCS in the sepsis scenario, Team 2 performed at the same level as another resident with four more years of experience. Using the CCS in the ARDS scenario, Team 1 arrived at the choice to treat the TENS patient by using a rotaprone bed an hour before Team 2.

## Discussion

Usability assessment results show participants were able to correctly perform clinical tasks more than 50% faster than the legacy IT system. Also, a majority of the 42 clinicians who participated rated the CCS system as good as, or better than, the legacy EMR they have used for years. The validation assessment case studies suggest the CCS enables clinicians to find and use patient data more efficiently, resulting in better care sooner. Participants' ability to reach decisions significantly faster using the CCS suggests that the information design successfully reflects actual clinical cognitive work and work processes.

## Conclusion

More efficient, reliable collaboration among members of the ICU staff who use the CCS is expected to improve patient safety and patient outcomes.

Clinical staff ability to find and use information faster using the CCS and their preference for the CCS over the existing EMR demonstrates the project's CSE methodology has produced a decision support tool that clinicians find inherently useful. The CCS is expected to improve the clinical decision making, accuracy, speed, and efficiency, which will be measurable in terms of increased patient contact time for clinicians, reduced incidence of medical misadventures, reduced time until discharge, and improved patient outcomes.

## References


1. Nemeth, C., Blomberg, J., Argenta, C., Serio-Melvin, M., Salinas, J. & Pamplin, J. Revealing ICU Cognitive Work Using NDM Methods. Special Issue on Expanding Naturalistic Decision Making. *Journal of Cognitive Engineering and Decision Making*. Human Factors and Ergonomics Society. (*in press*).
2. Nemeth, C., Hamilton, A., Laufersweiler, D., Serio-Melvin, M., Blomberg, J, Murray, S. & Pamplin, J. (2016, October ). Evidence of Usability: *Evaluation of Burn ICU Clinician Decision Support*. *Proceedings of the IEEE Systems, Man and Cybernetics International Symposium*. Budapest. (accepted)
3. Nemeth, C., Anders, S., Strouse, R., Grome, A., Crandall, B., Pamplin, J., Salinas, J., Mann-Salinas, E. (2016) Developing a Cognitive and Communications Tool for Burn ICU Clinicians. *Military Medicine*. Association of Military Surgeons of the United States (AMSUS).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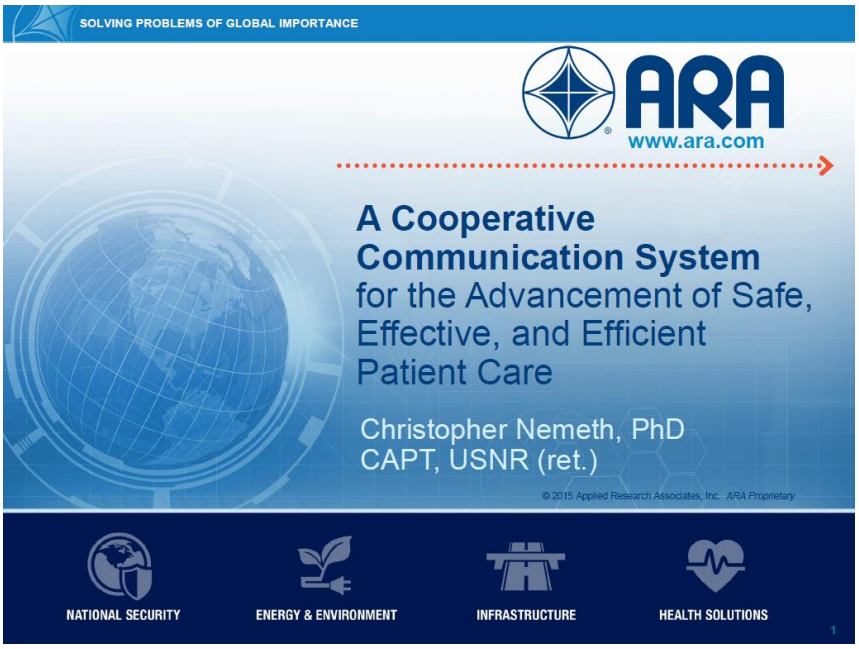
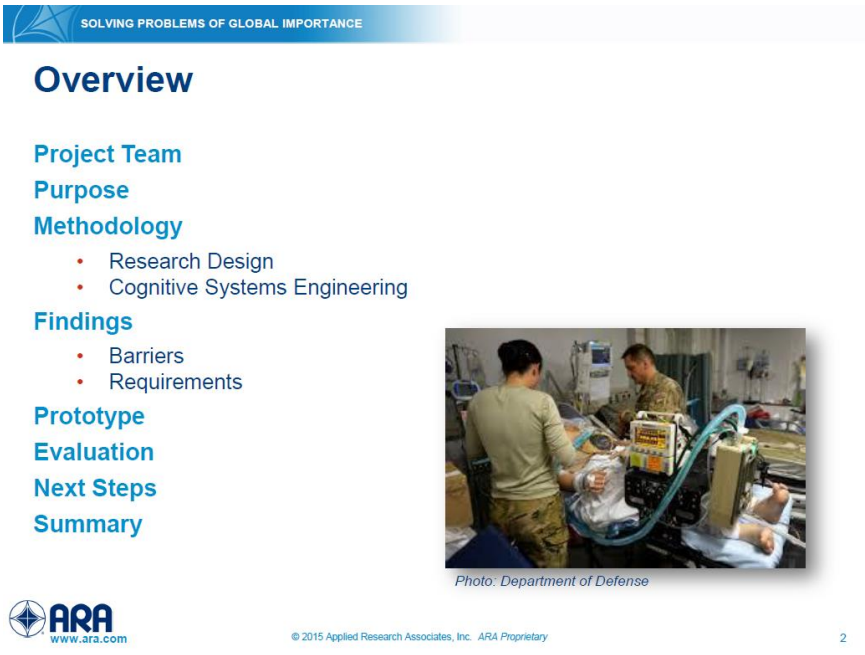
We offer thanks to Greg Rule, PE and Nicole Caldwell, RN for their help with this project, which is supported by a grant from the US Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (CDMRP) (W81XWH-13-2-0011).


*The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense. This study was conducted under a protocol reviewed and approved by the US Army Medical Research and Materiel Command Institutional Review board and in accordance with approved protocol.*

**Appendix Q.** Presentation. Army Institute of Surgical Research Scientific Symposium. Brook Army Medical Center. Joint Base Sam Houston, 6 January 2016.



# Project Team

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Charlie Fisher
Kyle Foley
Bill Parquet


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# Purpose

**Hypothesis:** The CCS support for BICU will improve clinician decision making and communication by making patient care more efficient, effective, and less prone to adverse outcomes and misadventures.

**Aims**: Clinical decision and communication support tool that provides:

- Improved clinician decision making, through presentation of salient patient data, and machine learning and communication support
- More efficient, reliable individual and team cognitive work resulting in improved patient outcomes (e.g., reduced length of stay)


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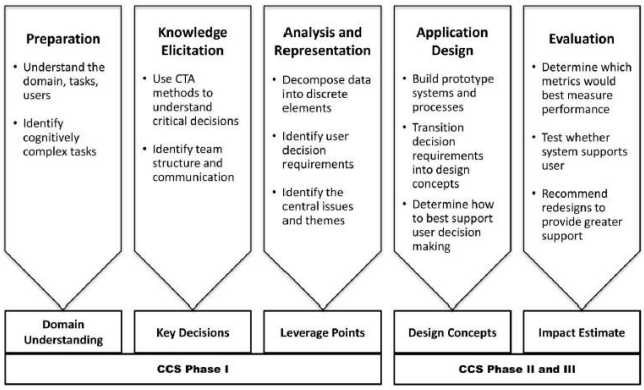
# **Methodology** Cognitive Systems Engineering





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# **Methodology** Research Design

## Year One

- *Literature Review*
- *Observation:* Five week-long visits to the BICU
- *Structured Interviews*: Typically 15-20 per visit
- *Artifact Analysis:* Collection, de-identification, and analysis of information sources
- *Thematic Analysis*: Detection of patterns among and across data elements
- *Participatory design:* Collaboration among ARA and AISR team members to create interface concepts complementary to BICU work practice and culture


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# **Methodology** Research Design

## Year Two

- *Validation interviews:* Review of representations with clinicians to confirm, adjust, and enrich findings (Iterative development)
- *Survey*: Research nurse data collection to answer focused questions, such as requirements priorities
- *Rapid prototyping*: Development of interface design based on Year One data
- *Agile prototyping*: Initial software development, including initial machine learning concepts (e.g., similar patients)


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# **Methodology** Research Design

## Year Three

- *Agile Prototyping*: Comprehensive software development, including machine learning (e.g., similar patients, trends)
- *Usability Assessment*: Determination of CCS suitability for individual decision making, compared with current IT
- *Validation Assessment*: Determination of CCS suitability for team decision making, compared with current IT


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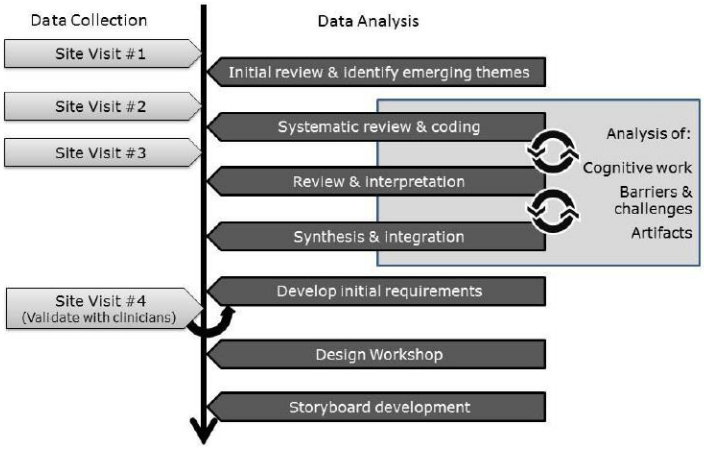
# Data Collection, Analysis





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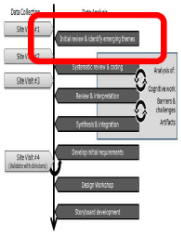
# Review, Emergent Themes



| Example Data Excerpts | Theme |
|---|---|
| *Surgeon and resident talk among themselves, and residents sometimes put in critical orders (e.g. blood). As a nurse I don't know this until I log in and see the note (bedside nurse)* | Information discontinuity |
| *When the Attending changes from week to week, you may find plans reversed from week to week. You end up with a yo-yo effect in the care that is frustrating…. (intensivist)* | |
| *It is a little tricky to align my goals with staff, which may vary from staff to staff (intensivist)* | Negotiation |
| *We have 6 or 8 people working on the problem in their lane. Give it a little time to simmer and then we all come together and sort of talk about it. (Head nurse)* | |
| *A lot of times with physician orders, there can be multiple consultants, plus attendings that make orders that are contraindicated. If that occurs I will bring it up to the fellow… (LVN)* | |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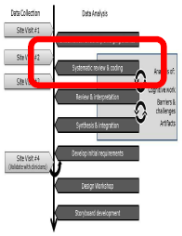
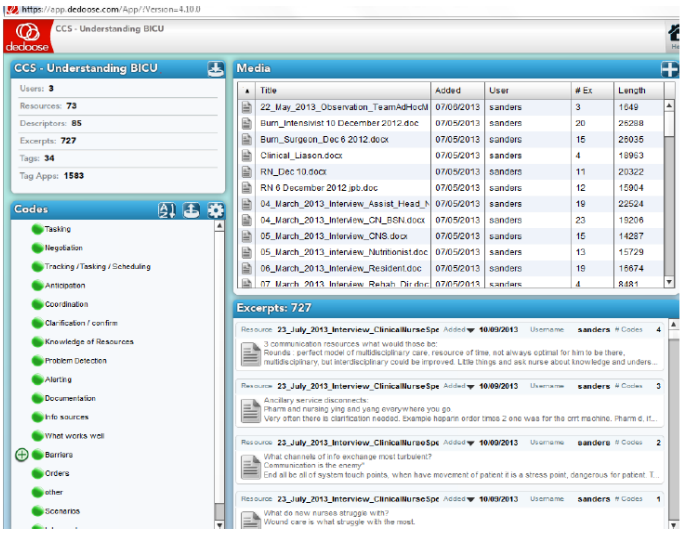
# **Analysis** Systematic Review and Coding







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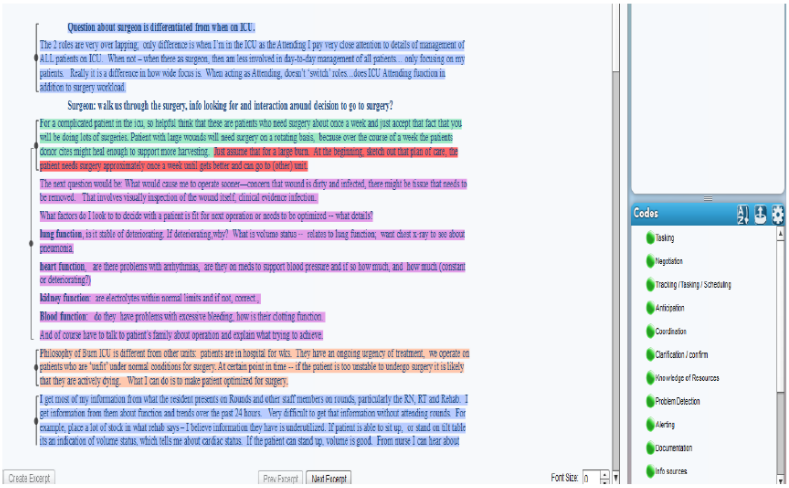
## *Example of a data record in Dedoose*





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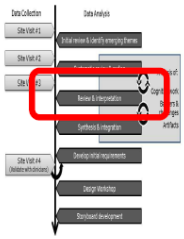
# **Analysis** Review and Interpretation



**Category: Procedural Drag**

**Title: 22_July_2013_Interview_OR-RN.docx**

Additionally, sometimes blood is not ordered early enough, and if we know there is going to be lots of bleeding, then we will sometimes wait and delay the case. In one particular situation, the blood was not in the OR, the anesthesiologist had the patient ready, but the decision was made to wait, to do any incision and grafting. The blood bank was not as quick as we wanted them to be. Usually the anesthesiologist orders blood in Essentris. If the patient in 4east or icu we may need to note. I assume that the majority of our patients are likely to need blood. I will ask about blood when I check in Essentris in the morning and it is not ordered. The anes tech or an OR runner will go get blood in cooler then put it in a fridge in the OR.

**Title: 21May_2013_Nurse_Burn_interview_transcript.doc**

sometimes the on call just doesn't see the importance. Maybe they just want to go through it real quick , but they are very busy and I understand that ICU patients are sick, so often I think they overlook these people that are doing well, in their eyes and they just want to throw over to 4E, but what they really need to do is review all those orders. And I mean, this has been years. I say years, before my time of being hired that they were having issues with these on call residents. You know, where the orders aren't written right for the transfer so I'm going to block the transfer. I'm going to say call on call, hey; I need this, this and this order fixed. And then they came down on us like no, no you can't be blocking transfers you know, but then my orders are inappropriate.

**Title: 21May_2013_Nurse_Burn_interview_transcript.doc**

also what bothers me from pharmacy is doing that many medications in pixes. Something that we are always good at because it is not in stock in our pixes then why don't you send it the day before so that you can always have it in stock and ready to go. So I need to call you every day? And harass you every day for it? Or should you just

**What are the main takeaways?**

**What cognitive activities are the individuals/or team engaging in?**

**What challenges are they facing?**

**What's getting in the way of them doing their work?**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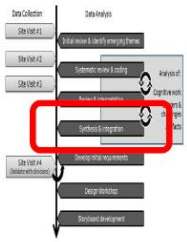
# Synthesis and Integration



**Alerting**

- Bringing issues of concern to one another's attention (i.e., alerting) facilitates team coordination and awareness of patient status.
- Means of alerting across the team depends on level of urgency. E.g. In urgent situations, members of team either bring an issue to someone's attention via F2F communication or via pager.
- Recognition of critical cues/red flags by members of the clinical team prompts alerting of attending. (and can be missed by those with limited experience)
- Physical presence of physicians in the ICU facilitates alerting.
- Lack of feedback/alert from others on team and across units prevents ability to anticipate and prepare. (e.g., neg: BICU requires heads-up from other units for patient transfers...when going to OR, etc.)

**Anticipation**

- Anticipating patient's trajectory, and pre-emptively intervening to head off problems and meet patient needs, is a key cognitive activity performed by clinicians. (needs to be supported by system we develop)
- Morning rounds are a central means for team members to foresee problems and plan treatment.
- Delayed orders obstruct nursing staff, RT, and OT/PT's ability to anticipate and coordinate treatment. (neg: need means to capture and disseminate orders close to real-time)
- Anticipating problems based on pt condition focuses clinician's attention/influences info they attend to. (Residents less able to do this due to limited expertise).
- Common process delays require staff to anticipate patient needs as early as possible so they can begin pushing things through the system.
- Staff use a set of cognitive aids to help them manage expectations and plan their work. (E.g., paper assignment board/charge nurse clip board - tell you who's taking care of what patients.)
- The BICU team anticipates and plans for high pt volume (and associated high workload/staffing needs) based on external factors (e.g., memorial day weekend has high injury potential)
- Experienced nurses and physicians anticipate novice errors (namely on the part of residents), and intervene pre-emptively to mitigate them.
- Requirements:
  - System needs to support clinician's ability to anticipate patient's trajectory and potential problems.
  - RNs need means to anticipate procedural activities and needs so they can prepare accordingly (otherwise, they don't get this information until surgeon walks into the OR).
  - Need better means to predict staffing needs
  - Need a means to get verbal orders into system at earliest point possible, and means to alert team to changes in orders.

**Tracking, Tasking, and Scheduling**

- Morning rounds are key activity used to develop team's tasking/treatment plans for the day.

**What is getting in the way of efficient, effective patient care and team coordination?**

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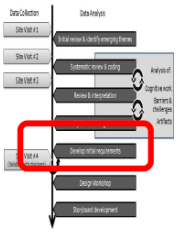
# Develop Initial Requirements



| Comprehensive Integrated View of Patient | | | |
|---|---|---|---|
| **Barrier** | **Needs** | **System Features** | **Impact** |
| **Reliance on clinician to integrate data** | Clinicians need a holistic/macro-view of the patient's trajectory (are they getting better or getting worse over last 24 hrs?) | System should provide trend data on key indicators (e.g., for each of the main bodily systems) | Reduced clinician time to locate data<br><br>Reduced clinician time to synthesize data<br><br>Reduced time to achieve consensus among clinicians |
| **Lack of interoperability among systems** | Minimize staff time spent as the 'system integrators' who move data from one system to another. (addressed in info management category) | System built on a Relational database that has all the info relevant to one patient, so that there is true interoperability: ability of separate systems to cross- populate data, in real time | Reduced clinician time spent entering, moving, repeating, reentering, data.<br><br>Increased time with patients; increased ability to attend to patient issues and needs<br><br>Decrease cognitive workload |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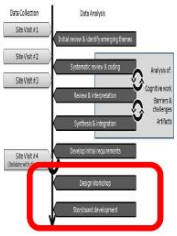
# Analysis to Representation



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# CSE Using Genotypes

***Phenotype**: Clinicians talk among each other, spend a good deal of time writing at terminals*
***Work-around***

***Genotype**:* *Disconnected databases*
***Source of brittleness***

***Barrier**:* *No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*
***Blocks synchronization***

***Requirement**:* *System shall provide access to a plan of patient care, visible to all care givers responsible for that patient*
***Source of resilience***

***Features**:*
*Current patient status and top-level assessment*
*Goals and goal priorities*
*Changes/updates, such as indication that plan is being updated when one caregiver is working on it*
*Schedule of activities and any changes, timeline*
*Orders and their status*
*Patient's care team identity and contact information*
***Facilitates synchronization***


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# Findings

## Descriptive Model of Cognitive Work

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
| **Synchronization** | **Clarification** | Reduce uncertainty<br>Manage ambiguity<br>Manage conflicting agendas<br>Manage communication |
| | **Coordination** | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | **Negotiation** | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | **Anticipation** | Forward thinking |


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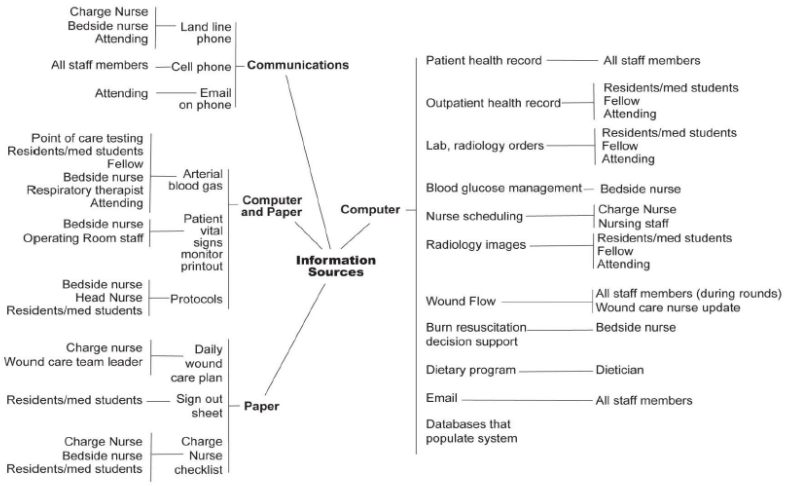
# Findings

## Information Sources





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# Findings

**Problem:** No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.

**Requirement:** System shall provide access to a plan of patient care, visible to all caregivers responsible for that patient that includes:

- Current patient status and top-level assessment;
- Goals and priorities for those goals;
- Changes/updates (e.g., indicating that plan is being updated when one caregiver is working on it);
- Schedule of activities and any changes, timeline;
- Orders and their status;
- Identity and contact information for patient's care team.


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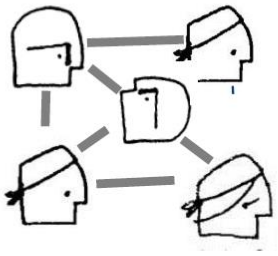
# CCS Elements



**Joint Cognitive System** includes patient, staff, care providers, family & information sources

**Machine learning finds relevant** patterns

**Interface Synthesizes, presents** salient data

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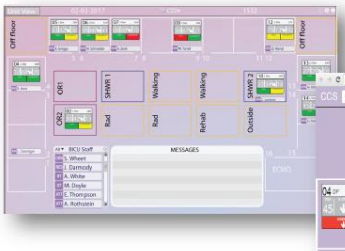
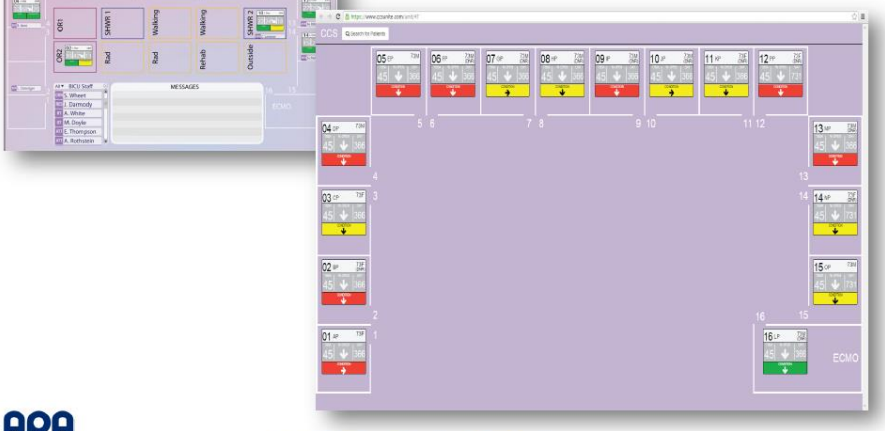
# **Prototype** Unit View

## Information Design



## Software

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# **Prototype** Patient View

## Information Design

## Software

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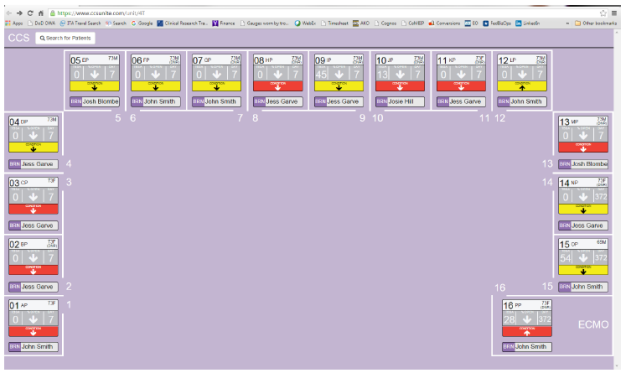
# Prototype



https://www.ccsunite.com/unit/4T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# Prototype

## Comparison with Essentris

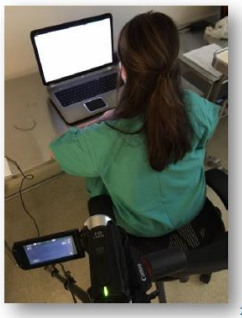
I can find the information I need in CCS **more quickly** than I can using Essentris.

I can find the information I need in CCS **more easily** than I can using Essentris

The CCS system is **easier to use** than Essentris

I would feel **more confident** making future clinical decisions and recommendation using CCS than using Essentris

CCS supports the **way I do my work** better than Essentris.

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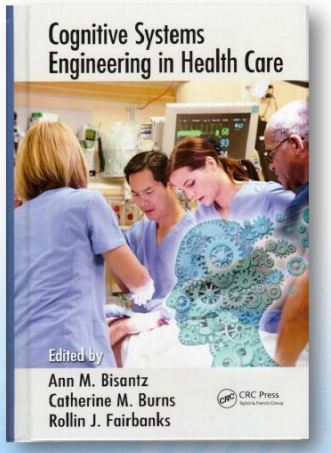
SOLVING PROBLEMS OF GLOBAL IMPORTANCE

# Publications

**Book chapter (1)**
**Journal paper (2)**
**Proceedings paper (2)**
**Abstract (8)**
**Report (1)**





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# Benefits

**Patient Safety.** Successful implementation of the CCS in the clinical environment has potential to reduce the incidence of medical misadventures.

**Patient care efficiency.** Safety and effectiveness of patient care can be increased by increasing the speed at which clinicians can make accurate clinical decisions.

**Patient care intensity.** Clinicians provided more direct interaction time with patients, by reducing the time burden to find, use needed information.

**Broad applicability.** Can provide the same real time decision support in clinical settings other than military facilities.


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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

# Next Steps

**Propose bridging project: TRL5 to TRL8**

**Conduct validation assessment**

**Complete prototype**

**Write final report**

*Photo: Department of Defense*


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## Summary

**Research**: Cognitive Systems Engineering methods successfully enabled the team to create an ecologically valid decision making and communication support IT system. JPC-1, TATRC, CDMRP, and USAISR support for publishing was a great help getting word to the professional community.

**Development**: Coordination with USAISR to map data elements from the Essentris healthcare record posed a challenge that the team needed to manage constantly through Year Two into Year Three.

**Administrative**: Institutional Review Board and Defense Health Information Technology security regulations posed challenges throughout the project.

**Transition**: Iterative development through the integration of end users to establish early buy-in is critical for successful implementation.


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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

## Your questions and comments are welcome

Christopher Nemeth
cnemeth@ara.com

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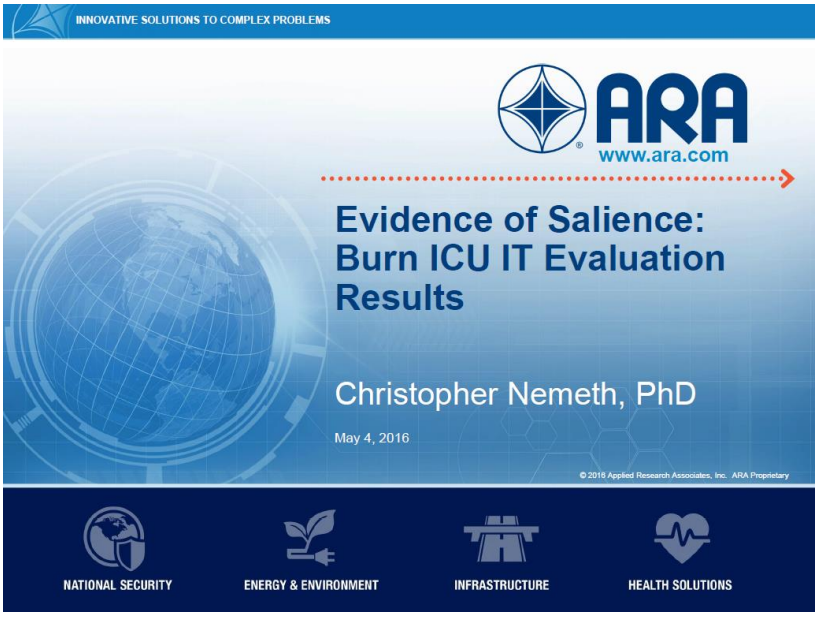
**Appendix R.** Evidence of Salience: Burn ICU IT Evaluation Results. HFES Healthcare Symposium. Human Factors and Ergonomics Society. 14 Apr, 2016. San Diego.



Objective

Research Design

Methods

Results

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## Objective

Improve tertiary hospital Burn Intensive Care Unit patient care through a real-time decision support and communications system.

*Photo: Department of Defense*

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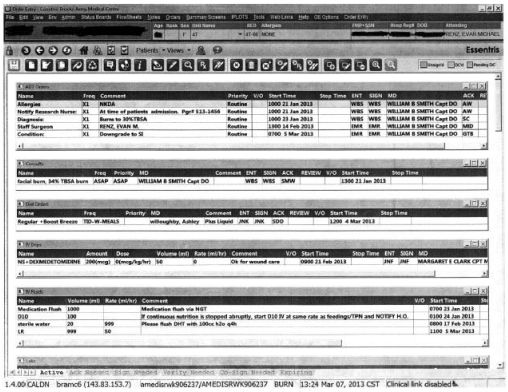
## Current EMR



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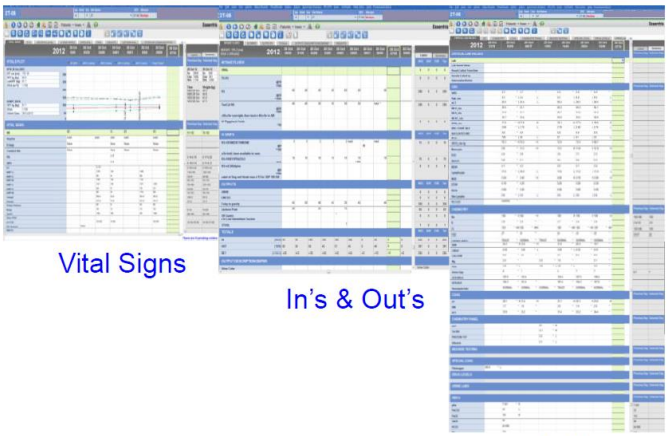
## Simple patient status check requires 8 separate screens

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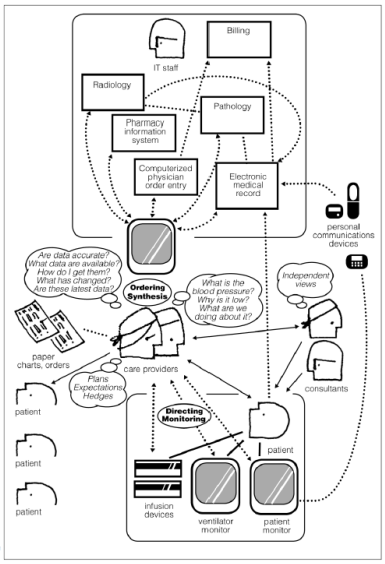
## The Burn ICU

- Joint cognitive system
- Macro-cognitive activities




Cacciabue, P.C. & Hollnagel, E. (1995). Simulation of cognition: Applications. *Expertise and technology: Cognition and human-computer cooperation*. In J.M. Hoc, P.C. Cacciabue, & E. Hollnagel (Eds.). Mahwah, NJ: Lawrence Erlbaum Associates. 55-73.

Klein, G., Ross, K. G., Moon, B. M., Klein, D. E., Hoffman, R. R., & Hollnagel, E. (2003). Macrocognition. *IEEE Intelligent Systems, 18*(3), 81-85.

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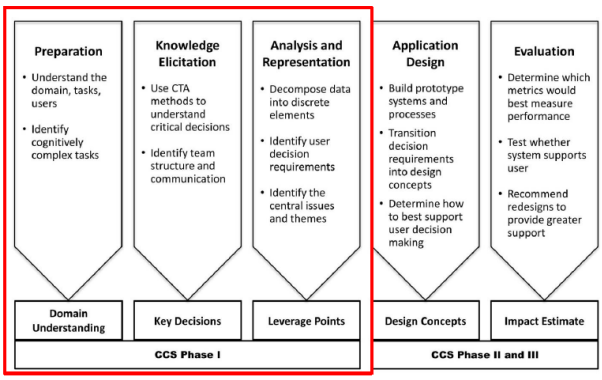
## Cognitive Systems Engineering (CSE)




Hollnagel, E., & Woods, D. D. (1983). Cognitive Systems Engineering: New wine in new bottles. *International Journal of Man-Machine Studies, 18*, 583-600

Woods, D. & Roth, E. (1988). Cognitive Systems Engineering, in M. Helander, (Ed.). *Handbook of Human-Computer Interaction*, Amsterdam: North Holland. 3-43.

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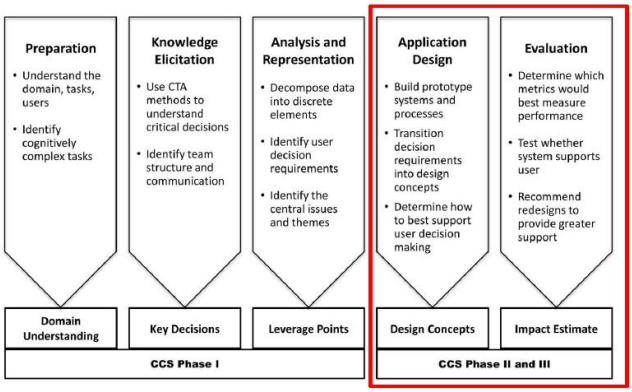
## Cognitive Systems Engineering (CSE)





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## CSE Reveals Genotypes

***Phenotype**: Clinicians talk among each other, spend a good deal of time writing at terminals*
***Work-around***

***Genotype**:* *Disconnected databases*
***Source of brittleness***

***Barrier:*** *No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*
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***Facilitates synchronization***


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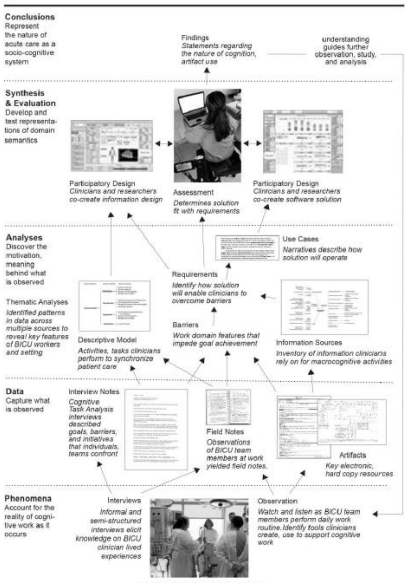
# Research Design




BICU Staff Synchronizing Care

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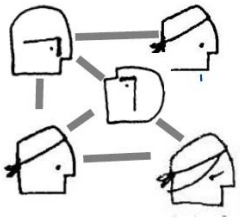
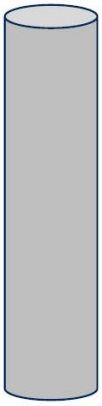
# Results



**Joint Cognitive System** includes patient, staff, care providers, family & information sources

**Machine learning finds relevant** patterns

**Interface Synthesizes, presents** salient data



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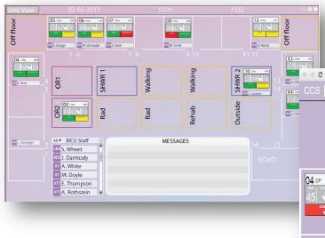
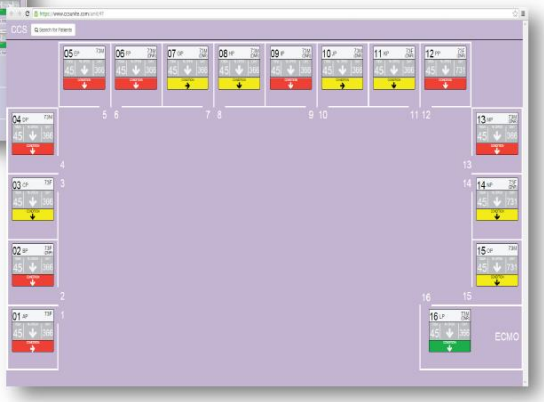
# **Prototype** Unit View

## Information Design



## Software



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# **Prototype** Patient View

## Information Design

## Software

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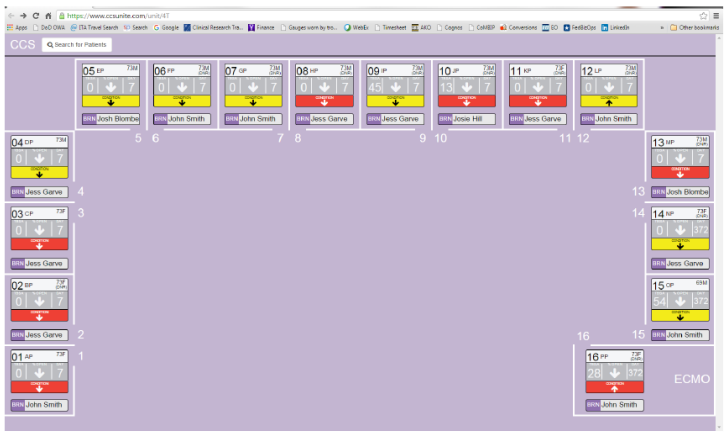


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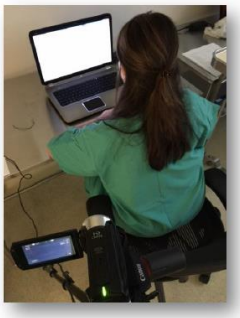
## Usability Assessment

12 physicians, 20 nurses
10 respiratory therapists

Two hypothetical yet clinically relevant scenarios: preparation for surgery, new admission

Asked a number of questions that required a decision about the patient.

Respiratory technicians performed the new admission scenario.

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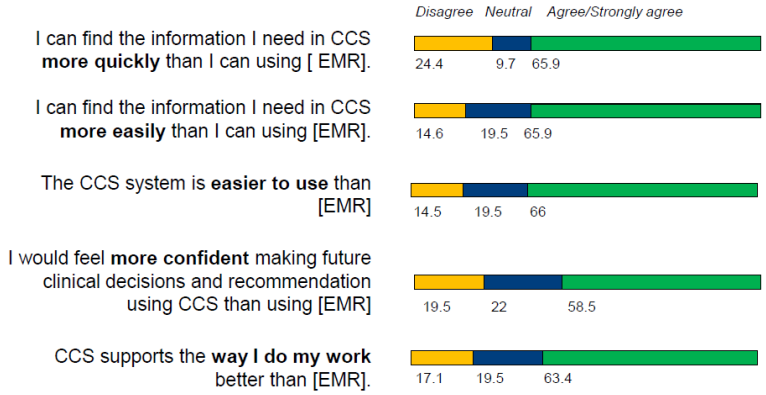
## Responses to Comparison Questions





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## Planned

Text/Alert/Message
Checklists
Machine Learning

Validation Assessment

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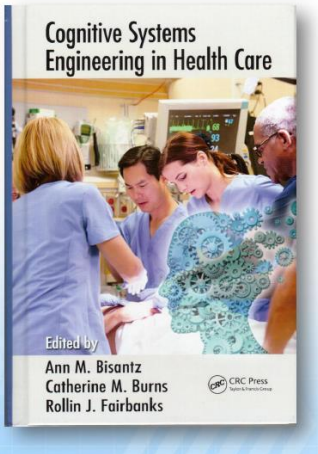
Your comments and questions are welcome

cnemeth@ara.com





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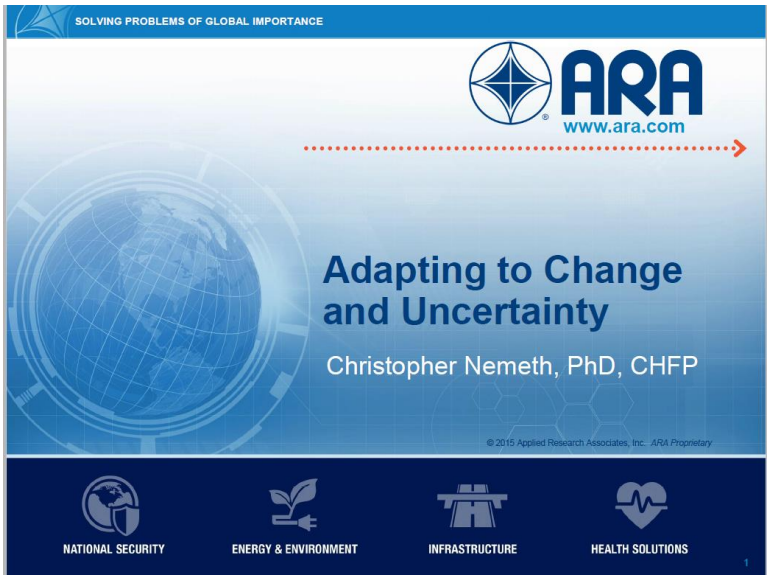
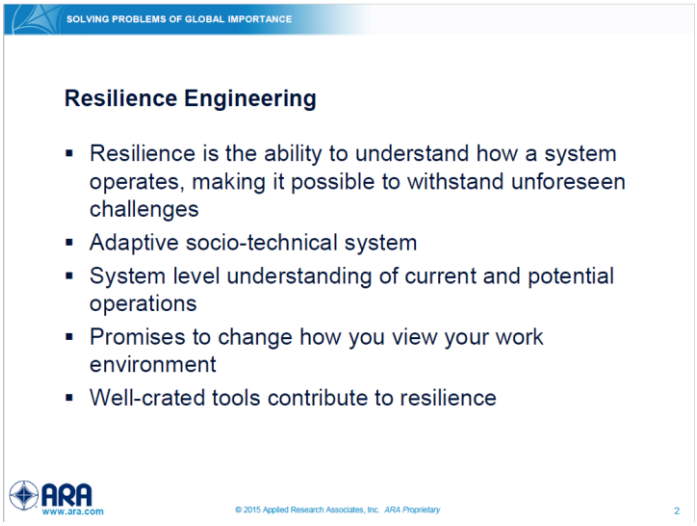
**Appendix S.** Invited speaker: Adapting to Change and Uncertainty. Pediatric Cardiac Intensive Care Society National Conference. 11 December 2015.



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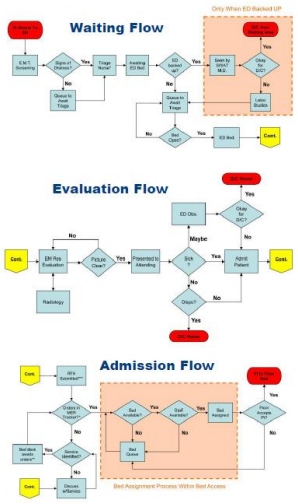



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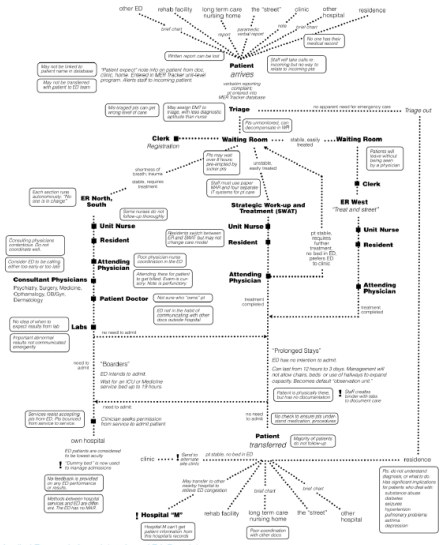
## Is *this* the ED?





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## New Tools, New Approaches

- Requires being open to new thinking, new tools to engage new challenge
- New approaches to development of *socio-technical systems* (Hollnagel and Woods, 2005)
- Resilience engineering observes, analyzes, designs and develops systems with the ability to anticipate and adapt to unforeseen demands, and continue operations. (Hollnagel, Woods, Leveson 2006)


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## Resilience

The intrinsic ability of a system to
*adjust its functioning* prior to, during,
or following changes and disturbances
so that it can *sustain required operations*, even
after a major mishap or in the presence of continuous stress.

The ability of systems to
*mount a robust response* to unforeseen,
unpredicted, and unexpected demands
and to *resume or even continue*
normal operations.


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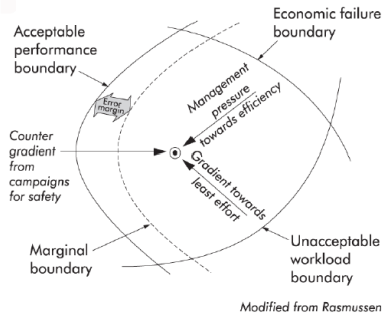
## The Need for Resilience

Organizations seek to remain economically viable and to leverage workforce capability

Pressure to improve efficiency and lessen workload push the operating state toward the marginal safety boundary




*Modified from Rasmussen*

*Safe operating envelope, adapted from Cook and Rasmussen, 2005.*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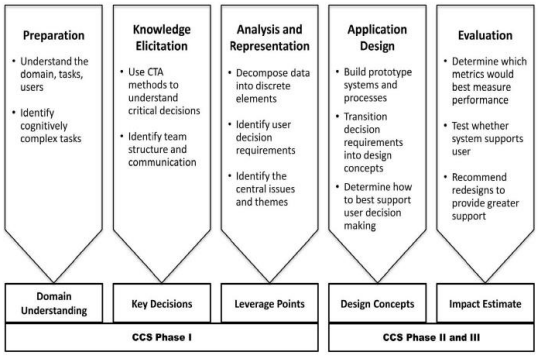
## Cognitive Systems Engineering





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# Cooperative Communication System

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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

## Research Site

- Burn ICU in tertiary care medical center,
- 16 beds, 2 reserved to serve as a post-anesthesia care unit (PACU), 1 dedicated to support Extracorporeal Membrane Oxygenation (ECMO).
- Other nearby units support the ICU, including a step down unit, burn operating room, and outpatient clinic.
- Population averages around 8 patients but as high as 13
- Patients have severe affliction from chemical, mechanical or electrical burns, or burn-like afflictions such as toxic epidermal necrolysis (TENS).
- Length of stay ranges from days to months.

*Photo: Dept. of the Army*

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## Research Design

- Goal is to improve care by better supporting the judgment of individuals and teams who care for patients through a cognitive aid that also assists communication.
- Three phases that were scheduled to take roughly a year apiece: foundation research, cognitive aid prototype development, and prototype assessment.

*Photo: Dept. of the Army*


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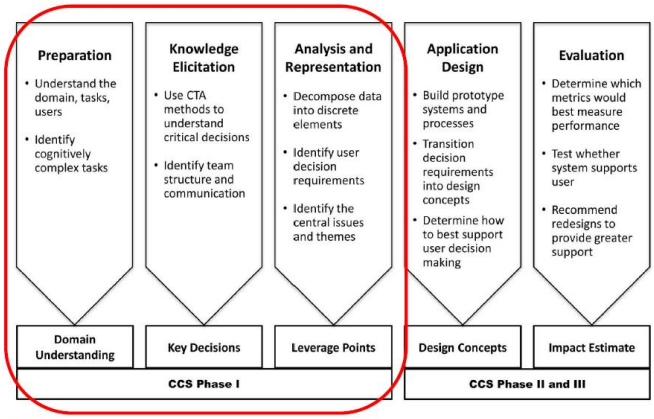
## CSE Phase 1





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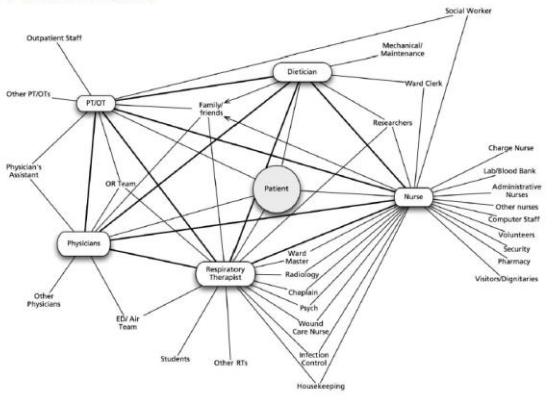
## BICU Patient Team





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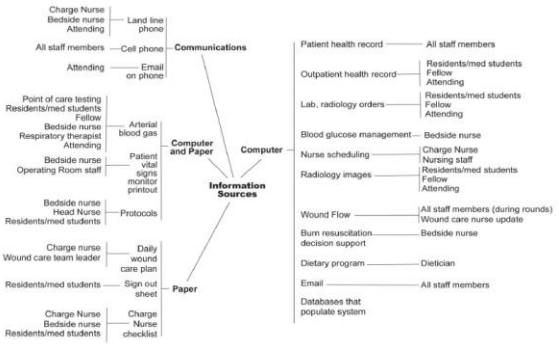
## BICU Information Sources





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## BICU Cognitive Model

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
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| | **Coordination** | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | **Negotiation** | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | **Anticipation** | Forward thinking |


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**Barrier**

*No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*

**Requirement**

*System shall provide access to a plan of patient care, visible to all care givers responsible for that patient that includes:*

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- *Goals and priorities for those goals*
- *Changes/updates, such as indication that plan is being updated when one caregiver is working on it*
- *Schedule of activities and any changes, timeline*
- *Orders and their status*
- *Identity and contact information for patient's care team*


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## *Pop Quiz!*

Q. What's the hardest part of this project?

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## *Pop Quiz!*

Q. What's the hardest part of this project?
A. Access to patient data.

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## **CSE** Phases Two, Three

| Preparation | Knowledge Elicitation | Analysis and Representation | Application Design | Evaluation |
|---|---|---|---|---|
| • Understand the domain, tasks, users<br>• Identify cognitively complex tasks | • Use CTA methods to understand critical decisions<br>• Identify team structure and communication | • Decompose data into discrete elements<br>• Identify user decision requirements<br>• Identify the central issues and themes | • Build prototype systems and processes<br>• Transition decision requirements into design concepts<br>• Determine how to best support user decision making | • Determine which metrics would best measure performance<br>• Test whether system supports user<br>• Recommend redesigns to provide greater support |
| **Domain Understanding** | **Key Decisions** | **Leverage Points** | **Design Concepts** | **Impact Estimate** |
| **CCS Phase I** | | | **CCS Phase II and III** | |


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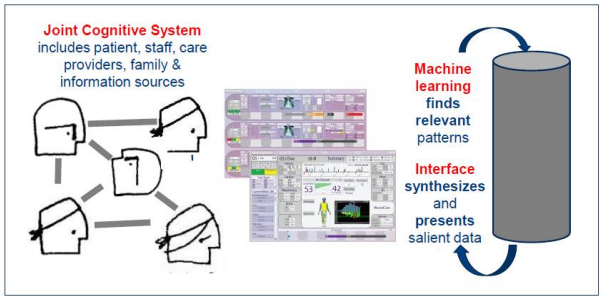
## Real time BICU decision /communication support

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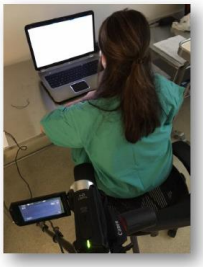
## Results

### Core Functions
- *Patient Identifier*
- *Unit View*
- *Patient View*
- *Care Team Manager*
- *Order Management*
- *Text/Alert/Message*
- *Rounds Checklists*

### Machine Learning
- *Data Exploration*
- *Data Access Layer*
- *Element Analytics*
- *Sequence Analytics*
- *Similarity Analytics*
- *Semantic Analytics*
- *Metadata Analytics*

### Evaluation
- *Usability Assessment*
- *Validation Assessment*



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## **Information Design** Unit View

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## **Information Design** Patient View

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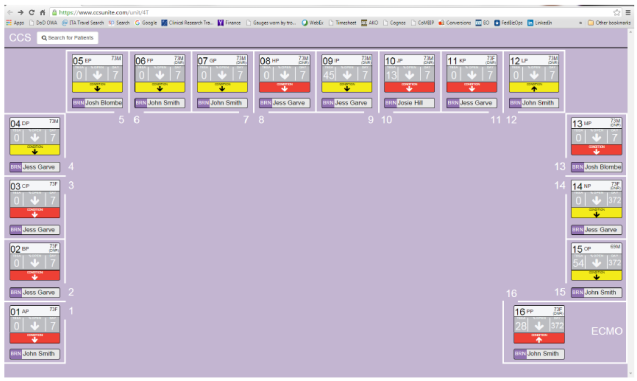
## Software Prototype

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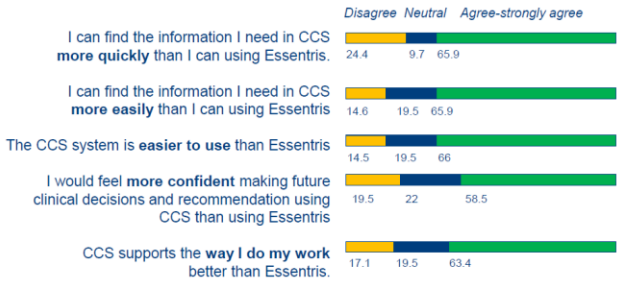
## Usability Assessment Results





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## Usability Assessment Results

Aspects of CCS that were particularly useful (all of sample)
- 48% Information presentation: layout, look, feel, navigation
- 29% Trends

Would a system like this be easily adopted?
- 86% Yes


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## Resilience

Three characteristics that CSE can assist:

- *Being self-aware*--Disconnection among specialties is aggravated by disconnected information sources.
- *Able to identify and apply resources*--Scheduling is currently done using hard copy forms and in-person negotiation, which makes it difficult to develop and maintain an optimal plan.
- *Able to adapt to surprise*--Use of CSE makes understanding what goes right, and what occasionally does not, a routine learning process that can improve the ability to adapt.


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Your comments and questions are welcome:

Christopher Nemeth, PhD

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cnemeth@ara.com
847-869-3621

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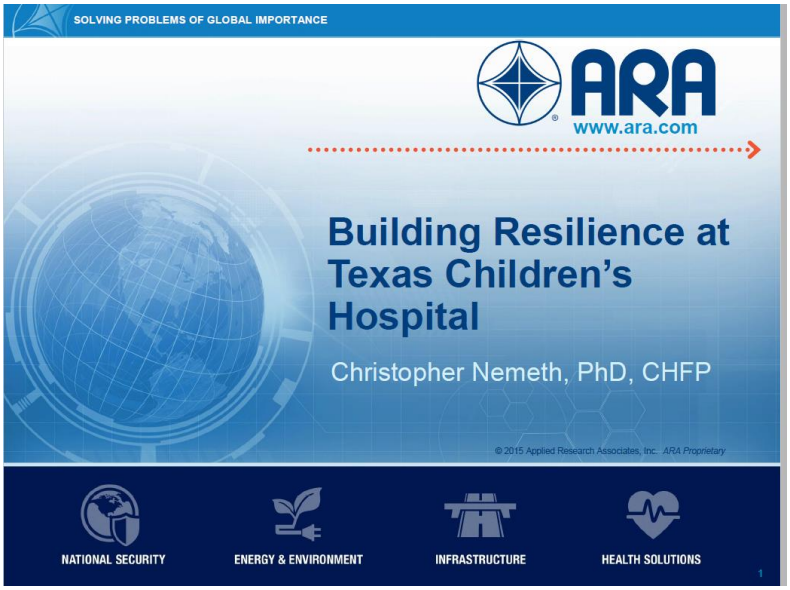
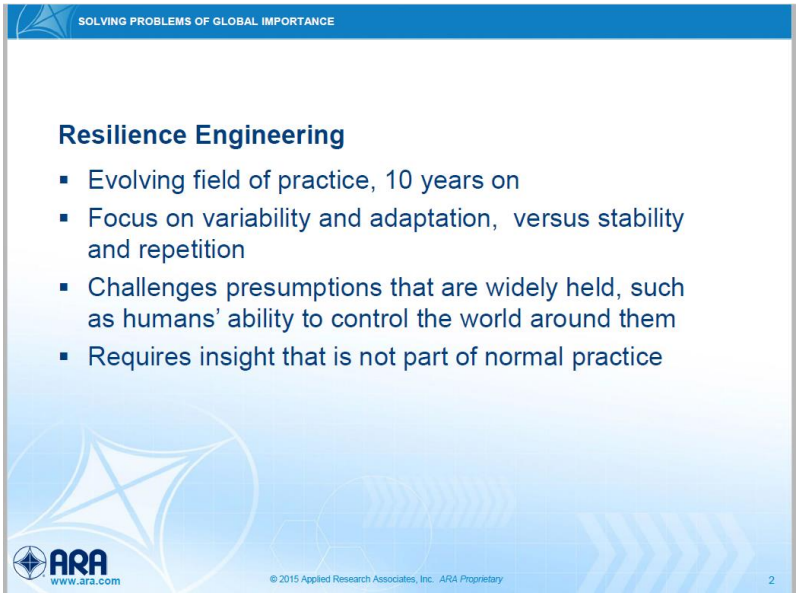
**Appendix T.** Presentation: Building Resilience. Texas Children's Hospital. 11 December 2015. Houston, TX.

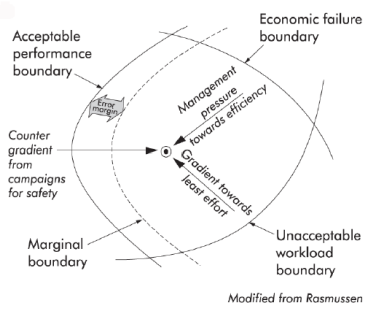


## The Need for Resilience

Organizations seek to remain economically viable and to leverage workforce capability

Pressure to improve efficiency and lessen workload push the operating state toward the marginal safety boundary




*Safe operating envelope, adapted from Cook and Rasmussen, 2005.*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**Engineering**

**Systems Engineering**

**Resilience Engineering**

**Cognitive Systems Engineering**


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## Resilience

The intrinsic ability of a system to
*adjust its functioning* prior to, during,
or following changes and disturbances
so that it can *sustain required operations*, even
after a major mishap or in the presence of continuous
stress.

The ability of systems to
*mount a robust response* to unforeseen,
unpredicted, and unexpected demands
and to *resume or even continue*
normal operations.


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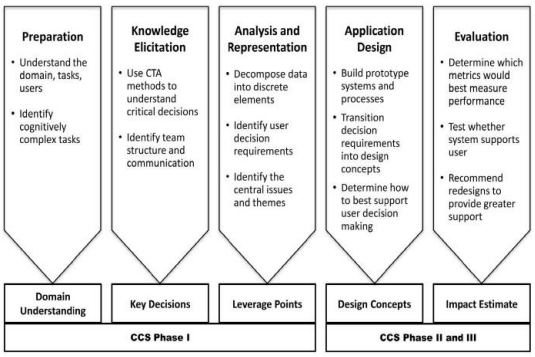
## Cognitive Systems Engineering





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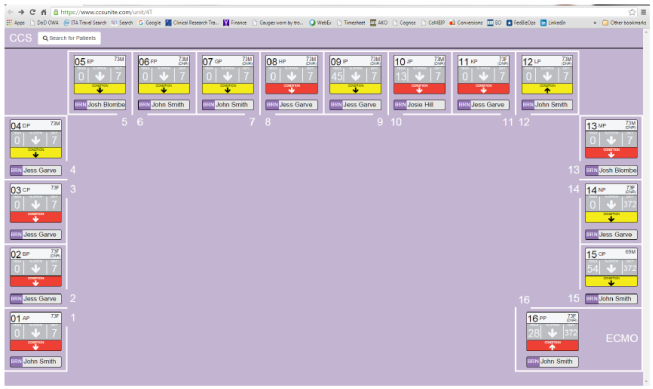
## CCS Software Prototype




https://www.ccsunite.com/patient/35/1672552800000/1672776000000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## Research Site

- Burn ICU in tertiary care medical center,
- 16 beds, 2 reserved to serve as a post-anesthesia care unit (PACU), 1 dedicated to support Extracorporeal Membrane Oxygenation (ECMO).
- Other nearby units support the ICU, including a step down unit, burn operating room, and outpatient clinic.
- Population averages around 8 patients but as high as 13
- Patients have severe affliction from chemical, mechanical or electrical burns, or burn-like afflictions such as toxic epidermal necrolysis (TENS).
- Length of stay ranges from days to months.

*Photo: Dept. of the Army*


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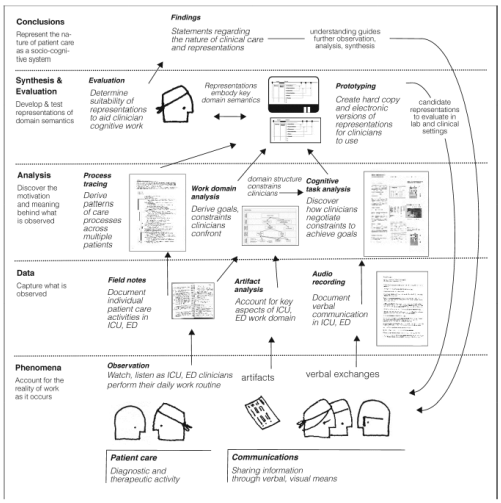



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## BICU Cognitive Model

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
| **Synchronization** | **Clarification** | Reduce uncertainty<br>Manage ambiguity<br>Manage conflicting agendas<br>Manage communication |
| | **Coordination** | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | **Negotiation** | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | **Anticipation** | Forward thinking |


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## CSE Approach Reveals Inter-dependencies

***Phenotype***: *Clinicians talk among each other, spend a good deal of time writing at terminals*

***Work-around***

***Genotype***: *Disconnected databases*

***Source of brittleness***

***Barrier:*** *No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*

***Blocks synchronization***

***Requirement:*** *System shall provide access to a plan of patient care, visible to all care givers responsible for that patient*

***Source of resilience***

***Features:***

*Current patient status and top-level assessment*
*Goals and goal priorities*
*Changes/updates, such as indication that plan is being updated when one caregiver is working on it*
*Schedule of activities and any changes, timeline*
*Orders and their status*
*Patient's care team identity and contact information*

***Facilitates synchronization***


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## Use Case

*"At 0630, a bedside nurse has started his preparation for the day **shift** by reviewing information on the patient he is responsible for. Opening CCS, he can see a **roster of patients on the unit**, chooses his patient's **"at-a-glance" view** that shows **recent vital signs, current orders, medications, care plan,** and **notes from the night shift**. He checks the patient's standing **care plan** and **treatment goals** (from the electronic healthcare record), and **reviews orders** (from the laboratory test database) that are pending as well as the day's **care activities that the Wound Care team, Respiratory Therapists, and Physical Therapists** have recommended and **what times** they can perform them…"*


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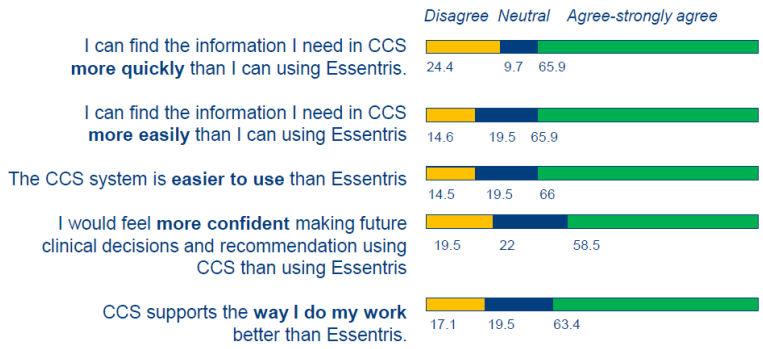
## Usability Assessment Results





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## Resilience in Practice

Three characteristics that CSE can assist:

- *Being self-aware*--Disconnection among specialties is aggravated by disconnected information sources.
- *Able to identify and apply resources*--Scheduling is currently done using hard copy forms and in-person negotiation, which makes it difficult to develop and maintain an optimal plan.
- *Able to adapt to surprise*--Use of CSE makes understanding what goes right, and what occasionally does not, a routine learning process that can improve the ability to adapt.


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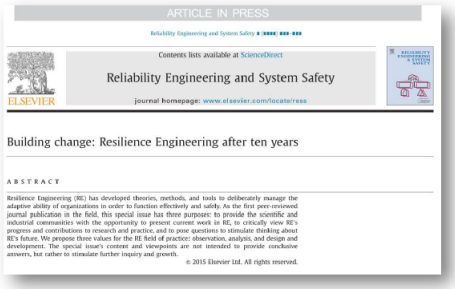
## RE Requires New Approaches & Tools

How can we be better at:

- Observation
- Analysis
- Design and Development



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Reliability Engineering and System Safety ■ (■■■■) ■■■–■■■

Contents lists available at ScienceDirect

Reliability Engineering and System Safety

journal homepage: www.elsevier.com/locate/ress

Building change: Resilience Engineering after ten years

ABSTRACT

Resilience Engineering (RE) has developed theories, methods, and tools to deliberately manage the adaptive ability of organizations in order to function effectively and safely. As the first peer-reviewed journal publication in the field, this special issue has three purposes: to provide the scientific and industrial communities with the opportunity to present current work in RE, to critically view RE's progress and contributions to research and practice, and to pose questions to stimulate thinking about RE's future. We propose three values for the RE field of practice: observation, analysis, and design and development. The special issue's content and viewpoints are not intended to provide conclusive answers, but rather to stimulate further inquiry and growth.

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## To Build Resilience

- Reconceptualize: multi-role, multi-eschelon networks
- Study what goes right
- Cultivate requisite imagination
- Create new tools to develop and operate systems
- Develop tools to signal how to make production vs. safety tradeoffs and sacrifice decisions.
- Cultivate ways to visualize and foresee side effects
- Promote and use good design
- Acknowledge and manage variability


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Your comments and correspondence are welcome.

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cnemeth@ara.com

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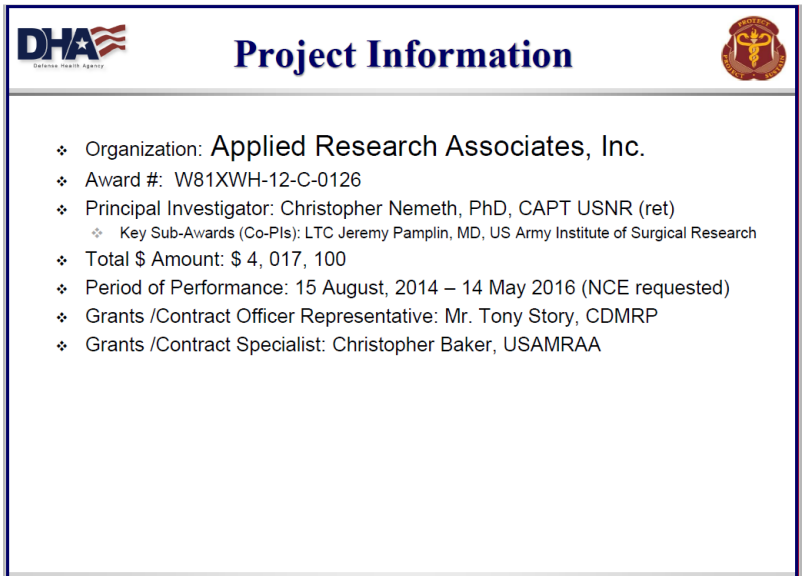
**Appendix U.** Presentation: A Cooperative Communication System for the Advancement of Safe Effective and Efficient Patient Care, JPC1 IPR, Ft. Detrick, MD, 1 December 2015.



## Overview of the Research Project

- **Purpose**. Develop an ecologically valid computer-based cognitive artifact to provide real time support for Burn ICU clinician decision making and communication.
- **Methodology**: Cognitive Systems Engineering
- **Deliverable**: Software tool that provides a customizable graphical user interface that presents the right information to the right user at the right time and is linked in real time to the existing EHR.
- **Expected Outcomes**: Reduced complications and costs, and improve patient outcomes, resulting from making salient information evident and better communication among healthcare team members that enable effective decisions

## Research Question/Hypothesis & High Level Objectives

- **Hypothesis**:
  The CCS support for BICU will improve clinician decision making and communication by making patient care more efficient, effective, and less prone to adverse outcomes and misadventures (sometimes referred to as "medical errors").

- **Project Aims**: Clinical decision and communication support tool that provides:
  - Improved clinician decision making, through presentation of salient patient data, and machine learning and communication support
  - More efficient, reliable individual and team cognitive work resulting in improved patient outcomes (e.g., reduced length of stay)

## Research Question/Hypothesis & High Level Objectives

- PHASE 1:
  - Describe patient progress through burn intensive care to create a shared mental model for clinicians of all specialties;
  - Provide a thorough account of the clinician cognitive work (i.e., work flow and decision requirements) for clinical work in the Burn ICU, including accountability of all pertinent recorded and non-recorded data;
  - Present design requirements for the information, the underlying cognitive networking rules, and the display format of an IT-based cognitive aid for healthcare delivery (the Cooperative Communication System);
  - Derive quantitative evaluation criteria for comparative evaluation of clinical support tools;
- PHASE 2:
  - Present a prototype CCS design for testing and implementation in the USAISR Burn ICU;
- PHASE 3:
  - Develop a test bed based on the clinical environment for Test and Evaluation of the CCS and other clinical support tools.

## Tasks & Milestone Update

**Phase 1**

- *Task 1.1: Initial Observation of the Burn ICU*
- *Task 1.2: CTA Structured Interviews and Observation.*
- *Task 1.3: Integrated Data Analysis and Model Development.*
- *Task 1.4: Decision Model and Design Requirements.*

**Phase 2**

- *Task 2.1: Scoping and Planning.*
- *Task 2.2: Analysis.*
- *Task 2.3: Design Phase.*
- *Task 2.4: Implementation, Integration and Testing.*

**Phase 3**

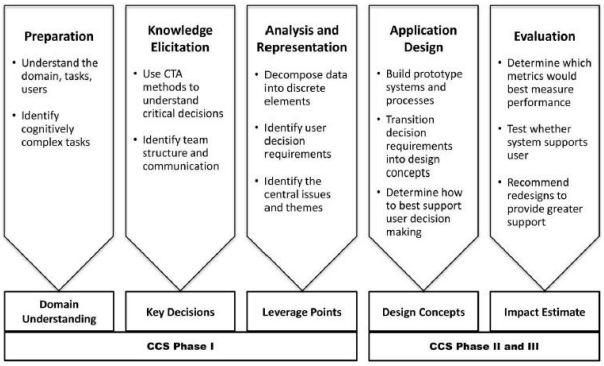
- *Task 3.1: Participatory Design.*
- *Task 3.2: Evaluation Testing.*
- *Task 3.3: Usability Assessment.*
- *Task 3.4: Validation Testing.*
- *Task 3.5: CCS Delivery and Transition.*

# Tasks & Milestone Update

- **Deliverables**
  - Human Subject Protocol Approved: 27 Feb 2013, Amended Apr 30, 2013
  - Quarterly reports Feb 2013-present; Bi-Weekly updates March 2015-present
  - Visit Reports (x4): March-November 2014
  - Annual Reports September 2013, 2014, 2015
  - Initial Software User Interface Designs: January 2014
  - Burn ICU Cognitive Model: February 2014
  - Phase 1 Final Report: February 2014
  - Finalized User Interface Designs: April 2014
  - Initial Burn ICU Metrics: September 2014
  - Controlled test environment: Started October 2014
  - First iteration of working Prototype: December 2014
  - Second iteration of prototype: October 2015
  - Usability assessment of prototype: November 2015
  - Third iteration of prototype: expected January 2016
  - Validation assessment of prototype: expected February 2016
  - Finalized CCS program: expected April 2016

# Research Methodologies

**Cognitive Systems Engineering**



## Research Methodologies

- **Year One**
  - *Literature Review*
  - *Observation:* Five week-long visits to the BICU
  - *Structured Interviews*: Typically 15-20 per visit
  - *Artifact Analysis:* Collection, de-identification, and analysis of information sources
  - *Thematic Analysis*: Detection of patterns among and across data elements
  - *Participatory design:* Collaboration among ARA and AISR team members to create interface concepts complementary to BICU work practice and culture
- **Year Two**
  - *Validation interviews:* Review of representations with clinicians to confirm, adjust, and enrich findings (Iterative development)
  - *Survey*: Research nurse data collection to answer focused questions, such as requirements priorities

## Research Methodologies

- **Year Two** (cont'd)
  - *Rapid prototyping*: Development of interface design based on Year One data
  - *Agile prototyping*: Initial software development, including initial machine learning concepts (e.g., similar patients)
- **Year Three**
  - *Agile Prototyping*: Comprehensive software development, including machine learning (e.g., similar patients, trends)
  - *Usability Assessment*: Determination of CCS suitability for individual decision making, compared with current IT
  - *Validation Assessment*: Determination of CCS suitability for team decision making, compared with current IT

# Results to Date

**Approval Update from HRPO and IRB:**

- Amendment (personnel changes) to Protocol M-10280 (approved 26 Dec14)
- Continuing Review for 2014 for CCS Phase I (approved 5 Jan 2015)
- Machine Learning Protocol amendment #1 (approved 27 Mar 2015)
- Lab Protocol (L.15.004) (approved 18 Jun 2015)
- Lab Protocol (L-15-004) Usability Study amendment (approved 21 Oct 2015)

# Results to Date

- **CCS Seven Core Functions**
  - *Patient Identifier*
  - *Unit View*
  - *Patient View*
  - *Care Team Manager*
  - *Order Management*
  - *Text/Alert/Message*
  - *Rounds Checklists*
- **Machine Learning**
  - *Data Exploration*
  - *Data Access Layer*
  - *Element Analytics*
  - *Sequence Analytics*
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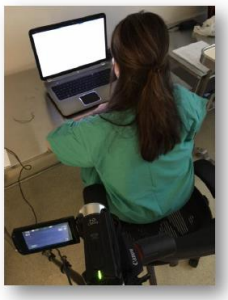
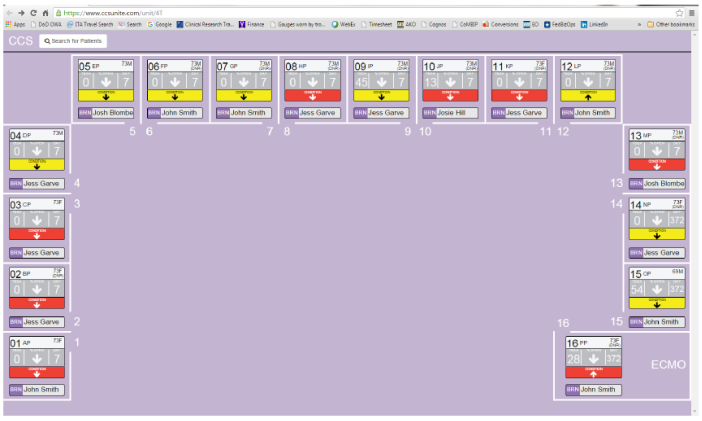
  - *Semantic Analytics*
  - *Metadata Analytics*
- **Evaluation**
  - *Usability Assessment*
  - *Validation Assessment*



# Results to Date

## Real Time CCS Demonstration



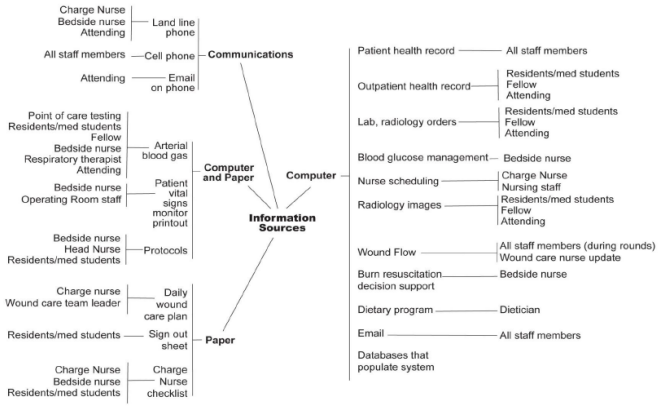

# Results to Date

## Descriptive Model of Cognitive Work

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
| **Synchronization** | **Clarification** | Reduce uncertainty<br>Manage ambiguity<br>Manage conflicting agendas<br>Manage communication |
| | **Coordination** | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | **Negotiation** | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | **Anticipation** | Forward thinking |

# Results to Date

## Information Sources




# Results to Date

**Problem:** No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.

**Requirement:** System shall provide access to a plan of patient care, visible to all caregivers responsible for that patient that includes:

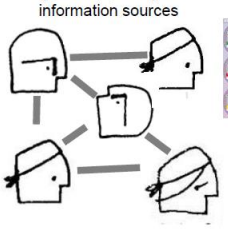
- Current patient status and top-level assessment;
- Goals and priorities for those goals;
- Changes/updates (e.g., indicating that plan is being updated when one caregiver is working on it);
- Schedule of activities and any changes, timeline;
- Orders and their status;
- Identity and contact information for patient's care team.

**Each of 39 requirements is directly connected to CCS features**

# Results to Date

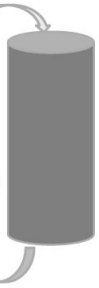
**Real time BICU decision and communication support**

**Joint Cognitive System**
includes patient, staff, care providers, family & information sources



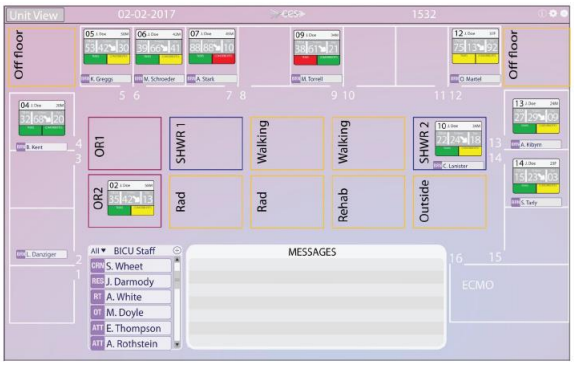
**Machine learning finds relevant patterns**

**Interface synthesizes and presents salient data**



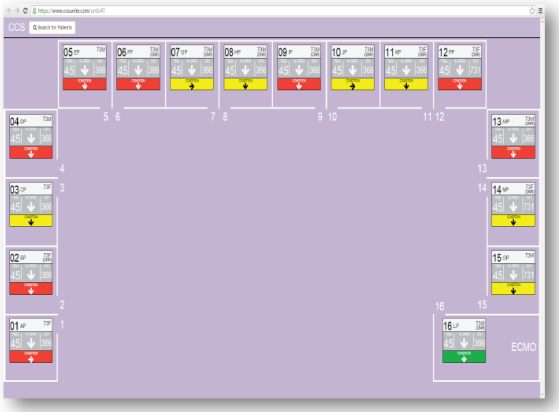
# Results to Date

**Unit View** Information Design Prototype



# Results to Date

**Unit View** Software Prototype




# Results to Date

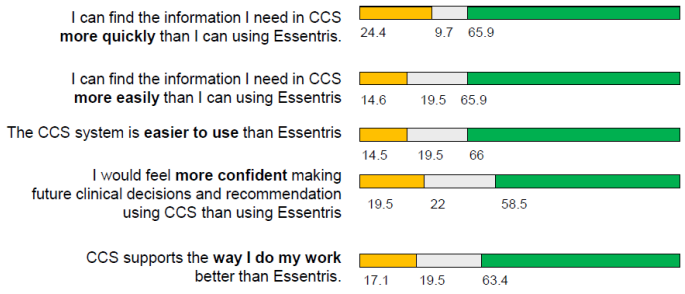
**Patient View** Information Design

# Results to Date

**Patient View** Software Prototype

# Results to Date

- Usability Assessment at AISR, 2-6 Nov 2015
  - 41 participants (physicians, nurses, techs) performed 2 clinically relevant scenarios. Comparison with Essentris (green strongly agree/agree, grey neutral, yellow disagree) after 2-3 minute orientation and 2 scenarios:



## Tasks in Progress & Future Tasks

- Tasks in Progress
  - *Agile prototyping*: Complete software development, including machine learning (e.g., similar patients, trends)
- Future Tasks
  - *Validation Assessment*: Determine CCS suitability for *team* decision making, compared with current IT (planned for February 2016)

## Barriers / Issues

- Issues that have had significant effect on progress.
- **IRB.** Approval for human subjects research. Six month delay made NCE request necessary.
- **Sub contractor**. Small business SSCI was unable to perform according to project needs for machine learning. After 1 year, replaced with ARA team.
- **Access to Data**. Year long delay made second NCE request necessary.
- **Funding for AISR**. Support for data mapping from Essentris EHR delayed by three months.

## Risks & Risk Mitigation Plan

- **Risk**: Validation Study Delayed
  IRB review and approval process may cause delays, forcing us to reschedule the validation study in January.
- **Mitigation**: NCE
  The NCE we have requested should provide sufficient buffer in the schedule to complete approval if there is a delay from the review and enable us to complete all analysis and reporting.

## Metrics

Depending on BAMC IT support for CCS requirements:

- The final CCS prototype will be validated in the Burn ICU in a side by side comparison with the current Essentris system.
- We will obtain clinicians consent to participate as care teams and will run patient care scenarios using both CCS or the existing Essentris-based system
- Use of either system will be measured:
  - Quantitatively: e.g., Time to make decisions, steps to find data
  - Qualitatively: Clinician insights on match with work needs and flow
  - By clinical expert: Decision quality using CCS, using Essentris
- Results will be assessed through statistical analysis of the data collected from the participating care teams to reveal the difference between the two systems. in terms of performance and acceptability

## Anticipated Impact
### as an Outcome of Research

- **Patient Safety.** Successful implementation of the CCS in the clinical environment has potential to reduce the incidence of medical misadventures.
- **Patient care efficiency**. Safety and effectiveness of patient care can be increased by increasing the speed at which clinicians can make accurate clinical decisions.
- **Patient care intensity.** Clinicians provided more direct interaction time with patients, by reducing the time burden to find, use needed information.
- **Broad applicability**. Can provide the same real time decision support in clinical settings other than military facilities.

## Transition Plan

- The CCS project will include several deliverables from the current contract:
  - A prototype user interface comprised of core functions, and a final report
    - Source code will be directly handed off to the USAISR
    - Development momentum will be maintained within the Comprehensive Intensive Care Research Task Area managed by Jose Salinas"
  - Multiple professional publications
  - Recommendation for follow-on to evolve CCS from TRL 5 to TRL 8
    - Eventual clinical use will require additional controlled trials and FDA approval.
- End customer: DoD healthcare system. Other prospective end customers include Veteran's Administration, civilian healthcare systems

## Conclusions

- **Research**: Cognitive Systems Engineering methods successfully enabled the team to create an ecologically valid decision making and communication support IT system. JPC-1, TATRC, CDMRP, and USAISR support for publishing was a great help getting word to the professional community.
- **Development**: Coordination with USAISR to map data elements from the Essentris healthcare record posed a challenge that the team needed to manage constantly through Year Two into Year Three.
- **Administrative**: Institutional Review Board and Defense Health Information Technology security regulations posed challenges throughout the project.
- **Transition**: Iterative development through the integration of end users to establish early buy-in is critical for successful implementation.

**Appendix V.** Presentation: A Cooperative Communication System. Defense Innovation Summit, Austin, TX. December 2015

# A Cooperative Communication System (CCS)

Gregory Rule, P.E.[1]; LTC Jeremy C. Pamplin, MD[2]; Anna Grome, MS[1];
Dawn Laufersweiler[1]; Josh Blomberg[1]; Tony Hamilton[1]; Jose Salinas, PhD[2]; Christopher Nemeth, PhD[1]
1. Applied Research Associates, Inc.; 2. United States Army Institute for Surgical Research, JBSA Fort Sam Houston, TX

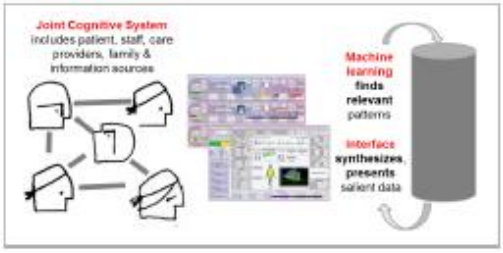
## Introduction

- An *ecologically valid* IT system to support military Burn Intensive Care Unit (ICU) decision and communication.
- Improves individual and team decision making and patient safety to optimize patient outcomes.
- Used Cognitive Systems Engineering (CSE) mixed methods approach to:
  - > Study ICU, and clinician activity (Year 1)
  - > Develop requirements and prototypes (Year 2)
  - > Evaluate usability for individuals and teams (Year 3)

## *A Joint Cognitive System for Better Patient Care*

## Impact

- Increased efficiency, and reduced potential for error during patient care.
- More efficient, reliable collaboration among members of the ICU staff.
- Reduces time clinicians are required to search for data and increases the time they can spend on patient care.




## Capabilities

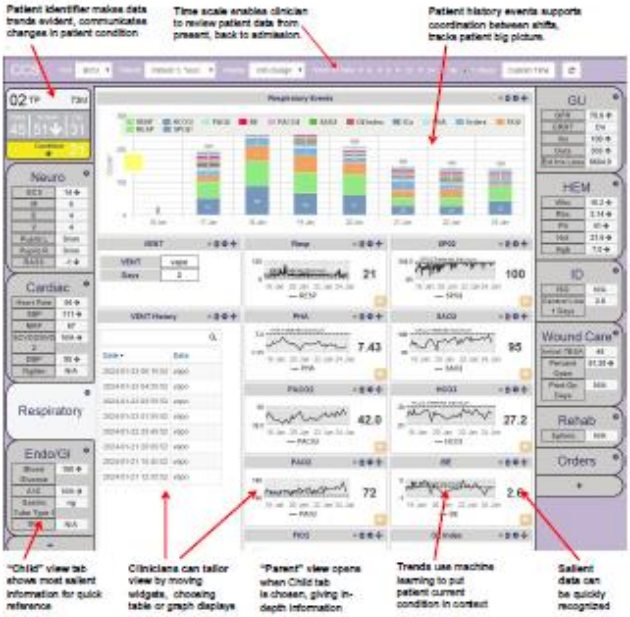
**Machine learning**. Automated techniques analyze data from many diverse historical Burn ICU patients to identify patterns that help inform the care team. Clinicians save time and are better informed because CCS provides easy access to knowledge from previous cases that are the most relevant for each unique patient.

*Key Machine Learning Use-Cases:*

1) *Given a patient's care to date and current physiological condition, CCS identifies most similar / appropriate cohorts from the historic records to help a clinician make decisions about future care.*
2) *Model patient condition to objectively determine how a patient's wellness is changing over time and their overall trajectory towards future discharge or increased care requirements.*
3) *Provide clinicians with recommendations regarding potential or evolving problems based on a patient's current physiology data and how it relates to cases previously treated.*

**Multiple information displays** Task oriented/role based views ensure only salient information is displayed.

- ***Patient Identifier*** (at right) Presents critical information for quick recognition of patient condition, trends.
- ***Patient View*** (at right) Unified view can be configured to individual preference. Improves resource use/prioritization, and care coordination/planning.
- ***Scheduling*** Enables unit managers to identify available team resources, assign patient care teams.
- ***Unit View*** Enables unit managers to see condition, trends among and across all patients on the unit.
- ***Order Management*** Tracks orders status to reduce uncertainty about therapeutic interventions.
- ***Smart Checklists*** Provides required steps to ensure guideline compliance, and better coordinate unit task performance at interdisciplinary rounds.
- ***Tasking, Messaging, Alerting*** Enables care team members to pose, answer critical questions related to patient care. Improves situational awareness, efficiency.

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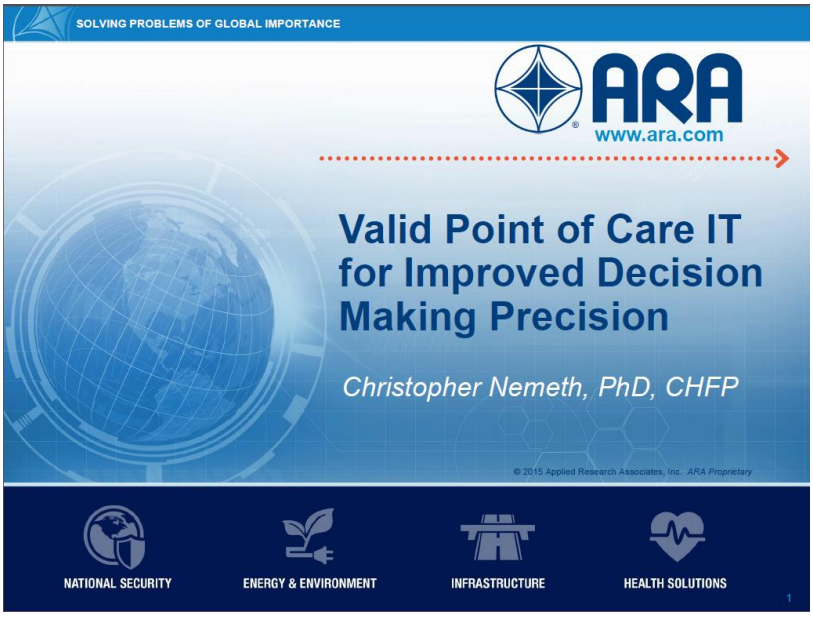
1. Nemeth, C., Anders, S., Grome, A., Crandall, B., Dominguez, C., Pamplin, J., Mann-Salinas, E. & Serio-Melvin, M. (2014) Support for ICU resilience: Using Cognitive Systems Engineering to build adaptive capacity. *Proceedings of the Systems Man and Cybernetics Society 2014 International Symposium*. Institute of Electrical and Electronic Engineers. San Diego.
2. Nemeth, C., Pamplin, J., Blomberg, J., Argenta, C., Serio-Melvin, M. & Salinas, J. Support for Salience: IT to assist burn ICU clinician decision making and communication. *Proceedings of the Systems Man and Cybernetics Society 2015 International Symposium*. Institute of Electrical and Electronic Engineers. Hong Kong. *(accepted)*
3. Nemeth, C., Anders, S., Strouse, R., Grome, A., Crandall, B., Pamplin, J., Salinas, J., Mann-Salinas, E. Developing a Cognitive and Communications Tool for Burn ICU Clinicians. *Military Medicine*. Association of Military Surgeons of the United States (AMSUS). *(In press)*.

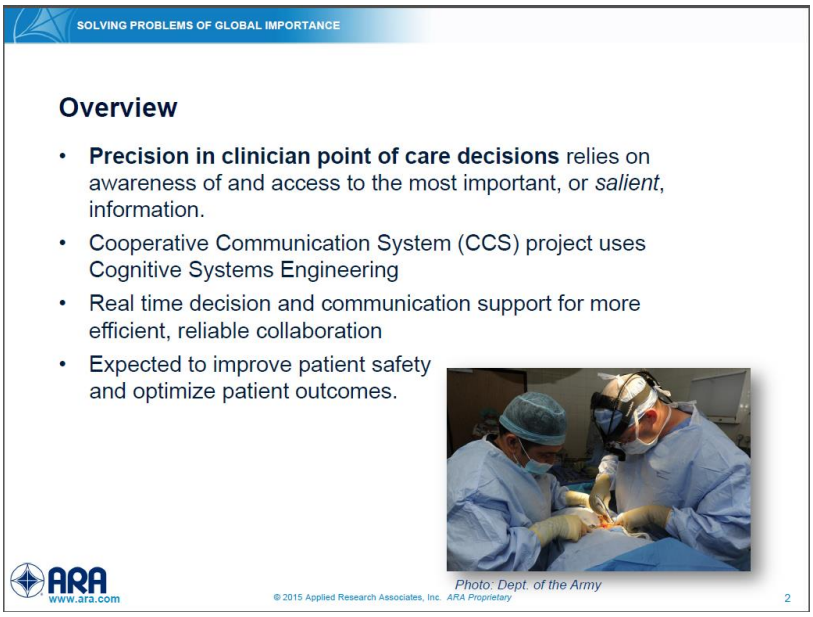
## Acknowledgements

Thanks to Nicole Caldwell, RN for her help with this project, which is supported by a grant from the US Army Medical Research and Materiel Command Congressionally Directed Medical Research Program (W81XWH-13-2-0011) and was conducted under a protocol reviewed and approved by the US Army Medical Research and Materiel Command Institutional Review Board.

DODIS-15, Board 362

**Appendix W.** NIH-IEEE Point of Care Conference Presentation 10 Nov 2015: Valid Point of Care IT for Improved Decision Making Precision



## EHR Table Format

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## Research Site

- Burn ICU in tertiary care medical center,
- 16 beds, 2 serve as a post-anesthesia care unit (PACU), 1 dedicated for Extracorporeal Membrane Oxygenation (ECMO).
- Other nearby units support the ICU, including a step down unit, burn operating room, and outpatient clinic.
- Population averages around 8 patients but as high as 15
- Patients have severe affliction from chemical, mechanical or electrical burns, or burn-like afflictions such as toxic epidermal necrolysis (TENS).
- Length of stay ranges from days to months.

*Photo: Dept. of the Army*


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## Pop Quiz!

**Q.** What is **point of care precision** in the case of healthcare IT?

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## Pop Quiz!

**Q.** What is **point of care precision** in the case of healthcare IT?

**A.** A *keen understanding* of the work domain, and clinician cognitive work, embodied by an *ecologically valid* solution.

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## Research Design

- Goal is to improve care by better supporting the judgment of individuals and teams who care for patients through a cognitive aid that also assists communication.
- Three phases, roughly a year apiece: foundation research, cognitive aid prototype development, and prototype assessment.

*Photo: Dept. of the Army*


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## Cognitive Systems Engineering

| Preparation | Knowledge Elicitation | Analysis and Representation | Application Design | Evaluation |
|---|---|---|---|---|
| • Understand the domain, tasks, users<br>• Identify cognitively complex tasks | • Use CTA methods to understand critical decisions<br>• Identify team structure and communication | • Decompose data into discrete elements<br>• Identify user decision requirements<br>• Identify the central issues and themes | • Build prototype systems and processes<br>• Transition decision requirements into design concepts<br>• Determine how to best support user decision making | • Determine which metrics would best measure performance<br>• Test whether system supports user<br>• Recommend redesigns to provide greater support |
| **Domain Understanding** | **Key Decisions** | **Leverage Points** | **Design Concepts** | **Impact Estimate** |
| **CCS Phase I** | | | **CCS Phase II and III** | |


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## BICU Cognitive Model

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
| Synchronization | Clarification | Reduce uncertainty<br>Manage ambiguity<br>Manage conflicting agendas<br>Manage communication |
| | Coordination | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | Negotiation | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | Anticipation | Forward thinking |


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## Core Functions

Seven elements comprise the CCS, which are essential to support the BICU cognitive model:

- Patient Identifier
- Unit View
- Patient View
- Scheduling
- Order Management
- Checklists
- Tasking, Messaging, and Alerting

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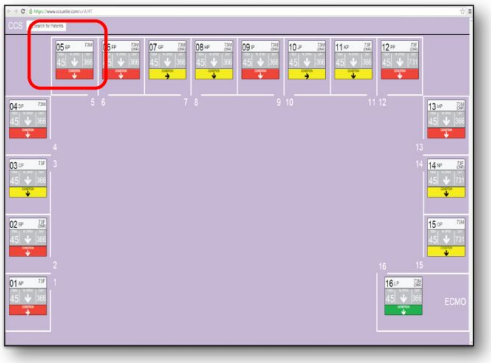
## Unit View

Patient identifier

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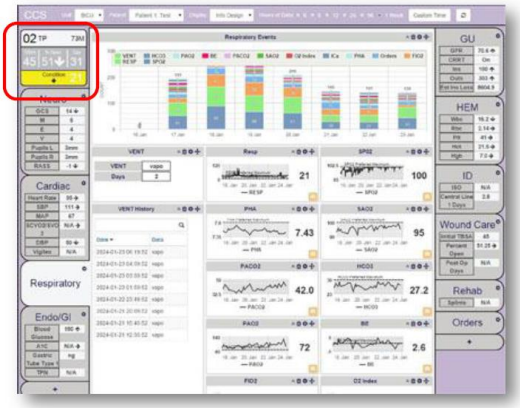
## Patient View

Patient identifier

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## Patient View

Time scale

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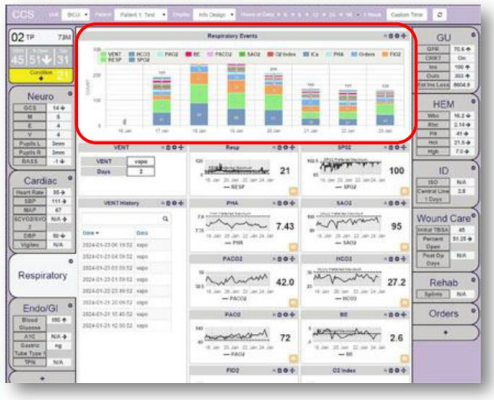
## Patient View

Patient history events

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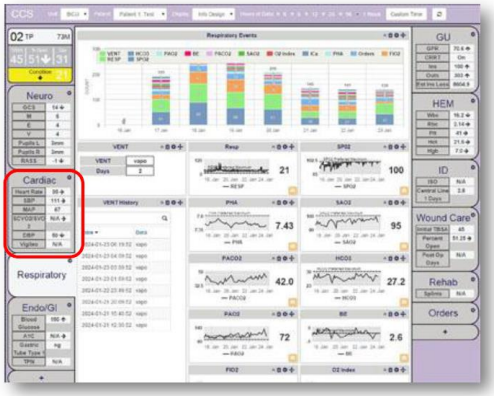
## Patient View

"Child" view tab





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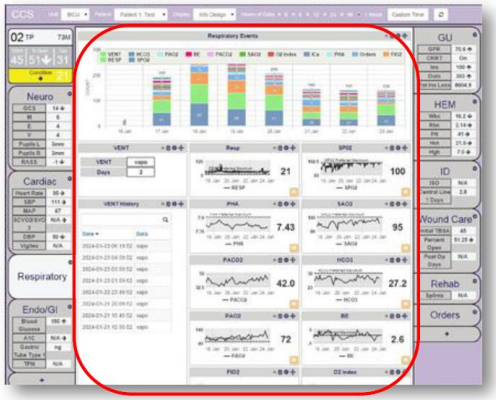
## Patient View

"Parent" view





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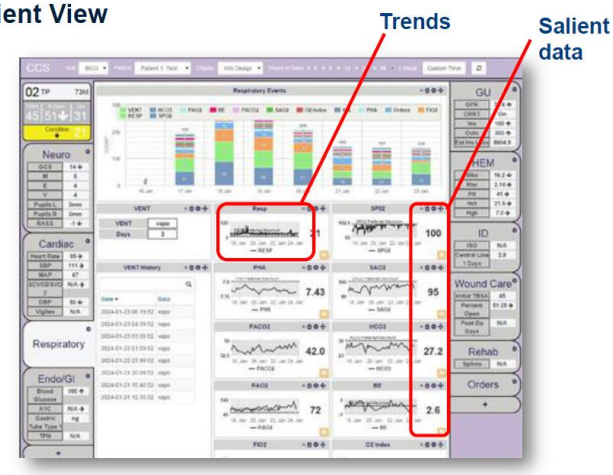
## Patient View





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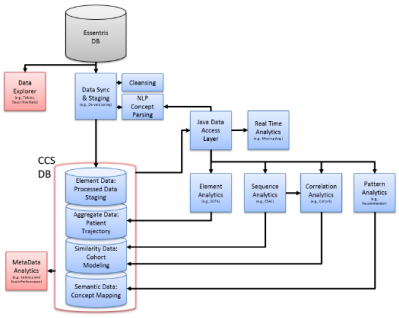
## Machine Learning

- *Data Exploration*
- *Data Access Layer*
- *Element Analytics*
- *Sequence Analytics*
- *Similarity Analytics*
- *Semantic Analytics*
- *Metadata Analytics*





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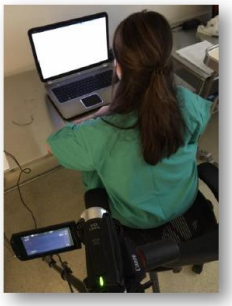
## Usability Assessment

- 2-6 Nov, at research site
- 43 participants (13 physicians, 20 nurses, 10 techs)
- 2 clinically relevant scenarios for individual use: prep for surgery, new admissions
- Quantitative (e.g., time to complete task)
- Qualitative (e.g., level of effort)
- Strong evidence on behalf of concept

- Assessment to validate team use scheduled for Feb 2016

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## Valid Point of Care IT for Improved Decision Making Precision

- Good decision support is actually needed on the most *difficult* problems which are the ones that experts confront,
- The way that a problem is presented can improve or degrade the cognitive work performance.
- Understanding cognitive work of patient care requires probing more deeply under the surface descriptions of the work domain, to reveal and understand underlying patterns of systemic factors that form them.
- Point of care decisions, and intensive care decisions in particular, pivot on current, accurate, available information that requires *ecologically valid* IT support.


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Your comments and correspondence are welcome.

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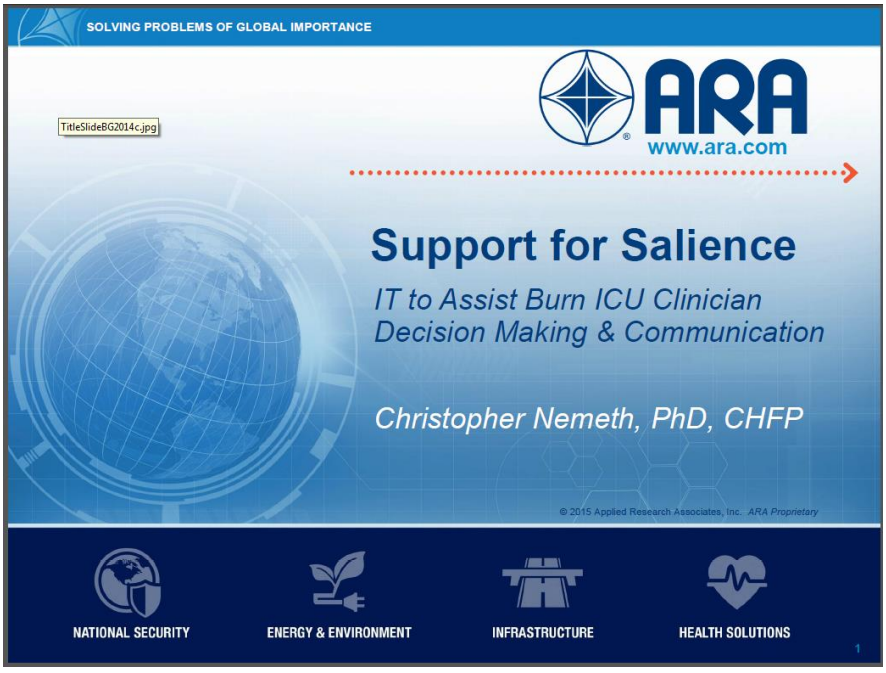
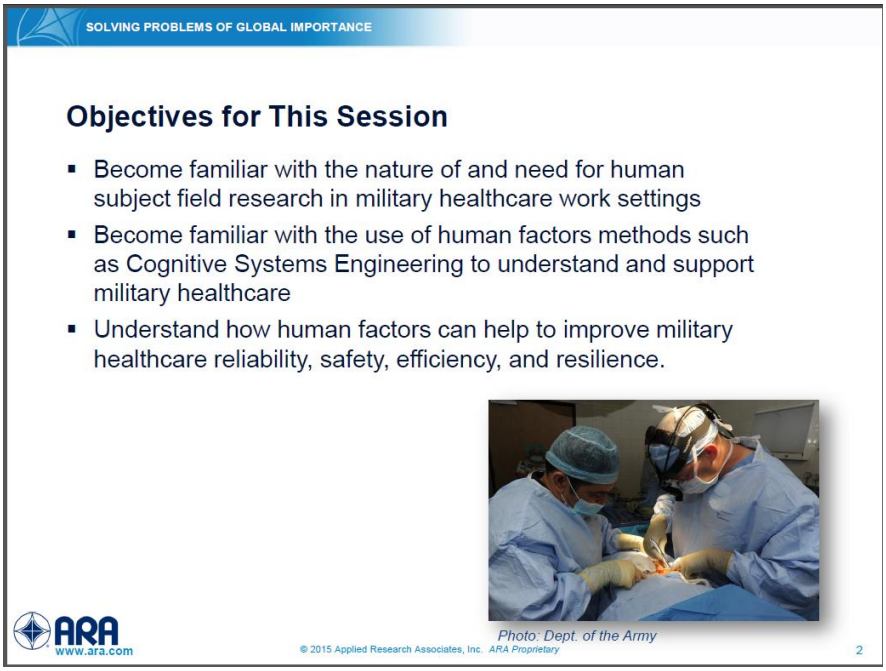
**Appendix X.** Support for Salience: IT to Assist Burn ICU Clinician Decision Making & Communication. IEEE Systems Man and Cybernetics International Symposium. October 2015. Hong Kong. (presentation)



## Research Site

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- Length of stay ranges from days to months.

*Photo: Dept. of the Army*


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## Research Design

- Goal is to improve care by better supporting the judgment of individuals and teams who care for patients through a cognitive aid that also assists communication.
- Three phases that are scheduled to take roughly a year apiece: foundation research, cognitive aid prototype development, and prototype assessment.

*Photo: Dept. of the Army*


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## EHR Table Format

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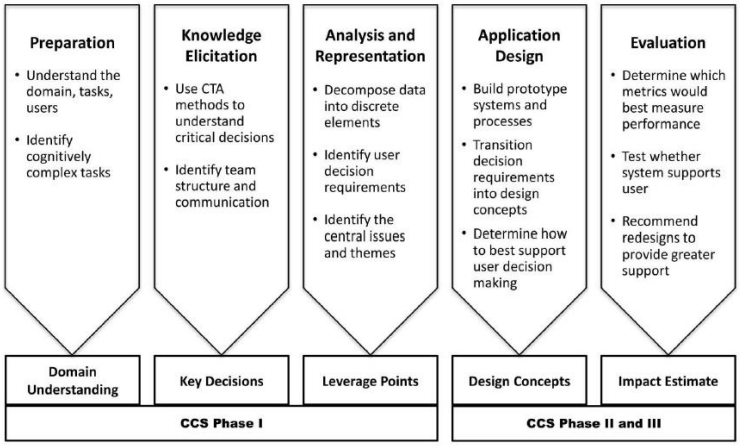
## Cognitive Systems Engineering





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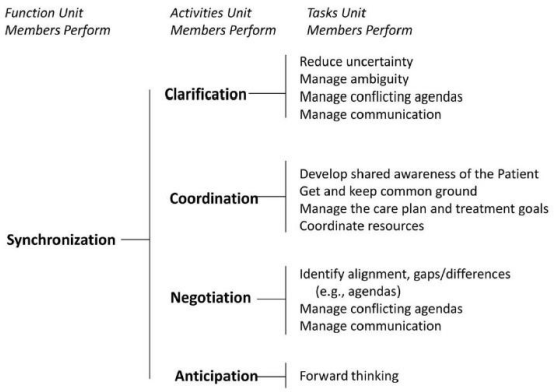
## BICU Cognitive Model





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## Core Functions

Six elements comprise the CCS, which are essential to support the BICU cognitive model

- Unit View
- Patient View
- Scheduling
- Order Management
- Checklists
- Tasking, Messaging, and Alerting


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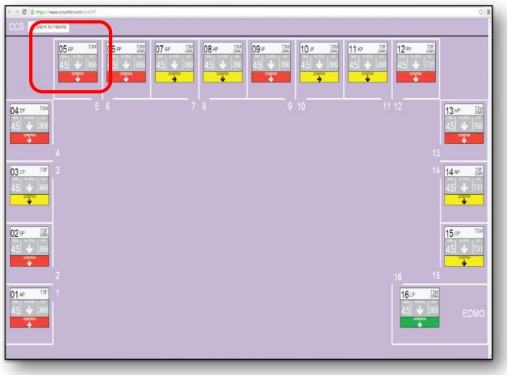
## Unit View

Patient identifier

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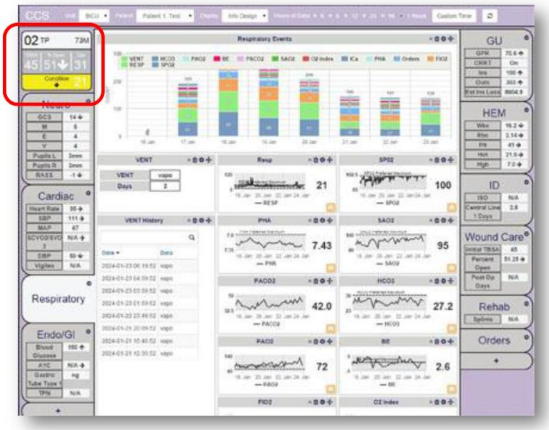
## Patient View

Patient identifier





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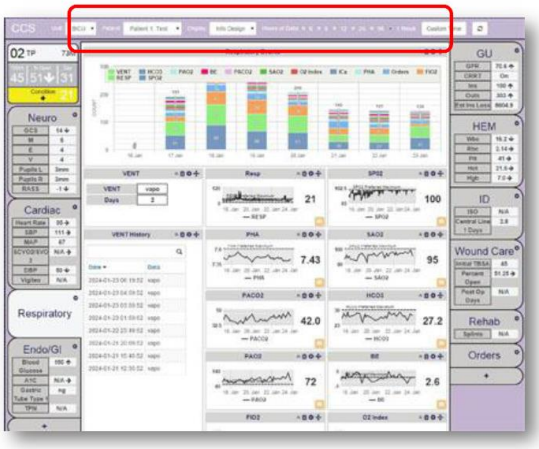
## Patient View

### Time scale

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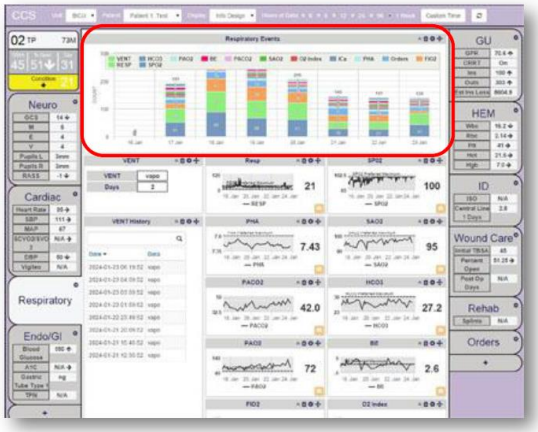
## Patient View

### Patient history events

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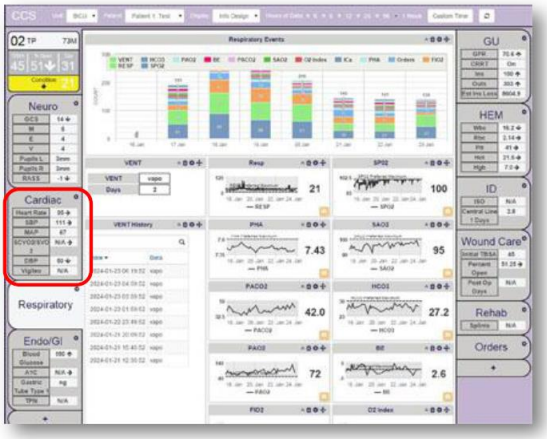
## Patient View

"Child" view tab





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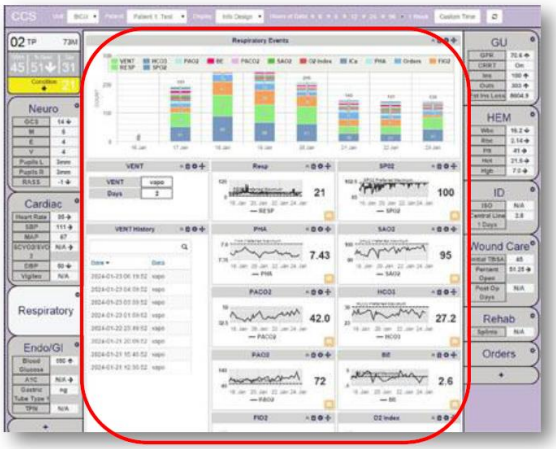
## Patient View

"Parent" view





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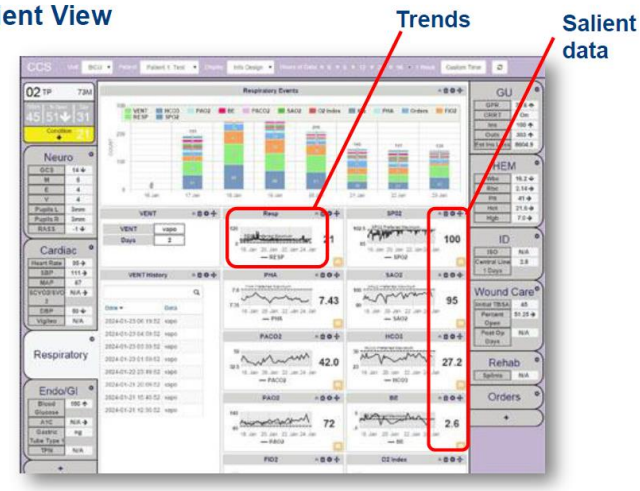
## Patient View





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## Machine Learning

- *Data Exploration*
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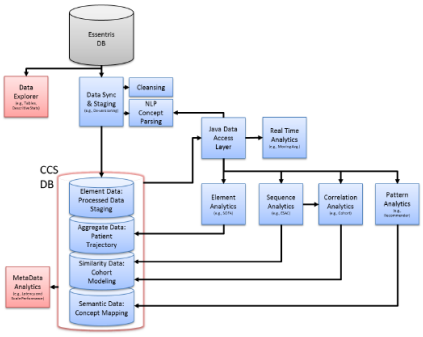
- *Metadata Analytics*





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Your comments and correspondence are welcome.

Christopher Nemeth, PhD
cnemeth@ara.com

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**Appendix Y.** Resilient Health Care Network Recognition Application

**1. Title:** A Cooperative Communication System (CCS) for Safe, Effective, and Efficient Patient Care

**2. Names of applicants**: Christopher Nemeth, PhD, LTC Jeremy Pamplin, MD

**3. Lead applicant**: Christopher Nemeth, PhD

**4. Organisations**: Applied Research Associates, Inc. (ARA), U.S. Army Institute of Surgical Research.

**5. Background.** Caring for critically ill patients presents clinicians with unique challenges that stem from their complex combination of life-threatening injuries and illnesses they face, particularly those who are admitted to a Burn Intensive Care Unit (BICU). Care providers from multiple disciplines must collaborate to make effective decisions, develop treatment plans, assess patient progress, and refine care management over time to restore patient health following devastating injury. However, their decisions are only as good as the information that is available and evident when the decisions are made. The way a problem is presented can either improve or degrade clinicians' cognitive and macro-cognitive work [1,2]. Critical information needed to make decisions is routinely difficult to obtain, often unavailable, and difficult to share. Gaps among information sources and among care providers impede decision making and healthcare delivery.

Through a Cognitive Systems Engineering (CSE) [3] approach (Fig. 1), our project team identified 20 key challenges and barriers to cognitive work on the BICU (e.g., "no means to synchronize care"), and translated them into concise problem statements and 39 system requirements, (e.g., "system shall provide access to a plan of patient care, visible to all care givers responsible for that patient"). We developed representations to describe the BICU environment and key resources clinician use there, formulated a set of use cases to describe for developers how the

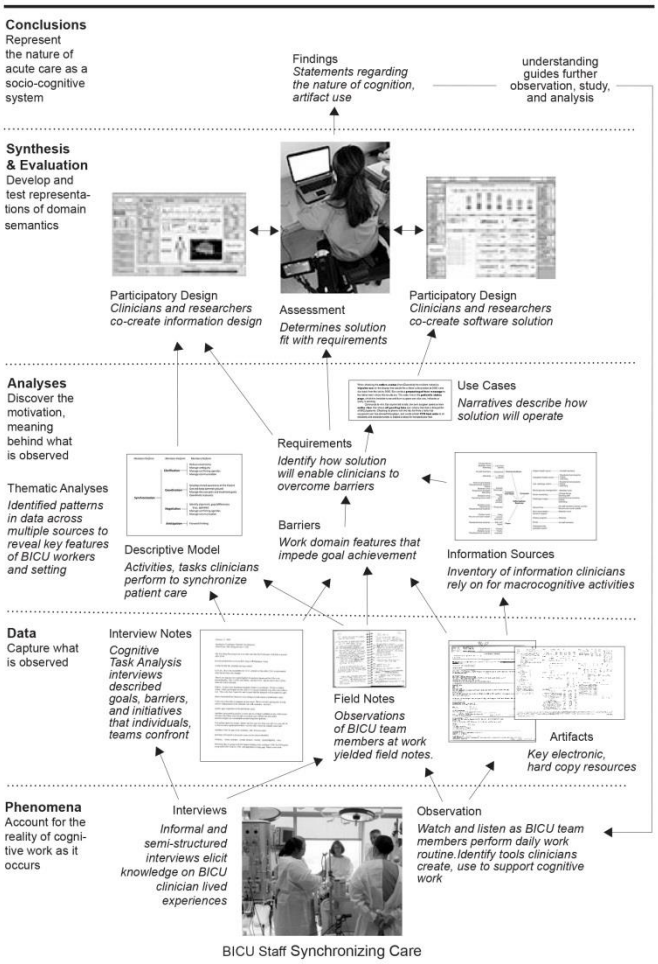


*Fig.1: Research design using CSE (Copyright © 2016 ARA, Inc.)*

system is intended to work, and developed a descriptive model of Burn ICU cognitive work showing care synchronization as the unit's primary mission. The information designer and programmers used the requirements and use cases to develop, evaluate, and refine both information design and software prototypes (Fig, 2). Displays are organized by body system in parent-child tab format to enable immediate recognition and assessment among systems (e.g., cardio-pulmonary, or cardio-renal). Our usability assessment found over 65% of 42 BICU clinicians preferred the CCS over their legacy IT system.

*Figure 2: CCS Patient View (Copyright © 2016 ARA. Inc.)*

**6. Resilience Innovation.** Understanding a work setting can improve worker ability to operate in spite of significant challenges such as unexpected changes in the type, rate, and volume of care demand. Insights from CSE studies can also help to contribute to the system's ability to adapt—to be more *resilient* [4]—when workers confront unforeseen challenges. The CCS supports resilience through:

a. *Ablility to Adapt to Surprise.* The use of CSE makes understanding what goes right, and occasionally does not, a routine learning process that can improve the CCS and the unit's ability to adapt.
b. *Ablility to Identify and Apply Resources.* Making trade-off options evident through the scheduling view supports planning and re-planning by improving clinician ability to identify and use resources.
c. *Awareness.* The data mining feature seeks and extracts important but subtle information patterns about the unit, patients or clinician(s) to reveal hidden interdependencies that would otherwise go unnoticed. Its messaging feature, unit-level view, and scheduling function enable clinicians to make informed trade-off decisions and develop and maintain common ground to synchronize care.

**7. How it will contribute to improved health care.** Intense collaboration among human factors researchers, information designers, developers and clinicians has resulted in 6 contributions by CCS to improved care:

*a. Unified picture for clinical data.* Presents salient data in one plane to facilitate accurate decisions. Users can customize patient view layout to refine what data are displayed and how they are shown.
*b. Built from the user to the system, not system to user.* Based on clinical mental models, unit practices.
*c. Directly support clinical work processes.* Satisfies requirements that we found are essential to this type of cognitive work. Messaging enables clinicians to detect problems, plan/re-plan, develop common ground.
d. *Evolvable/self-teaching.* Can identify patterns such as trends, comparable patients and care regimens, and metadata on how clinicians use the system so the CCS can evolve as the unit evolves.
*e. Pattern finding.* Machine Learning algorithms find, reveal patterns in patient data that would otherwise go unnoticed. Detects subtle interactions that threaten patient (e.g. incipient sepsis).
f. *Interoperability*. As a platform agnostic system, CCS can assemble and present salient data from multiple information sources including electronic medical records (EMRs), databases, and medical devices.

**8. Potential generalisability.** Founded on understanding work-as-done rather than work-as-imagined [5], the CCS supports adaptation and resilient performance (which are critical features of clinical work) and improves clinician collaboration and patient safety across care settings.

**9. Plan for take-up elsewhere.** The CCS could be adapted to devices and any EMR database to provide novel, task oriented, real-time role-based views of clinical data. Applied Research Associates will promote the adoption of the CCS in public and private care settings globally.


[1] Woods. D. D. (1988). Coping with complexity: The psychology of human behaviour in complex systems. In L.P. Goodstein, H.B. Andersen, and S.E. Olsen (Eds.). *Mental Models, Tasks and Errors*, Taylor & Francis, London. 128-148.

[2] Cacciabue, P.C. & Hollnagel, E. (1995). Simulation of cognition: Applications. *Expertise and technology: Cognition and human-computer cooperation*. In J.M. Hoc, P.C. Cacciabue, & E. Hollnagel (Eds.). Mahwah, NJ: Lawrence Erlbaum Associates. 55-73.

[3] Hollnagel, E. & Woods, D.D. (1983). Cognitive systems engineering: New wine in new bottles. *International Journal of Man-Machine Studies*. 18(6): 583-600.

[4] Hollnagel, E., Woods, D. & Leveson, N. (2006). *Resilience Engineering: Concepts and Precepts*. Aldershot, UK: Ashgate Publishing.

[5] Hollnagel, E. (2015). Why is work-as-imagined different from work-as-done? In Wears, R., Hollnagel, E. & Braithwaite, J. (Eds.). *Resilient Health Care, Volume 2: The Resilience of Everyday Clinical Work*. Farnham, Surrey, UK: Ashgate Publishing Ltd.

**Appendix Z.** Literature Review on Clinician Decision Making

Fifteen papers from professional literature provide an overview of clinician decision making and efforts to support it through various means including IT systems. Each summary is organized according to: Reference / Summary/ Method/ Findings/ Conclusions/ Relevance for CCS.

**Ahmed, A., Chandra, S., Herasevich, V., Gajic, O., & Pickering, B. W. (2011). The effect of two different electronic health record user interfaces on intensive care provider task load, errors of cognition, and performance. *Critical Care Medicine*, *39*(7), 1626-1634.**

Summary: This highly- structured comparative study employed a randomized crossover design to examine whether the manner in which data is organized and displayed to practitioners can affect users' ability to synthesize data into meaningful information. The study tested the hypothesis that novel user interfaces that present high-value, system-based data to provider will reduce task load and cognitive errors when compared to standard user interfaces. Participants used one of two interfaces to review the medical record of an ICU patient experiencing a specific clinical event ('active bleeding'), and responded to a structured questionnaire designed to assess the quality of their clinical decisions. Additional measures included task load and use of standard EMR vs novel use interface

Methods: 20 physicians (6 attending, 14 residents) examined patient data for 8 patients, 4 using a standard EMR interface and 4 using a novel interface, producing datasets of 160 responses (80 for each interface condition) for each of several measures. Participants responded to a 7-item forced-choice questionnaire designed to evaluate accuracy of clinical reasoning/decision making. Inaccuracy/errors were defined as deviations from correct responses to questionnaire items as determined by two SME respondents. Additional measures included task load (NASA TLX), speed to task completion, and number of data elements considered.

Findings: Results suggest that the configuration of the standard ICU user interface contributed significantly to task load, time to task completion, and the number of cognitive errors associated with identification and use of relevant patient data.

Conclusions: User interface configuration has a demonstrable effect on ICU practitioner performance. Task specific use interfaces, developed on the basis of a thorough understanding of user information requirements offer significant advantages over interfaces contained in standard electronic health systems. "EMRs, which indiscriminately present the entire data set every time, impose an unnecessary task load on the provider, are wasteful of time, and (are) associated with unnecessary error." (pg 1633). Authors conclude that standard EMRs flood practitioners with overwhelming amounts of data, which has cascade of effects that include increased uncertainty, difficulty finding key information embedded in multiple screens, increased cognitive workload and increased likelihood of errors.

Relevance for CCS: Study is directly relevant to CCS in its demonstration of significant effects of user-informed interfaces on clinical practitioner performance. However, the study has a number of limitations including:

- Use of a single clinical scenario, and requirements that participants complete their task in a fixed sequence.
- Task was deliberately structured to eliminate variability in clinical questions and responses and doesn't not represent full range of the clinical challenge
- Study focused exclusively on physicians and did not include input/data from others on the clinical team, family members or patient.

**Croskerry, P. (2002). Achieving quality in clinical decision making: cognitive strategies and detection of bias. *Academic Emergency Medicine*, *9*(11), 1184-1204.**

Summary: This article is a selective review and discussion of cognitive bias in context of Emergency Medicine. Author also describes some approaches to de-biasing, in order to mitigate diagnostic errors by ED physicians.

Method: Review

Findings: Author contends that in order to manage the extreme density and complexity of decision making in the ED, physicians adopt several decision-making strategies that are part of an informal Bayesian approach and which serve to reduce decision complexity and build economy and redundancy into the process. Author notes that strategies do not conform to any formal analytical decision making process, and include pattern recognition, rule-out-worst-case-scenario, exhaustive method, hypothetico-deductive method, heuristics and cognitive disposition to respond. Each of these strategies is described in detail, and a catalogue of heuristics, biases is presented that includes general properties, typical consequences and strategies for mitigation.

Conclusions: In the author's view heuristics and biases are account for errors in decision-making, so that improvement in quality of care and patient safety is directly linked to de-biasing efforts. Author also notes that errors are most likely to occur under conditions of uncertainty, particular in early stages of the decision process.

Relevance for CCS: Within the paradigm described in this paper, it seems reasonable to assume that decision tools that help clinical teams manage uncertainty would address what the author contends is the underlying cause of decision errors.

**Elstein A.S. & Schwartz A. (2002). Clinical problem solving and diagnostic decision making: selective review of the cognitive literature. British Medical Journal, 324, 729-732.**

Summary: Article is offered as a selective review of 30 years of research on clinical diagnostic reasoning. Primary focus is on the distinction between rational decision models and problem solving models and the insights each offers regarding clinicians' cognitive processes.

Method: Selected review

Findings: Problem solving approaches focus on diagnostic reasoning as a process of testing hypotheses. Solutions to difficult problems are identified by generating a small set of hypotheses early on and using them

to guide subsequent search for data. Problem solving processes of experienced physicians are more efficient and of higher quality than those of novice physicians, and employ a range of strategies, flexibly applied in response to feature of the cases such as difficulty.

In contrast, in traditional decision research, diagnosis is treated as opinion revision, with opinion updated with imperfect information (the clinical evidence). The standard tool for accomplishing this task is Bayes theorem. The authors note that Bayes theorem provides information about how clinicians should reason, but not about how opinions are revised. The focus is on statistical models of reasoning under uncertainty, and departures from those standards.

Conclusions:

Problem solving and decision making are distinct paradigms for conducting research on clinical reasoning, with distinctly different assumptions and methods. Authors suggest that both approaches have focused more on the mistakes clinicians makes than on what they get right. Nonetheless, the authors contend that the prevalence of these errors has not been established, and that expert clinical reasoning is very likely to be right in the majority of cases.

Relevance for CCS:

Research on clinical decision making has involved distinctly different paradigms. The CCS research team, in its emphasis on macrocognitive models and contextual features has adhered more to a problem-solving paradigm than a decision research paradigm. Differences between more and less experienced physicians in their approaches to diagnostic reasoning suggests the importance of tools and technologies that are designed for use by clinicians at a variety of skills and experience levels.

**Falzar P.R., Moore B.A., & Garman D. M. (2008). Incorporating clinical guidelines through clinician decision-making. Implementation Science 3 (13) doi:10.1186-5908-3-13**

Summary: As part of a larger discussion of the role of evidence-based practice in psychiatric treatment decision-making, this article offers an in-depth review and comparative discussion of several models of decision making and their relevance to clinical practice. (see "Findings" for synopsis)

Method: Detailed, integrative literature review

Findings: Major points contained in the article include the following:

- Studies of clinicians' failure to adopt evidence-based practice have been taken as evidence of systematic decision biases. Authors note that claims of systematic decision biases are firmly based in an extensive research literature demonstrating that clinicians do not adhere to probabilistic models that define 'optimal decisions' as those that most closely match actuarial prediction. Within this paradigm clinicians are characterized as sub-optimal decision makers, because they perform less capably than statistical models. Decisions are seen as binary events (correct vs incorrect) and performance is assessed against a standard of correctness.

- Classical decision theory (CDT) is characterized by authors as having limited application to the task of understanding how clinical make treatment decisions in real-world settings. The major drawback of CDT is its emphasis on optimal decisions derived from the adoption of logical models. Among its

shortcoming is the assumption of a 'friction-free' environment that fails to account for the complex clinical situations that medical decision makers routinely face.

- Authors note that naturalistic decision models appear to have great applicability to medical decision making. These approaches emphasize the importance of situational understanding to determining courses of action.

- Authors describe Image Theory (IT) in detail noting that it posits that decision-making involves the application of multiple strategies (in contrast to CDT which posits decision making as the complex application of a single strategy). IT describes the decision making as a process of winnowing down, or filtering out, unacceptable alternatives and then selecting a preferred alternative. The filtering process is posited to employ a screening strategy that relies on internally-held criteria (e.g. speed, proximity, cost).

Conclusions: (n/a)

Relevance for CCS: The article provides a helpful overview of CDT and naturalistic decision models and the application of each to clinical decision making. However, issues surrounding measurement of decision making are not addressed directly. For example, if one were to adopt a CDT approach, it would require somehow specifying each individual decision across the clinical practice team and identifying the statistical probabilities associated with that decision. Given the complexity, lack of complete information, and rapidly changing situation, those probabilities are essentially unknowable. For IT or other naturalistic paradigms, decisions are driven by internally held judgments, perceptions, knowledge and understanding within the context of a complex and fluid socio-technical system that eventuate in a selection of a course of action (e.g. a treatment decision). The 'goodness' of a decision depends on all those factors, and in such complex environments there are often multiple 'good' decisions that might occur in response to the same set of events.

**Friedman C.P., Elstein A.S., Wolf F.M., Murphy G.C., Franze T.M., Heckerling P.S., Fine P.L. et al (1999). Enhancement of clinicians' diagnostic reasoning by computer-based consultation. JAMA Vol 282 no 19 pg 1851 – 1856.**

Summary: Study examined the extent to which consultations with computer-based diagnostic support systems (DSS) improved clinicians' diagnostic hypotheses in a set of diagnostically challenging cases. The study was undertaken because most studies of clinical system support have emphasized the accuracy of the computer system alone. For example, how often a system in the hands of expert users could identify the correct diagnosis. In this investigation, clinicians were placed in the role of direct users of the DSS.

Method: The study employed an experimental procedure to elicit clinicians' diagnostic hypotheses before and after DSS consultation, in response to an assigned set of cases. Effects of consultation with the DSS were determined using pre-post DSS comparisons. Two mature DSS were selected for use in the study (ILIAD and Quick Medical Reference). The study was conducted at three academic medical centers. Data was collected over a three year period. Sample consisted of 12 faculty physicians, 12 residents and 12 medical students from each medical center, assigned to one of the two DSS used in the study. All participants were trained individually on the DSS to which they were assigned.

Cases used in the study consisted of 36 detailed case summaries developed by the investigators, and based on actual cases from each of the three participating medical centers. Each participant received a set of 9 cases. Before and after consultation with their assigned DSS, participants generated a list of up to 6 diagnostic hypotheses for each case.

Quantitative measures of diagnostic quality were developed specifically for the study.

Findings: Across the full sample of clinicians and cases, consultation with DSS had a modest positive effect on diagnostic reasoning. Although significant at all three experience levels, effects of DSS consultation were greatest for medical students. Smaller effects for more experienced physicians indicated that any case difficult enough to challenge an experience clinician is also likely to challenge the systems used in the study.

Conclusions: Authors note the diagnostic hypothesis formation is only one aspect of the clinical process, and that DSS may be more useful in other ways, such as suggesting tests and other aspects of patient evaluation. The authors emphasize the importance of considering both the clinical user's experience and knowledge and the context in which diagnostic reasoning occurs. Specifically:

- A clinician's own medical knowledge plays a critical role in a his/her interaction with a DSS. Revision of a diagnosis is a joint functions of what the clinical knows and the information provided by the DSS
- Variation in how clinician-users interact with the DSS is important. The system's clinical value depends in part on how clinicians choose system features, and how they enter and retrieve information.
- Consultation with a DSS may have both positive and negative effects on a clinician's diagnostic reasoning. The DSS may offer advice that is "appealing but incorrect" (pg. 1852).

Relevance for CCS: First, it is important to take into account that use of health IT and effects on decision making and diagnostic reasoning are likely vary by clinical role and experience level. Second, this is a large, long-term and very carefully designed study that, like so many others in the literature, focuses on physicians, uses highly-structured tasks, and was conducted in a laboratory setting.

**Garg, A. X., Adhikari, N. K., McDonald, H., Rosas-Arellano, M. P., Devereaux, P. J., Beyene, J., ... & Haynes, R. B. (2005). Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *Jama*, *293*(10), 1223-1238.**

Summary: Article reports on a systematic and comprehensive review of studies using controlled trials to assess the effects of computerized clinical decision support systems (CDSS) and to identify sources of benefit.

Method: Based on pre-selected inclusion criteria, 100 studies were identified for inclusion in the review. Reviewers abstracted data on methods, setting, CDSS characteristics, patient characteristics and outcomes. Abstracted data were examined and findings compiled for 2 primary research questions: 1) do CDSSs improve practitioner performance or patient outcomes? 2) Which CDSS and study-level factors are associated with effective CDSSs? Authors note that expert physician opinion or clinical practice guidelines usually formed the knowledge bases for the CDSS

Findings:

- Issues that impact the effectiveness of CDSSs include user acceptance, workflow integration, compatibility with legacy systems, system maturity, and upgrade availability.
- Cheaper, non-computerized alternatives maybe equally or more effective in improving care and reducing medical errors.
- Evaluation of CDSS effectiveness is difficult to assess because more studies are not able to enroll sufficient numbers of patients for statistical tests of improvements in patient outcomes. Given that, 'effectiveness' is limited to influence of CDSSs on practitioner performance

Conclusions:

- Evidence from this systematic review suggests that evidence that CDSS improve efficiency and reduce costs is limited. Cost-effectiveness of systems remains essentially unknown.
- Systems are proliferating and their technical performance and usability are improving. In parallel, the number and quality of evaluation is increasing, and show that many CDSSs improve practitioner performance.
- Additional research is needed to demonstrate the effects of CDSSs on patient outcomes.

Relevance for CCS: This review study provides a basis of comparison of the CCS evaluation with prevailing standards.

**Gittell, J. H., Beswick, J., Goldmann, D., & Wallack, S. S. (2015). Teamwork methods for accountable care: Relational coordination and TeamSTEPPS®.*Health care management review*, *40*(2), 116-125.**

Summary: In accord with IOM's call for development of a culture of teamwork that functions at multiple levels throughout a health care system, this review paper seeks to identify teamwork measures that provide diagnostic information on an organization's teamwork along with validated interventions.

Method: The research team reviewed 37 teamwork measures published in a previous review by Valentine et al (2013)[1] against 4 criteria of psychometric validity: internal consistency, interrater reliability, structural validity, and content validity and that also were designed to measure teamwork at multiple levels across an organization. Authors identified 10 measures that met all four criteria and they are presented in the body of the report.

Findings: Authors present helpful and detailed information on teamwork measures in healthcare and employs a relational coordination model to organize the available measurement tools. They use the same relational coordination model to organize and present validated teamwork intervention tools. Relational coordination employs 3 relational dimensions (shared goals, shared knowledge, and mutual respect) and four

[1] Valentine M., Nembhard, I., & Edmondson, A. (2013) Measuring teamwork in health care settings: A review of survey instruments. *Medical Care* 53, no. 4 e16–e30.

communication dimensions (frequent, timely, accurate, problem-solving) that together are held to underlie effective coordination of work.

Authors cite studies in support of associations between relational coordination and a wide range of outcomes, and present a table of the various outcomes, organized as follows: quality outcomes, efficiency outcomes, patient/family engagement, worker outcomes.

Conclusions: The review provides a detailed catalogue of team process measures and outcomes that have been linked in prior research to the teamwork construct of relational coordination.

Relevance for CCS: Given that the CCS is intended for use by clinical practice teams, it has embedded within it a number of features designed to support and enhance communication and coordination among clinical providers. Evaluation of that aspect of the CCS requires measures that reflect teamwork and/or outcomes associated with teamwork.

**Kushniruk, A. W. (2001). Analysis of complex decision-making processes in health care: cognitive approaches to health informatics. *Journal of biomedical informatics*, *34*(U), 365-376.**

Summary: The first portion of the article presents the theoretical foundations for the study of decision making in medicine and other complex work domains. Author notes that although conceptually similar, medical problem solving and decision making in complex tasks have studied from different theoretical perspectives and using different methodologies. Study of medical problem solving typically focuses on generation of diagnostic hypotheses and overall situation assessment that precede a diagnostic decision. Research on decision making typically focuses on the 'decision event' itself. In real-world contexts however, reasoning and decision-making are tightly linked. Decisions are the outcome of problem-solving processes, where the decision represents the solution to the problem, and leads to an action. The author discusses various theoretic approaches that are relevant to the study of medical problem solving/decision making including: the recognition-primed decision model, studies of situation assessment; the cognitive continuum; and, the role of expertise. The author discusses issues in the study of cognition and medical decision making that warrant additional attention, including the relationship between the study of complex decision making and application of findings from those studies to the development of improved decision support systems in health care.

The author then briefly presents results of a study (published elsewhere), that demonstrates use of think-aloud methods for conducting a cognitive task analysis (CTA) of complex decision making in the ICU. The study illustrates an approach to studying decision making by clinical practitioners dealing with a complex clinical event (pulmonary embolism).

Method: Participants were 24 physicians at three levels of experience (8 medical students, 8 residents, and 8 ICU specialists). Participants were provided written case studies that described patients' overall clinical presentation as well as evidence from specific tests and scans. Some cases contained consistent evidence of PE, and others presented varying degrees of conflicting information. Participants were asked to 'think aloud' while they considered each case and arrived at decisions regarding treatment.

Findings: Findings indicated differences in strategies for dealing with ambiguity of evidence as function of physician experience level. When confronted with conflicting evidence, medical students tended to base their decisions on scan and test results. Expert physicians were more likely to focus on the overall clinical picture rather than a specific test results. Faced with conflicting evidence, residents most often sought to defer the decision. In addition, expert physicians focused on developing a strong situation assessment for each case, and to use that in interpreting specific test results.

Conclusions: Author suggests that findings from the research literature and the example study indicate the importance of considering cognitive processes of potential system users in order to adequately support them in making complex decisions. Findings suggest that users at differing levels of experience may employ significantly different strategies, consider different information, and require different types of decision support. Taking those differences into account in design of systems is necessary if systems are going to offer effective decision support.

Relevance for CCS: Offers convergent evidence for use of CTA methods to study clinician problem solving/decision making; the importance of considering cognitive requirements in design of decision tools, and the need for flexibility in those designs in order to support clinical providers in different roles and different levels of experience.

**Landman, A. B., Redden, L., Neri, P., Poole, S., Horsky, J., Raja, A. S., ... & Poon, E. G. (2014). Using a medical simulation center as an electronic health record usability laboratory.** ***Journal of the American Medical Informatics Association*****,** ***21*****(3), 558-563.**

Summary: A case study report of use of a medical simulation center to perform usability tests on health information technology, as part of a project to examine how Emergency Department (ED) physicians use the electronic health records that are currently available to them. The article provides a detailed description of requirements for conducting usability tests in a medical simulation center.

Method: Project employed a single clinical scenario representative of a typical ED visit. The scenario was intended to study use of electronic documentation rather than medical knowledge or technical skills, and was therefore intentionally straightforward. Participants were ED residents (number of participants is not included in the research report). The simulation scenario required four research staff, including a physician-actor who play the role of the patient; a research analyst who facilitated and moderated the session; a research analyst who took notes during the session; a simulation center technician. Sessions were also recorded on videotape.

Findings: The key tasks and resources required to set up and use an electronic health record in a medical simulation center were compiled and presented.

Conclusions: EHRs can be successfully integrated into existing simulation centers, which may provide realistic environments for usability testing, training and evaluation of human-computer interactions.

Relevance for CCS: Case study offers a roadmap for the tasks and resources required to conducted usability tests of health information technology in medically realistic environments. Authors note that more complex simulations scenarios, the tasks and resources will require additional planning and resources.

**Ng, L. S., & Curley, M. A. (2012). "One More Thing to Think about…" Cognitive Burden Experienced by Intensive Care Unit Nurses When Implementing a Tight Glucose Control Protocol. *Journal of diabetes science and technology*, *6*(1), 58-64.**

Summary: This case study examined clinical protocols that surround tight glucose control in the ICU as an exemplar case that demonstrates the cognitive workload issues that ICU nurses experience as a function of rapid increases in the number and complexity of protocols they are expected to know and implement.

Method: Integrative literature review that incorporates research studies from nursing, critical care medicine, decision science, human factors and cognitive systems engineering.

Findings: Evidence-based clinical protocols may not seem burdensome when considered individually, but in the context of real-world clinical practice, nurses are expected to know multiple protocols and be capable of successfully implementing then during ongoing patient care. Authors suggest that clinical protocols may function as a cognitive burden that interrupt the nurse's primary task of patient care by adding complexity and busyness and increasing mental workload. Studies of computer-based protocols suggest that when nurses are involved in design and application of protocols, cognitive workload is reduced.

Conclusions: Coupled with well-designed computerized algorithms, reduction of clinical cognitive burden will enhance clinical practice and support improved patient outcomes

Relevance for CCS: The ICU bedside nurse is a critical focal point for implementation of protocols and other aids intended to optimize care. Poorly designed tools that fail to reflect the socio-technical system in which nurses function can have significant negative effects, increasing cognitive workload and distracting nurses from their primary patient care function.

**O'Sullivan, D., Fraccaro, P., Carson, E., & Weller, P. (2014). Decision time for clinical decision support systems. *Clinical Medicine*, *14*(4), 338-341.**

Summary: Paper provides overview of current state of health care IT systems, including impediments to successful adoption of clinical decision support systems (CDSS) across large-scale medical systems, suggestions for addressing current limitations and strategies for future design and development.

Method: Literature review and synthesis

Findings: Clinical decision support systems offer a range of supports for clinical practitioners including improved efficiency and safety. Despite 50+ years of robust research by the academic computer science community, implementation of CDSS has been limited. Reasons identified in this paper include:

- Volume of high-quality data required for state-of-the-art systems and translation of that data to machine-readable states
- mapping of CDSS to existing clinical processes and workflows
- Focus by large-scale commercial developers on well-structured problems such as order-entry and alarms and alert functions
- Poor interoperability among existing clinical systems that limit development of generic, reusable, and scalable CDSS

- Systems that are poorly designed and have limited utility due to lack of attention to the socio-technical context in which clinical practitioners operate

- Reluctance on the part of clinical practitioners to adopt systems that lack transparency re system algorithms and methodologies

Conclusions: Development of effective CDSS requires close collaboration between computer scientists and clinicians, so that each community better understands the other. Adoption will require better-informed end users (e.g. through enhanced training and instruction for clinical practitioners). Authors assert that technology capability is sufficiently advance to offer meaningful, effective support for clinical decision makers. What needs to be addressed are the challenges identified above.

Relevance for CCS: Note that the CCS project is an example of close collaboration among system developers, cognitive engineering professionals and the clinical community. Nonetheless, the team has had to grapple with several of the challenges noted in the Findings section (e.g. data volume, interoperability issues).

**Patel, V. L., Kaufman, D. R., & Arocha, J. F. (2002). Emerging paradigms of cognition in medical decision-making. *Journal of biomedical informatics*, 35(1), 52-75.**

Summary: A comprehensive and detailed review of theory and research on leading paradigms of decision-making and their relevance to decision making in healthcare. Authors also provide an examination of technology-mediated decision-making[2].

Method: Critical, integrative review

Findings: Paper is organized in six sections and built around a number of key claims that characterize the vast literature that is the basis for this review (the reference list contains 123 citations). Claims are described as hypotheses about the decision-making process that have substantial support in the literature. Authors offer the following definitions relating to decision making: "decisions involve choosing a course of action among a set of options with the intent of achieving a goal….. good decisions are those that effectively choose means that are available in a given situation to achieve as well as possible the individual's goals." (pgs. 53-54).

Conclusions: The authors put forth the following Claims which summarize their key findings

- Claim #1: **Heuristics and biases significantly impact the process of decision-making had have been well documented in the context of health-related decisions**. This research that supports this claim is based on rational choice approaches (also referred to as 'traditional' or 'classical' decision research) that compare decision making to a normative standard (e.g. subjective estimated utilities or Bayesian models). Systematic deviations from normative standards are characterized as biases, and the source of error.

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[2] Despite its publication date, this paper continues to be one of the best in-depth summaries of decision research and its application to clinical practice available.

- Claim #2: **The classical approach and research on heuristics and biases do not adequately characterize decision-making process.** In this section, authors summarize philosophical and empirical criticisms of rational approach models. The authors conclude that the 'impoverished situations presented to physicians in judgment studies may have no true analog in the world of clinical medicine' (pg 60).

- Claim #3: **Medical decision-making research and problem solving research employ distinct theoretical and methodological approaches that draw on diverse research traditions to study the same phenomena, resulting in substantially different conclusions.**

- Claim #4; **Decision heuristics and biases often form the basis of robust reasoning strategies by expert clinicians**. Authors refer to 'medical cognition' as an overarching concept for studies of cognitive process, including perception, comprehension, reasoning, decision-making and problem solving in the health care domain. They note the guiding metaphor for decision research has been rational choice among alternatives. In problem solving research, a key concept is search of the problem space, in which the problem solver is seen as performing an operation to move toward a solution or goal state (e.g. diagnosis, treatment plan). In the very detailed discussion provided, authors describe several studies that suggest the importance of considering differences in level of expertise (typically part of the problem solving paradigm) in understanding heuristics and biases.

- Claim #5: **Conceptual knowledge differs in important respects from procedural knowledge and has a qualitatively distinct and predictable effect on decision practices.** Authors note that research in the problem-solving tradition indicates that as expertise develops, the clinician's knowledge of disease process becomes more depending on clinical experience and is increasingly guided by examples and analogies, rather than a functional understanding of the system in question. Understanding of basic science plays a role in reasoning about complex problems, generating explanations and justifications for decisions.

- Claim #6: **Decision making in 'real world' situations imposes unique demands (e.g. time pressure, stress, ambiguity) on the decision process and these demands are not adequately captured in most laboratory decision studies.**

- Claim #7: **Decision making in realistic settings is often characterized by period assessment of a single option rather than evaluation of a fixed set of alternatives. Systematic weighing of discrete pieces of evidence is the exception rather than the rule.**

- Claim #8: **Decisions in high stress situations necessitate immediate response behavior and perceptual cues may play a more prominent role in the decision process.**

- Claim #9: **Team decision-making is characterized by emergent properties that cannot capture by merely studying individual decision makers.** Authors describe several studies that provide descriptive accounts of team decision making in ICU settings and suggest that the team's decision making involves: a) management of multiple information streams; b) communication and coordination among individuals and across different data sources. They further suggest that the communication space constitutes the bulk of the information transaction and clinicians time.

- Claim #10: **Technologies mediate the decision making process in distinct and often counterintuitive ways that can produce unintended consequences.**

  Claim #11: **Decision technology does not merely facilitate or augment decision making rather it reorganizes decision making practices.** Authors conclude that technology that directly supports communication among clinicians should greatly improve how organizations acquire, present, and use information.

Relevance for CCS: This review shows the complexity of examining decision making in the clinical setting. Normative decision research is extensive and well-replicated but of limited utility to understand how decisions are made, how to better supports them, and how to measure/evaluate them. Naturalistic and problem solving paradigms are more useful, in part because they take into account 1) individual different in cognitive process as a function of level of expertise, 2) the role of contextual factors (time pressure, uncertainty); 3) importance of acknowledging the individual decisions are embedded in the communication/coordination of the clinical team 4) role of technology in mediating and shaping decision processes.

**Patterson, E. S., Ebright, P. R., & Saleem, J. J. (2011). Investigating stacking: How do registered nurses prioritize their activities in real-time? *International Journal of Industrial Ergonomics*, *41*(4), 389-393.**

Summary: Qualitative study sought to describe how nurses organize and prioritize the myriad tasks required to care for hospitalized patients, and the sorts of replanning and reprioritization required in real-time acute-care settings. The authors employ the concept of "stacking" to describe how nurses at the bedside prioritize one task over another, and advance a normative framework of task prioritization that encompasses a 7-level hierarchy of nursing activities.

Methods: Study participants were 30 RNs representing a range of hospital-based clinical settings. Each participant was observed for a 3-hour period in the work setting and then interviewed about their prioritization decisions using semi-structured knowledge elicitation methods. Interviews were transcribed and coded using 12 categories of tasks.

Findings: Based on coding of 422 prioritization decisions, findings suggest a 7-level hierarchy of prioritization of nursing activities as follows (from highest to lowest)

- imminent clinical concerns
- high uncertainty activities
- significant, core clinical caregiving and managing pain,
- relationship management
- document, helping other, patient support
- system improvement, cleaning/preparing supplies
- person interactions/social activities (lowest priority). Among the most experienced nurse

Conclusions: Prioritization along this continuum allows nurses to manage and group activities. However, uncertainty can interfere with efficient management and reprioritization, increase workload and inefficiency, and fatigue (distance walked).

Relevance for CCS: Reducing uncertainty allows nurses to work more efficiently and provide optimal patient care, by allowing them to plan and prioritize their tasks.

**Pickering B.W., Gajic O., Ahmed, A., Hersevich V. & Keegan M. T. (2013). Data utilization for medical decision making at the time of patient admission to ICU. Critical Care Medicine Vol 41,#6, 1502 – 1506.**

Summary: Study examined the extent to which information overload in electronic medical record (EMR) might hinder providers' abilities to identify important clinical data and in doing so contribute to medical error. Study objective was to identify clinical information needs of ICU physicians, as compared to information provided by EMRs. Authors suggest "the workload associated with the extraction of data from an environment equipped with a comprehensive EMR is large and can be associated with errors of cognition." (pg 1503). Authors identify periods of care that are particularly prone to error, including patient admission, handoff, and discharge where failure to pass along information may lead to patient harm.

Method: Findings are based on observations of ICU admissions conducted between 2008 – 2012 in three ICUs at a single academic health care center equipped with a comprehensive EMR. Admitting teams consisted of an attending physician, a senior and a junior resident. Data elements and categories of information used during initial diagnosis and admission for specific patients were captured using a questionnaire, which was completed within three hours of admission. The EMRs of those patients were examined and the total amount of clinical data available was calculated for pre-selected categories (e.g. vitals signs, medications, lab results). Outcome measures included the clinical information clinicians reported using and the total information available to them for each patient, for each of the pre-selected information categories.

Findings: Findings indicate that physicians use only a small number of available clinical information categories as they make diagnostic and treatment decisions of patients recently admitted to the ICU. Despite the vast array of information available through the EMR, the median number of concepts used by any provider during the admissions process was 11, (6 – 16).

Conclusions: EMRs contain an abundance of infrequently used or never-used data, raising the possibility that EMRs present a great deal of information to physicians that they neither want nor use. The overabundance of clinical data may be distracting or overwhelming clinicians. Authors further suggest that study findings are consistent with other research indicating the negative impact of EMRs on physicians' abilities to find the appropriate clinical information with which to make time-critical medical decisions. This study and other research cited indicate the need for clinical information management strategies that allow access to infrequently used information, and prioritize display of commonly-used information categories. "Most evidence would suggest that the development of parsimonious views of clinical data, based on user information needs, has the potential to reduce information overload and improve provider performance" (pg 1506).

Relevance for CCS: Findings from the study align closely with findings from the CCS CTA and recommendations from Year one. Since the study uses different methodology to arrive at the same set of conclusions, it provides strong confirmatory evidence of the validity of CCS findings, and the value of the overarching design approach the team was taken.

**Wright, M. C., Taekman, J. M., & Endsley, M. R. (2004). Objective measures of situation awareness in a simulated medical environment.*Quality and Safety in Health Care*, *13*(suppl 1), i65-i71.**

Summary: Article addresses the need for objective measures of performance (including cognitive performance) that can be used to evaluate the skills and training of individual and teams of clinical practitioners, and to evaluate the impact of new processes, technology, and equipment. The authors describe the importance of situation awareness (SA) to decision making and performance in dynamic environments and, discuss the procedures required to develop objective measures of SA.

Method: focused review

Findings:

- Available assessment instruments include direct and indirect measures of performance, mental workload measures, and analytic measures of specific aspects of performance (e.g. communication). Examples include:
    - Direct performance measures typically involve a "score" e.g. time on task, error rate, degree or error (deviation from a defined path). Maybe difficult to define in the medical arena because there may be many possible solutions to a particular problem. Examples from prior research with medical simulators include: success/failure at a given task or scenario; time to identify a problem or adverse events that has been pre-programmed; errors; time to detection of a problem or diagnosis; task completion time.
    - Indirect performance measures typically involve subjective judgments e.g. self-ratings or observer ratings. Cites research by Gaba that observer ratings of behavior, including cognitive components such as decision making or team communication skill is considerably more difficult (and less reliable) than for motor skills or technical performance.
    - Mental workload measures include subjective ratings of workload, secondary task measures (ability to perform a secondary task implies lower workload) and physiologic measures
    - Task analytic measures include time and motion studies, time spent on subtask components, analysis of communications
- Offers a simplified definition of SA as an internal mental model of the current state of an individual's environment, along with Endsley's formal definition, which breaks the construct into three levels (perception, comprehension, projection into the future).
- Endsley distinguishes SA from decision making and performance but asserts that it is an essential component of dynamic decision making such that improved SA results in improved decision making.

- Subjective ratings of SA may reflect participants' confidence in their SA ( accurate or not) rather than providing a true measure of their SA

- Authors introduce and describe the situation awareness global assessment technique (SAGAT); they suggest that SAGAT has not been widely used in real-world medical environments and applications, though it may be useful in simulated medical environments. They cite one study that indicates limited utility of SAGAT in evaluation of SA in medical environments.

- Authors provide very detailed description and explanation of the technique for developing a task (or domain) specific SAGAT. The technique appears to have many uses but is extremely resource intensive to develop the array of materials and knowledge documents it requires.

- Authors note the importance of assessing team SA in complex decision environments.

Conclusions: Future research is necessary to establish the SA requirements for a variety of medical tasks, roles, and teams. Authors suggest that SAGAT may be a valuable tool for doing that.

Relevance for CCS: Situation awareness is a key component for understanding decision making in real-world settings. The approaches described in this paper are promising but not fully developed as measures. However there may be concepts or sub-elements that could be helpful in developing measures for use in the CCs evaluation.

## Appendix AA. Initial Requirements Analysis

Based on the synthesis and integration of findings, the team developed an initial set of system requirements for CCS using the following framework:

- What is the barrier or challenge the clinical team faces?
- What does the clinical team need/require to overcome that challenge?
- What system or display features could help address that challenge?
- What is the anticipated impact of meeting that requirement on team coordination, efficiency, and patient care?

This Appendix contains the full set of initial requirements, the problems they are intended to address, the system features suggested by requirements, and initial ideas about how system features might impact patient care, efficiency and length of stay.

| **Problem/Barrier** | **Needs/Requirements** | **System Feature Concepts** | **Anticipated Impacts** |
|---|---|---|---|
| No effective means to synchronize and adapt different aspects of patient care over the course of a shift (e.g., among RN, OT/PT, wound care)<br><br>Lack of awareness around activities/ events that are tightly | • Need to determine optimal timing and sequence of activities<br>• Need awareness of planned/scheduled patient care activities (e.g., wound care, rehab, line changes, etc.)<br>• Means to share the plan<br>• Means to adapt the plan in real time and share changes across the team.<br>• Bedside nurse needs to shift the goals and priorities<br>• Means to know how changes in orders affect/change planned activities<br>• Means to know what planned events are and who needs to be there | • Visualization of patient schedule for shift (patient x time), shareable across team<br>• Ability to sequence or overlap patient care activities<br>• Configurable patient groupings<br>• Prepackaged text to indicate changes to schedule (e.g., there's a ½-hour delay in PT)<br>• Sequence, time of planned activities<br>• Provide reason for delay, and remedy (using pre-packaged text)<br>• Overview through time, for unit management<br>• Visually connect interdependent events<br>• Prompt/notify appropriate person when change impacts their activity (e.g., when wound care | • Patients get needed care with fewer delays<br>• Efficient use of staff time<br>• Reduces unmet treatment plans and intentions<br>• Supports replanning – helps staff identify windows of opportunity |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| coupled<br><br>No efficient communication of patient status change across disciplines | • Practitioners need to understand what's going on with their group of patients across the shift (whatever their group happens to be) | impacts PT/OT and RT) | |
| Updated information is available but not readily accessible or visible to clinicians (e.g., cultures) | • Clinicians need to be aware that updated information is available, particularly re: lab cultures | • System provides news feed from lab about cultures.<br>• Red/amber/green about status of labs (received or not; in progress; completed) | • Fewer care delays<br>• More efficient tracking and follow up<br>• Better use of staff time<br>• Less reliance on verbal exchanges |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| Orders late, missing, or overtaken/replaced by other orders<br><br>Reliance on verbal orders and no standardized way to share orders | • Need efficient, accurate way to specify meds, procedures<br>• Physicians need access to orders from Charge Nurse's checklist<br>• Physicians need prompts to enter orders<br>• Need indicator of status of order entry (has it been placed or not?)<br>• Need indicator of status of order (in process, completed)<br>• Physicians need to be aware when entering order that it's the same as or different from previously entered orders<br>• Changes to orders need to be disseminated to wider team so that team has common ground. Changes in orders need to be apparent to whole team | • Order pick list and window per patient to support real-time order entry during rounds<br>• Order status (have orders been received? Completed?)<br>• Notify others if needed (e.g., infections control)<br>• Provide prompt for delayed order entry (based on programmable timing tripwire)<br>• Display the information required to make decisions about an order available with the order (the relevant parameters)<br>• Provide molar/aggregated view of delays for a given patient<br>• System will track (and possibly highlight) when an order has been changed.<br>• System will provide timestamp for orders | • Fewer care delays<br>• More efficient order entry and tracking<br>• Better use of staff time – reduced need for repeated follow-ups<br>• Reduced reliance verbal orders |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| Documentation requires significant time from key members of the clinical team (RNs, Residents, RTs etc.) and is often redundant | • Information Management tools and processes built around efficient use of staff time and effort<br>• Minimize staff time required to capture information by reducing redundant information gathering and entry<br>• Minimize staff time spent as the 'system integrators' who move data from one system to another<br>• Need 'user-friendly' interfaces/systems | • System built on a relational database that has all the information relevant to a given patient, so that there is true interoperability: ability of separate systems to cross-populate data, in real time<br>• System supports capturing and displaying time-based, patient-based, unit-based data<br>• Interfaces support simple data entry and pulling information (faster, more efficient documentation; errors/disconnects more easily spotted)<br>• System's ability to recognize 'repetition' when new documentation is introduced (e.g., 'we already capture that data over here')<br>• System features that scan new documentation requirements for novel information/redundancies (don't just add more) | • Decreased time spent entering, moving, repeating, re-entering, data<br>• More time with patients; increased ability to attend to patient issues and needs<br>• Decrease cognitive workload<br>• Decrease in potential data entry errors (repeated entry of same data increases chance for error) |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| Lags in information updates means information in system is sometimes stale/inaccurate | • Means to indicate if patient is highly unstable (because information for unstable patients can become inaccurate in short timeframe)<br>• Means to know whether information in system is up-to-date (e.g., is this an accurate reflection of the patient's status right now?)<br>• Means to know whether orders are in process but results not entered into system yet (e.g., cultures, lab results)<br>• Means to know recency of information updates<br>• Means to capture and disseminate changes to orders that occur verbally within sub-teams | • Information should be time stamped (Q: which information in particular?)<br>• System should highlight recent results—e.g., lab results, cultures. And also highlight orders that are in process<br>• System should highlight/provide alert when orders are changed<br>• System should highlight/alert staff to contraindications (e.g., patient positioning, nutrition) | • Optimized patient care<br>• Better use of staff time – reduced need for repeated follow-ups<br>• Reduced reliance verbal orders<br>• Reduced potential for error |
| Trends are important information, but can't get them from Essentris or other IT.<br><br>No ability to keep track of patient status over time > 24 hours. | • Clinicians need trend information<br>• Need view of patient that is more than just this shift. Both macro level view of indicators and over longer time spans | • System should display trend information for key parameters (to be identified by clinical staff)<br>• System should provide trend information over different time slices<br>• Provide access to views of patient beyond current 12 or 24 hours | • Optimized patient care<br>• Increased ability to spot changes in patient status, intervene more quickly |
| What clinical staff are currently on the unit? | • Need to know who is available, and where to find them<br>• Need access to nurse assignments by shift, by patient<br>• Means to access assistance, guidance, decision makers | • Names of who is working on unit that day, with patient assignments by room<br>• Call/staff assignment roster<br>• Shareable across disciplines<br>• Map view of floor and display showing location of staff. | • Allows staff to readily know who is available so they do not spend time away from patient trying to locate staff<br>• More efficient |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| | • Need to know which specialty is assigned to each patient (e.g., RT) and patient acuity | • Text paging/pre-populated messages<br>• ID with RFI tag | communication<br>• Mitigates care delays<br>• Can get help when it is needed |
| Is patient ready for upcoming surgical procedure | • Need means to know whether patient is prepared for procedure (have they gotten blood products, antibiotics, consent, pregnancy test) | • Provide roster of needed items (e.g., blood, antibiotics) and indication of whether those items have been satisfied | • Prevent delay in procedures |
| OR RN does not know enough about upcoming procedure<br><br>to prepare surgical suite properly<br><br>Bedside RN does not know enough about surgery as it is being performed to prepare properly for patient's return | • OR nurse needs procedure specific description (need to know more about specific information needs)<br>• Bedside Nurse needs means to know what to expect re patient needs following procedure (e.g., what was worked on, how much blood given or lost, sedation?) | • Provide information about intended procedure<br>• Provide information about surgery in process and patient status | • Nursing staff better prepared to care for specific patient needs at earliest opportunity |
| Rounding Checklist not readily available/accessible to all members of clinical team | • Means to construct checklist in real time (during Rounds) or immediately after<br>• Means to post checklist so all staff have ready/easy access<br>• Means for staff to 'check off' completed items, makes notes re: hold ups, changes/revisions<br>• Means for incomplete items to 'roll over' to | • Checklist needs to interact with order and other clinical systems<br>• Unit level view that is easy to access and track<br>• "Roll up" function: ability to look across patients/shifts/types of activities to examine when there are particular activities consistently missed/delayed; or care for a particular patient consistently delayed | • Fewer care delays<br>• More efficient order entry and tracking<br>• Better use of staff time<br>• Reflect on/improve on checklist performance<br>• Potential unintended consequence: |

| Problem/Barrier | Needs/Requirements | System Feature Concepts | Anticipated Impacts |
|---|---|---|---|
| Impact of dropped tasks, gaps, and lapses not known or tracked<br><br>Checklist management is unclear (responsibility for making sure items are completed is unclear). | populate next day's check list and to be reviewed at next-day Rounds | • System supports task tripwires (e.g., timing). Ability to recognize disconnects between orders and implementation (e.g., order entered, but not reviewed)<br>• Provides alerting function when tripwire is crossed<br>• Tripwires are definable by the staff | alarm/alert fatigue |
| Reliance on clinician to mentally integrate data | • Clinicians need a holistic/macro-view of the patient's trajectory (e.g., are they getting better or getting worse over last 24 hrs.?) | • Provide trend data and key indicators (e.g., for each of the main bodily systems)<br>• Trends on vitals, wound healing, medication dosing, infections | • Clinician better able to focus on problem detection, anticipate need for changes in treatment plans, optimize decision making around patient care |

**Appendix AB.** Usability Memo and Slide Enclosures

APPLIED RESEARCH ASSOCIATES, INC.

30 January 2016

From: Christopher Nemeth, PhD

To: LTC Jeremy Pamplin, MD
Cc: Maria Serio-Melvin, MSRN

Subj: Summary of Qualitative Data Findings from November Usability Assessment

Encl: (1) Ratings Analysis
(2) Priorities and Recommendations for CCS System Revisions
(3) CCS Usability Assessment-Qualitative Data Analysis-Rating Responses
(4) CCS Usability Assessment-Qualitative Data Analysis-Open-Ended Question Responses

1. The CSD team recently analyzed data from the 2-5 November 2015 usability assessments of the CCS. We collected data from 42 BICU clinicians as they performed two clinically-relevant scenarios. Enclosures (1) through (4) provide details to support the following summary findings.

2. Process

The user study was focused on gathering data regarding our prototype CCS system in terms of interface design, functions, and usability. We were interested to learn:

- How usable is the CCS system in terms of ease of use, interface, perceived efficiency, and supporting cognitive work?
- How usable is it compared to the legacy system?

The system was evaluated for performing tasks in two clinically relevant BICU scenarios: a new admission and preparing for surgery.

Two types of qualitative data were collected: usability ratings and responses to open-ended questions. In the first, users rated the usability of the CCS system on several dimensions after completing each scenario, then compared the CCS to their own experience with the legacy system. Details from the rating analyses are found in the tables in Enclosures (1) and (3). Second, qualitative data analyses are based on participants' responses to open-ended questions posed after each scenario (i.e., "Were there aspects of CCS you found difficult or challenging to use? Was there any information you needed for this scenario but were unable to find?") and at end of the session after rating scales had been administered ("What aspects of the CCS Interface did you find particularly useful? Would a system like this be easily adopted?"). Responses were coded using 36 categories of system features and patient data. Enclosure (1) includes details of the coding scheme and findings from the qualitative analysis. Finally, based on the open ended questions, a set of recommendations for changes to the CCS system are described.

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3. Key Findings

a. Based on the rating analysis, Nurses found it took more effort to get the information they needed than Physicians did in the surgery preparation scenario, but there was no difference in perceived effort for the new admission scenario.
b. Overall, users rated the CCS system as good as or better than the legacy system on several usability dimensions (Enclosure (1), Table 4).
c. The responses to open-ended questions align well with the rating results, and provide additional detail.
d. In general, participants were positive about the CCS and liked the way in which information is presented. When asked whether CCS would be easily adopted, over 80% of participants in each clinical role responded affirmatively (83% PHYs, 85% RNs, 90% RTs)
e. The qualitative data suggest that there are differences among clinical providers according to whether they found particular aspects of the system difficult to use, and what aspects of the system were particularly useful. Physicians were more positive about the system than were RNs or RTs.
    1) A majority of physician participants (83%) found the information presentation (layout/look & feel/navigation) particularly useful, while only 25% of RNs and 50% of RTs did.
    2) RNs noted the 'snapshot' view of the patient as useful (30%) more than did physicians (8%) or RTs (0%); physicians noted the trend data as useful (42%) more than did RNs (25%) or RTs (20%).
f. The data also provide insight into aspects of the system that participants found challenging.
    1) The most frequently cited challenge was the presentation of patient-specific information (Identified as challenging by 25% of PHYs, 45% of RNs and 38% of RTs after Scenario 1 and 50% of PHYs, 45% of RNs and 33% of RT's after Scenario 2.)
    2) Participants in all roles occasionally reported that they needed patient information for the scenarios but were unable to find what they needed.

3. Improvement Opportunities

One of the purposes of the November Usability Assessment was to identify system features for revisions in advance of the Validation Assessment scheduled for Spring 2016. We performed a separate analysis of the qualitative data for that specific purpose. We combined data across scenarios and rank-ordered system features and patient-specific data elements according to how frequently they were mentioned. We also looked at the participant's comments for recommendations and suggestions for revision and improvement. Those analyses can be found in Enclosure (2).

a. We forwarded Enclosure (2) to the software team on 12 December highlighting high priority items and specifically mentioning the need to provide an average for ins/outs, develop a Vent and a Labs tab, and reconsider the time scale controls.
b. Further priorities for system features included:
    1) Reduce the amount of scrolling required to find information.
    This could be accomplished by reducing the size of widgets as the information design prototype illustrated, or possibly overlapping widget windows
    2) Improve ways to make salient features more evident.
    This will likely be improved by clinicians repositioning widgets on the layout to fit their own preferences.

3) Revise the time scale control at the top of the Patient View
   Time representation was confusing for some participants. Some of that confusion could be mitigated by users being more familiar with the CCS, but it will be helpful if we can identify ways to make the feature more user-friendly and intuitive,
4) Revise graphical execution of the interface.
   Some participants found the interface formats, colors, and font sizes difficult to see.

c. Priorities for Patient View.
   Improve how ABGs, I/Os and Labs are organized and/or displayed. RNs want to be able to see all Labs in one place rather than distributed among the various tabs. RTs had a similar response to PEEP/VDR/Vent settings and data.

4. Please let me know if I can answer any questions about the November usability assessment data analysis.

C. Nemeth

Enclosure (1)

## Ratings Analysis

### Study Aims/Background

The user study was focused on gathering data regarding our prototype CCS system in terms of interface design, functions, and usability. Our specific questions were: How usable is the CCS system in terms of ease of use, interface, perceived efficiency, and supporting cognitive work? Second, how usable is it compared to the legacy system? The system was evaluated for doing two common BICU tasks or scenarios: a new admission and preparing for surgery.

### Methods

**Participants.** Forty-two BICU clinical staff used the CCS system in this user study and 41 provided the ratings and open-ended responses described below. This included 11 physicians (Phy), 20 nurses (N) and 10 respiratory technicians (RT). Overall in this sample, 23% had less than 1 year of experience in the BICU, 37% had 1-3 years, and 21% had more than 10 years. The breakdown of BICU years by Role is:

- Nurse: 90% 7+ years, 50% had 10+ years in BICU
- Physicians: 53% had 7+ years, 31% had 4-6 years
- RT: 50% 1-6 years, 50% 10+ years

Users' years of experience with the legacy system (Essentris) ranged from less than 1 year to 10+ years with a fairly even distribution across this sample. Years of experience were analyzed using a one-way ANOVA and comparing results by Role (Physician, Nurse, and RT) and Years in BICU. There was no statistically significant difference in the average number of years using the legacy system by Role, $F$ (2, 41) = 1.28, $p$ = .28, or Years in the BICU, $F$(2, 41) = 2.13, $p$ = .13.

Most clinicians (76%) reported being very comfortable with the legacy system. There was a main effect of Role on ratings of *comfort with the legacy system*. Nurses (M = 6.3, SD = .7) rated themselves as more comfortable than Physicians (M = 5.38, SD 1.5), while RT (M = 5.8, SD = .63) were in the middle.

**Procedure.** Users received 5 minutes of orientation/training to use the CCS system, and then completed 1 or 2 scenarios based on their role. For the preparation for surgery scenario, the questions were the same for Physicians and Nurses. There were four pieces of information to assess using the system. For the new admission scenario, each role had a different set of questions (2-4 questions) to answer using the system.

## RESULTS

Users rated each system in terms of the effort it took to answer each question and interface design; the ratings were not about how each question was answered.

In this section, the first research question focused on evaluating how usable is the CCS system. The data reported below are the ratings of the overall usefulness on a few different dimensions. We compare those by role for each information requirement. Then, we asked participants to rate the CCS usability after both tasks. Finally, we report on data collected from each participant after both tasks and compared ease of use to the legacy system.

**Scenario 1 Effort Ratings: Preparing for Surgery**

Using a t-test analysis, we compared how much effort it took for participants to answer the following questions: Is the patient's hemodynamic status getting worse? Is the patient's pulmonary status getting worse? Is the patient's volume status getting worse?

To answer questions about hemodynamic and patient's volume status; Nurses reported that it took more effort than Physicians. A MANOVA produced a marginally significant main effect of Role on effort ratings of finding hemodynamic status, $F(1, 30) = 4.03$, $p = .054$, and statistically significant difference on answering the question about the patient's volume status, $F(1, 30) = 4.87$, $p = .035$ (Table 1). In both cases, Nurses rated finding the information as more effortful than Physicians (see Figure 1 ). This is consistent with qualitative analysis in which Nurses reported that the CCS was designed more for a Physician perspective, than a Nurse.

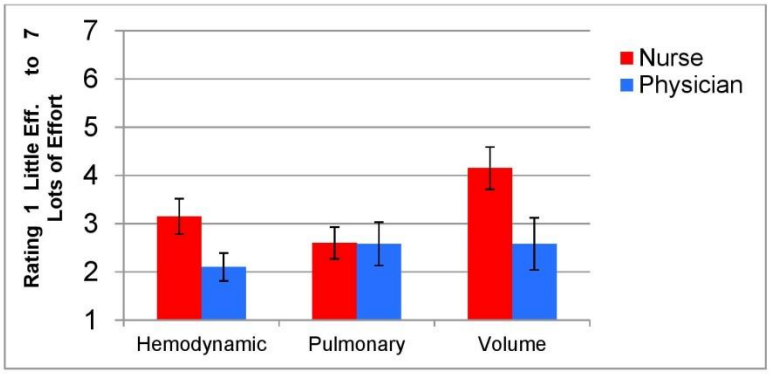



Figure 1. Scenario 1: Ratings of effort by question and role.

Examining Figure 1 further, there was some indication that it took more effort to answer the volume question using the CCS system, than the pulmonary question. This could be that the information was deeper in the system, or further down on the page on the screen.

Finally, we examined overall effort ratings by Role for the surgery preparation scenario. There were no statistically significant differences between Physicians and Nurses on effort, though Nurses reported slightly higher effort ratings (Table 1).

Table 1: *Physician and Nurse Ratings Using CCS: Scenario 1 Preparing for Surgery*

| *Question* | *Mean* | *SD* |
|---|---|---|
| I am confident in my decision/recommendation.<br>(56.3% Agree/Strongly Agree) | N: 5.2<br>Ph: 5.7 | 1.3<br>1.1 |
| The system was easy to use to make this decision.<br>(48.4% Agree/Strongly Agree) | N: 4.7<br>Ph: 5.6 | 1.7<br>1.1 |

| *Question* | *Mean* | *SD* |
|---|---|---|
| The system enabled me to quickly find the information I needed.<br>(56.3% Agree/Strongly Agree) | N: 4.9<br>Ph: 5.7 | 1.8<br>1.4 |
| It was straightforward to find the information I needed.<br>(53.1% Agree/Strongly Agree) | N: 4.75<br>Ph: 5.33 | 1.8<br>1.37 |

Note: Subjective Ratings 1 (Strongly Disagree) to 7 (Strongly Agree)

Nurses found it took more effort to get the information they needed than Physicians did. The question now is why? One possibility is that there was a system design fit and this early prototype was designed from a Physician's perspective, not that of a Nurse or RT. That can easily be rectified by adding role specific views to the CCS. Alternatively, it could a system training difference in that maybe Physicians spent more time training with the system than the Nurses (within that 5 minute window). Finally, it might be the case that this difference in ratings for two of the information items is to be expected and reflects the difficulty of the question for each role. Our qualitative analysis may unpack this.

**Scenario 2 Effort Ratings: New Admission**

In this scenario, Physicians, Nurses, and RT had different questions to answer. Therefore, there were no analyses by question as in the surgery preparation scenario. Overall, there was a main effect of Role on *Easy to use* ratings (Q2), $F(1,39) = 3.5$, $p = .039$, and *straightforward to find information ratings* (Q4), $F(1,39) = 4.24$, $p = .042$. Examining the means, Physicians reported higher ratings than the other two roles for both these questions. This effect is being driven by RT ratings being lower than the Physicians, suggesting that RTs needed more time/effort to answer their questions based on the CCS interface (Table 2).

Table 2: *Physician and Nurse Ratings Using CCS: Scenario 2 New Admission*

| *Question* | *Mean* | *SD* |
|---|---|---|
| I am confident in my decision/recommendation.<br>(70% Agree/Strongly Agree) | N: 5.85<br>Ph: 6.10<br>RT: 5.7 | 0.67<br>0.73<br>0.76 |
| The system was easy to use to make this decision.<br>(57.5% Agree/Strongly Agree) | N: 5.60<br>Ph: 6.10*<br>RT: 4.8 | 1.2<br>0.57<br>1.31 |
| The system enabled me to quickly find the information I needed.<br>(52.5% Agree/Strongly Agree) | N: 5.55<br>Ph: 5.70<br>RT: 4.8 | 1.2<br>1.16<br>1.31 |
| It was straightforward to find the information I needed.<br>(55% Agree/Strongly Agree) | N: 5.50<br>Ph: 6.20*<br>RT: 4.9 | 1.05<br>0.92<br>1.37 |

Note: Subjective Ratings 1 (Strongly Disagree) to 7 (Strongly Agree)

Next, we analyzed whether there were differences across the scenarios in terms of overall effort by scenario. The CCS would be used in a variety of situations. Therefore it is important to evaluate not just each scenario, but a comparison of effort across the two Scenarios. This provides information about whether the system works well in two different situations. We examined whether there were

differences in perceived usefulness across the two scenarios. Comparing effort ratings from Scenario 1 and Scenario 2, on average participants' ratings were slightly higher in Scenario 2 than Scenario 1. A repeated measures ANOVA for Scenario 1 vs. 2 was significant for, Q4: *Straightforward*, $F(1,28) = 4.67$, $p = .039$ and marginally significant for Q2: *Easy to Use*, $F(1,28) = 3.9$, $p = .057$, indicating that the New Admission scenario was more straightforward and easy to use the CCS to accomplish, than the Prepping for Surgery scenario. However, there was no statistically significant difference of Scenario on *Confidence*, $F(1,28) = 2.8$, $p = .102$, or *Quick to Find*, $F(1,28) = .95$, $p = .33$.

**Comparison overall CCS to Legacy**

Ratings comparing CCS to the Legacy system in terms of ease of use are below and reported by percentages. Overall participants agreed that the CCS system was as good, or better than the legacy system on the following dimensions (Tables 3 and 4).

Table 3: *Information Search Ratings Comparing the Legacy and CCS Systems*

| *Question* | *Legacy Better (Ratings 1-3)* | *Neutral Rating (4)* | *CCS Better Rating (5-7)* |
|---|---|---|---|
| I can find the information I need in CCS more quickly than I can using Essentris | 24.4% | 9.7% | 65.9% |
| I can find the information I need more *easily* than I can using Essentris | 14.6% | 19.5% | 65.9% |

Table 4: *Usability Ratings Comparing the Legacy and CCS Systems*

| *Question* | *Legacy Better (Ratings 1-3)* | *Neutral Rating (4)* | *CCS Better Rating (5-7)* |
|---|---|---|---|
| The CCS system is easier to use than Essentris | 14.5% | 19.% | 66% |
| I would feel more confident making future clinical decisions and recommendations using CCS than using Essentris | 19.5% | 22% | 58.5% |
| CCS supports the way I do my work better than Essentris | 17.1% | 19.5% | 63.4% |

**CONCLUSIONS**

Overall, the CCS is a very promising solution. Clinicians with 5 minutes of training using the CCS system were able to use it effectively. In fact, more than 60% of users rated it easier to use than the legacy system. Across the two typical scenarios, BICU scenario, overall 50-68% feel the CCS is easier to use than the legacy system. In each scenario, more than 50% had reported more confidence in their decision, ease of use and, ease of finding the information compared the Legacy system. Physician and nurse perspectives differed somewhat on preparing for surgery, but not for the second scenario, new admission.

Enclosure (2)

**Priorities and Recommendations for CCS System Revisions**

The following tables present findings from the analysis of qualitative data collected during the November 2015 CCS Usability Assessment. We also provide recommendations/suggestions for possible system revisions, based on participants' feedback about the system. Tables 1 and 2 present findings regarding the CCS interface. Tables 3 and 4 present findings regarding CCS presentation of patient data.

Table 1: CCS Features/Capabilities - Priority Rankings and Frequency of Instances (# people) by Role

| | *RN Priority* | *PHY Priority* | *RT Priority* | |
|---|---|---|---|---|
| Highest | Screens/windows/ scrolling | Formats - hard to see; confusing | Screens/windows/ scrolling | |
| Lowest | Acronyms/labels | Time Rep / Not intuitive | Acronyms/labels | |
| *Category* | *RN Freq (# ppl)* | *PHY Freq (# ppl)* | *RT Freq (#ppl)* | *Total Freq* |
| Acronyms/labels | 2 (1 ppl) | 2 (2 ppl) | 1 (1 ppl) | 5 |
| Screens/windows/ scrolling | 10 (8 ppl) | 3 (2 ppl) | 4 (3 ppl) | 17 |
| Formats - hard to see; confusing | 4 (4 ppl) | 3 (3 ppl) | 2 (2 ppl) | 9 |
| Time representation (D5) | 4 (4 ppl) | 1 (1 ppl) | 0 | 5 |
| Not intuitive or user friendly (D6) | 3 (2 ppl) | 1 (1 ppl) | 0 | 4 |

Table 2: CCS Features/Capabilities - Comments, Priority, and Recommendations/Suggestions

| *Category* | *Example comments* | *Priority* | *Recommendation* |
|---|---|---|---|
| Acronyms/ labels | • "Spacing to make words and acronyms more clear and different." (111Phy);<br>• "Didn't know all the abbreviations. ? RT/Exp. <Solution: Toggle area to fall what that means>" (102Phy);<br>• "Labels for info weren't bold, easy to see." (211RN);<br>• "Headers don't pop out." (211RN);<br>• "[Illegible] labels missing." (103RT) | Low | • Clear spacing<br>• Toggle for meaning of acronym<br>• Bold labels/headers<br>• Check for any missing labels |

| *Category* | *Example comments* | *Priority* | *Recommendation* |
|---|---|---|---|
| Screens/ windows/ scrolling | • "too much scrolling" (202PHY);<br>• "Compress values to reduce scrolling" (202 PHY);<br>• "helpful to have lab trend but early on, not avail." (208 PHY);<br>• "Just not knowing what was going to come up." (101RN);<br>• "Order of chart side-to-side should start with current and go back in time." (201 RN);<br>• "Condition of unfamiliar with lay out, where to look. Lot of info – distracting – not intuitive to see logically, how to navigate – blinded." (209 RN);<br>• "Looking for more BMP labs – didn't see them first time – didn't scroll down." (105RN);<br>• "No. Just the scrolling. Would like to see norms and range on lab values. Or if there's a specific value we need to treat I want to see that." (110RN);<br>• "…Difficult to find…" (220 RN);<br>• "hard to find when you have to click in each box." (101 RN);<br>• "Not but takes getting used to clicking when you scroll down you have to scroll back up to the top." (109RN);<br>• "Knowing where to find things. Some things could be in multiple tabs e.g. weight is in ENDO/GI." (221 RN);<br>• "once figured out scrolling" (117RT);<br>• "The scrolling – where multiple boxes you lose element name." (103RT);<br>• "Getting, navigating to resp." (203RT) | High | • Reduce scrolling or need for scrolling<br>• Make frequently used features more salient<br>• Lose element name when scrolling (?) – fix<br>• Note: we don't believe that compressing values (as per one of the comments) is a good idea given feedback about font, etc. |
| Formats - hard to see; confusing | • "Immediately busy. Care Team doesn't help. Bird's Eye view – HR, PR, Vent not wound care orders." (202PHY);<br>• "Resp. – pH oh graph with 1 data point, can't tell if data is there.<br>• Can't see single point in graph for ABG's." (119PHY);<br>• "Work on the color a little bit – the trend lines blend in; a little contrast in between the different – tables and rows to see faster and easier. All blends in." (218PHY);<br>• "ABGs - Hard to see trend on separate charts." | Med | • Use colors to make elements/feature salient<br>• Contrast<br>• ABG – make salient trends on separate charts<br>• Indicate values that are unavailable for that patient (color? shading?) |

| Category | Example comments | Priority | Recommendation |
|---|---|---|---|
| | (211RN);<br>• Hitting the button (standard time) changes everything. I didn't notice right away. Could cause errors if you're looking at historical data." (107RN);<br>• "Just coloring with Hgt/Hct graph but key helped." (205RN);<br>• "Getting used to set up, V Exp – should have seen something, couldn't tell if it was unavailable." (113RT);<br>• "Spread out vent settings." (222RT) | | |
| Time represen-tation (D5) | • "Click on last 24 or 48 hours. Contain [?] the times would be better." (102PHY);<br>• "I don't know what the time is." (213RN);<br>• Can I change the time? I would look at a wider span of time." (215RN);<br>• "Just the date thing (see previous questions).<br>• Hitting the button (standard time) changes everything. I didn't notice right away. Could cause errors if you're looking at historical data." (107RN);<br>• "Clicking on – hard to find when you have to click in each box. Easier over time period." (101RN) | Med | • Make time representation user friendly<br>• Include ability to select frequently used time scales/span<br>• Make clock salient |
| Not intuitive or user friendly (D6) | • "I/O grams – not intuitive, doesn't say where at a given point." (202PHY);<br>• "Condition of unfamiliar with lay out, where to look. Lot of info – distracting – not intuitive to see logically, how to navigate – blinded." (209RN);<br>• "Just confusing and hard to look for this stuff." [labs, electrolytes] (212RN);<br>• "Learning curve to manipulate – not intuitive." (209RN) | Low | • I/Os |
| Misc. | • "Not knowing where to find notes from radiology." (111PHY);<br>• "No. org well. Confusion with Px detail box. Not match scenario – "Hosp Day 55."" (211RN) | Low | • Notes from radiology – is there a 'notes' section on the interface?<br>• Patient detail box is confusing.<br>• For validity test – make sure patient data matches scenario |

Table 3: Patient Information - Priority Rankings and Frequency of Mention by Role

| Priority | RN Priority | PHY Priority | RT Priority | All Priority |
|---|---|---|---|---|
| HIGHER | LABS<br>I/Os<br>ABGs<br>HEM<br>PEEPS/VDR | ABGs<br>I/Os<br><br>Labs/Lactate | Vent<br>PEEPS/VDR<br>Xray | LABS<br>I/Os<br>ABGs<br>Vent settings/data<br>PEEPS/VDR |
| LOWER | BMP/Xray/<br>Lactate | Vent/HEM/IV | ABGs | |

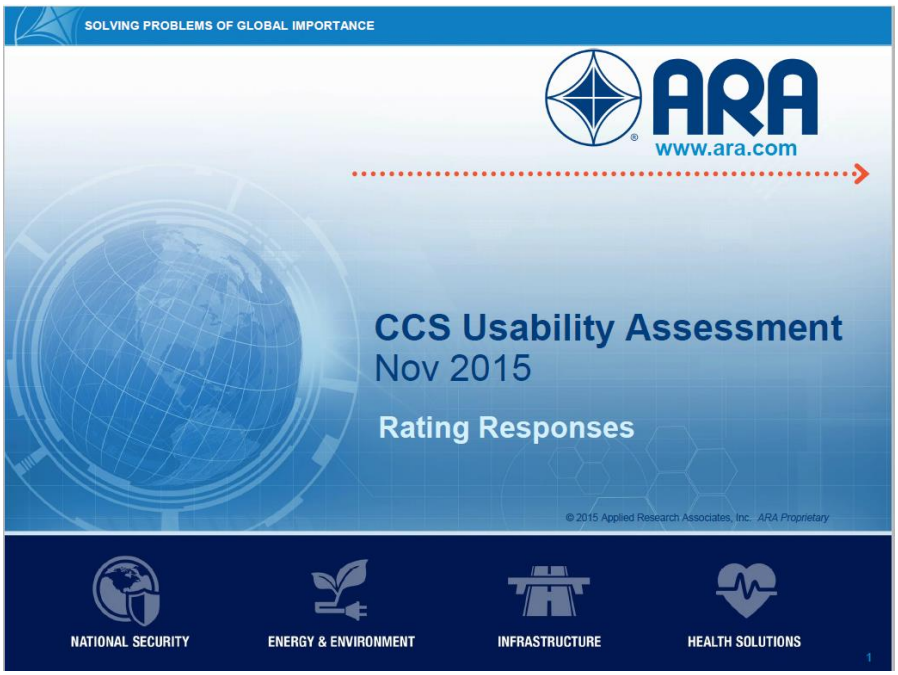
| Category | RN Freq | Phy Freq | RT Freq | Total Freq |
|---|---|---|---|---|
| ABGs | 4 | 7 | 1 | 12 |
| I/Os | 6 | 6 | | 12 |
| Labs | 11 | 2 | | 13 |
| PEEPS/VDR | 2 | | 3 | 5 |
| Vent settings/data | | 1 | 4 | 5 |
| Lactate | 1 | 2 | | 3 |
| LFTs | | | | 0 |
| HEM | 3 | 1 | | 4 |
| BMP1 | 1 | | | 1 |
| Xray access 4 | 1 | | 3 | 4 |
| IV | | 1 | | 1 |

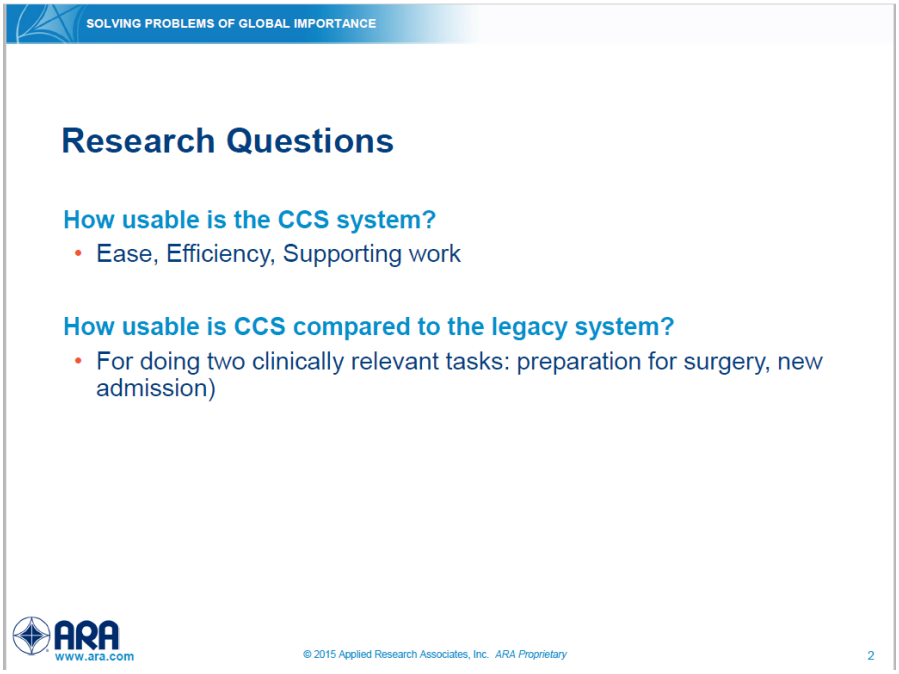
Table 4: *Patient Information - Comments, Priority, and Recommendations/Suggestions*

| | *Example comments* | *Priority* | *Recommendation* |
|---|---|---|---|
| ABGs | • I didn't like the way ABG written – whole ABG not here. (PHY)<br>• Didn't see ABGs, are they there? I didn't them…(N) | **HIGH** | Clarify with AISR…. Is ABG data incomplete, or is it something about the way displayed? |
| I/Os | • I/Os. Simple question how much Ins and Outs looks confusing. Can't tell if last hour versus total outputs. Hover over the graph to see the hourly and total at the end. Unclear what the net Ins and Outs are. (N)<br>• I/O not user friendly (N )<br>• I/O grams not intuitive (PHY) | **HIGH** | Need review by AISR… what are specific changes needed to fix confusion mentioned here |
| Labs | • Lab – used to having them in a single spot. Multiple clicks to diff areas – compartmentalize it. I'm looking for all the labs – including blood gasses which I didn't see. (N)<br>• My entire nursing career been used to looking at a single page with all the labs in one place and this separates the lab to each individual tab; probably something trying to adjust to but not a significant problem. (N )<br>• Would like to see norms and range on lab values. Or if there's a specific value we need to treat I want to see that. | **HIGH (esp for RNs)** | Create LABS tab with all LABS together? (for Validity test)<br><br>AISR: importance of norms and ranges in the display? If important, how to make available? |
| PEEPS/VDR | • PEEP settings for VDR have 2 types. PIP should be on summary tab. Pulse Frequency on VDR not there. (RT)<br>• Need: Current VDR setting, Pulse frequency, both PEEPs. (RT)<br>• PEEP settings for VDR 2 types.<br>PIP should be on summit.<br>Pulse frequency on VDR. | **HIGH (esp for RT)** | Create VENT tab with all VENT/respiratory data in one place? |
| Vent settings/data | • The vent settings kind of spread out compared to our current system where there is one area for each type of vent setting of a particular type of vent. Spread out is harder to follow.<br>X-ray results weren't available. (RT)<br>• Need the vent settings, have no idea what the settings (are) RT | **HIGH (esp for RT)** | See above |

| | *Example comments* | *Priority* | *Recommendation* |
|---|---|---|---|
| | • On vents – not shown, like I see MV Total looks like code (PHY) | | |
| Lactate | • Didn't/couldn't find LACTATE (PHY) | LOW | Give participants a more in-depth introduction to system and more time to explore so they have a better chance of knowing how to find information |
| HEM | • Some of the info under Heme – all the labs should be there. Or don't call it Heme. Because Heme you think BLOOD – blood results. (N)<br>• HEM confusing (PHY) | LOW | Is this addressed with LABS Tab (see above)<br>May need more info on what about HEM is confusing |
| BMP | • Looking for more BMP labs – didn't see them first time – didn't scroll down. Didn't see high/low values – norms available.<br>• Looking for BMP – Saw BUN, Creatinine, the chem should be more, maybe nothing drawn. (N) | LOW | Believe this is the same issues as addressed in "LABS Tab" above?<br><br>Not clear what the issue is…. |
| X-ray access | • Is there a way to look at X-rays (RT)<br>• Would be nice to have X-ray (RT) | LOW | Still not feasible, correct? |
| IV | • Don't know how it's set up for IV drips – would be nice to have the common drips that showed there – if they aren't there maybe it means they were not on it. If they were showing at least your eye could follow them – maybe the top three drips.(PHY) | LOW | Is it feasible to display IV drips as suggested by this PHY-participant? |

Ratings Responses



## Methods

### Usability assessment

- Quantitative: task performance
- Qualitative: subject perception

### Interviewed and observed 41 system testers using the CCS to do two everyday tasks

- 5-minute orientation and exploration of the system
- Users completed two typical clinical scenarios using new system
  - Scenario 1: Prepping for surgery
  - Scenario 2: New admission
- Asked questions about effort, ease of use, etc.

Rubin, J. (1994). *Handbook of Usability Testing*. New York: John Wiley and Sons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## Participants

| Physicians | Nurses | RTs |
|---|---|---|
| 12* | 20 | 10 |

**BICU experience:**

- 23% < 1 year, 37% 1-3 years 21% 10+ years
- Nurse 90% 7+ years, 50% had 10+ years
- Physicians: 53% had 7+, 31% had 4-6 years
- RT: 50% 1-6 years, 50% 10+ years

**Years' experience with legacy:**

- Range: <1 to 10+ years, even distribution
- Comfort with legacy: 76% very comfortable

*One physician did not complete scenarios


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# Scenario 1:
# **Preparing for Surgery**

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Scenario 1:
**How much effort to get information?**
(1 – Low; 7 – High)

| *Question* | *Mean* | *SD* |
|---|---|---|
| Is the patient's hemodynamic status getting worse? | N: 3.15*<br>Ph: 2.10 | 1.60<br>0.99 |
| Is the patient's pulmonary status getting worse? | N: 2.60<br>Ph: 2.58 | 1.50<br>1.56 |
| Is the patient's volume status getting worse? | N: 4.15*<br>Ph: 2.58 | 1.90<br>1.88 |

* Independent t-test, $p < .05$ $t(32)$

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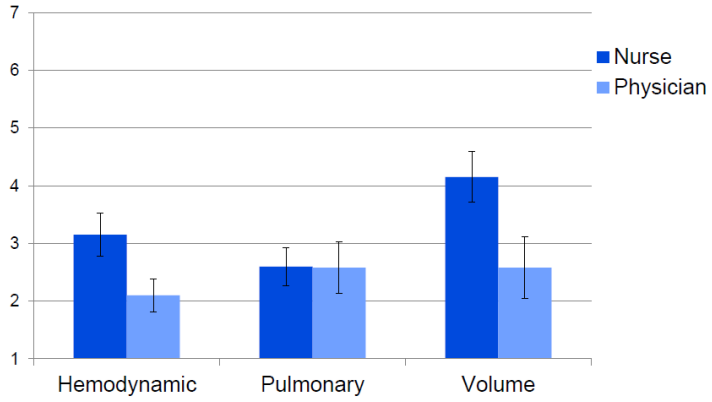
Scenario 1:
**Effort Ratings by Role**
1--Little Effort  7--Lots of Effort

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Post-Scenario 1:
**Preparing for Surgery**

1 – Strongly Disagree, 7 – Strongly Agree

| *Question* | *Mean* | *SD* |
|---|---|---|
| I am confident in my decision/ recommendation (56.3% Agree/Strongly Agree) | N: 5.2<br>Ph: 5.7 | 1.3<br>1.1 |
| The system was easy to use to make this decision (48.4% Agr/SA) | N: 4.7<br>Ph: 5.6 | 1.7<br>1.1 |
| The system enabled me to quickly find the information I needed (56.3% Agr/SA) | N: 4.9<br>Ph: 5.7 | 1.8<br>1.4 |
| It was straightforward to find the information I needed (53.1 %Agr/SA) | N: 4.75<br>Ph: 5.33 | 1.80<br>1.37 |

**DRAFT**

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## Scenario 1 Rating Interpretation

**Nurses found it took more effort to get the information than Physicians**

Why? May unpack in qualitative

This could be a system design fit or a system training difference

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Scenario 2
**New Admission**

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Post-Scenario 2:

## New Admission

(1 – Strongly Disagree; 7 – Strongly Agree)

| *Question* | *Mean* | *SD* |
|---|---|---|
| I am confident in my decision/recommendation (70% Agree/Strongly Agree) | N: 5.85<br>Ph: 6.10<br>RT: 5.70 | 0.67<br>0.73<br>0.76 |
| The system was easy to use to make this decision (57.5%Agree/Strongly Agree) | N: 5.60<br>Ph: 6.10*<br>RT: 4.80 | 1.20<br>0.57<br>1.31 |
| The system enabled me to quickly find the information I needed (52.5% Agree/Strongly Agree) | N: 5.55<br>Ph: 5.70<br>RT: 4.80 | 1.20<br>1.16<br>1.31 |
| It was straightforward to find the information I needed to make a decision/recommendation (55% Agree/Strongly Agree) | N: 5.50<br>Ph: 6.20*<br>RT: 4.90 | 1.05<br>0.92<br>1.37 |

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## Scenario 2: Rating Findings

### Overall differences by Position.

- Physicians found it easier to use and find information than Nurses or RTs.

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Overall
**Post both Scenarios, and Comparing to Legacy**


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## CCS-Essentris Comparison

| *Question* | *Legacy Better (Ratings 1-3)* | *Neutral Rating (4)* | *CCS Better Ratings (5-7)* |
|---|---|---|---|
| I can find the information I need in CCS more quickly than I can using Essentris. | 24.4% | 9.7% | 65.9% |
| I can find the information I need in CCS more easily than I can using Essentris | 14.6% | 19.5% | 65.9% |


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## CCS-Essentris Comparison (Cont'd…)

| *Question* | *Legacy Better (Ratings 1-3)* | *Neutral Rating (4)* | *CCS Better Ratings (5-7)* |
|---|---|---|---|
| The CCS system is easier to use than Essentris | 14.5% | 19.5% | 66.0% |
| I would feel more confident making future clinical decisions and recommendation using CCS than using Essentris | 19.5% | 22.0% | 58.5% |
| CCS supports the way I do my work better than Essentris. | 17.1% | 19.5% | 63.4% |


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## Conclusions

### After 5 minutes of using the system and across two typical scenarios

- Overall: 50-68% feel the CCS is easier to use the legacy system
- 50% + in each scenario
  - Confidence in decision
  - Easy to use to make the decision
  - Efficient to find information
  - Easy to find information needed
- Physicians' and Nurses' perspectives differed slightly


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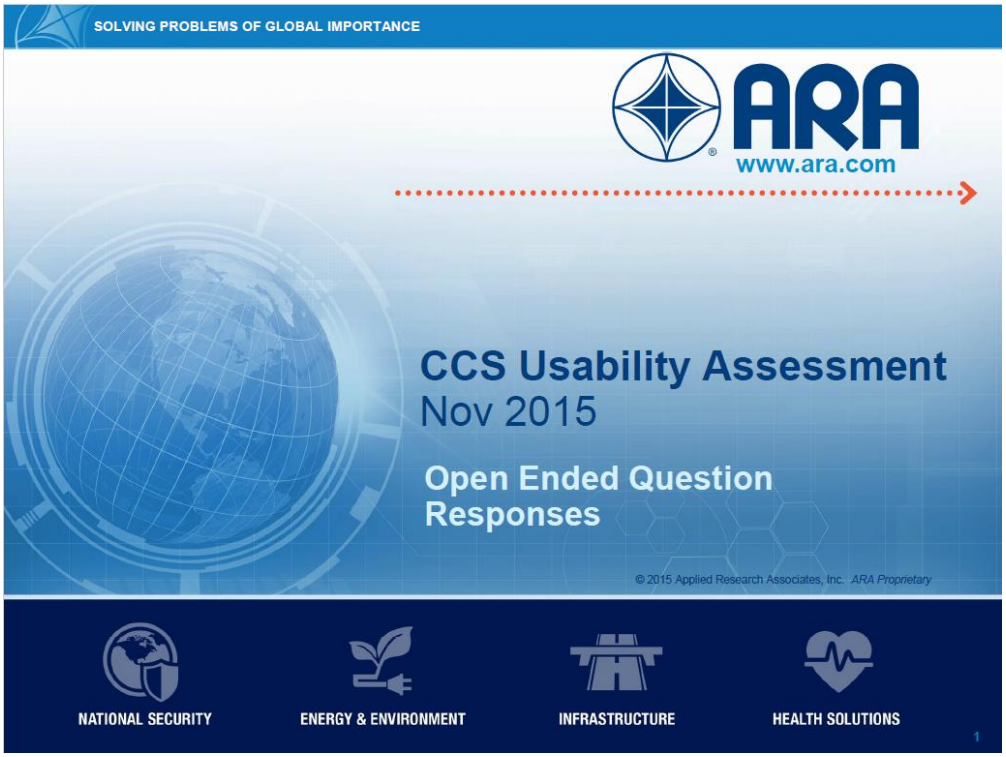
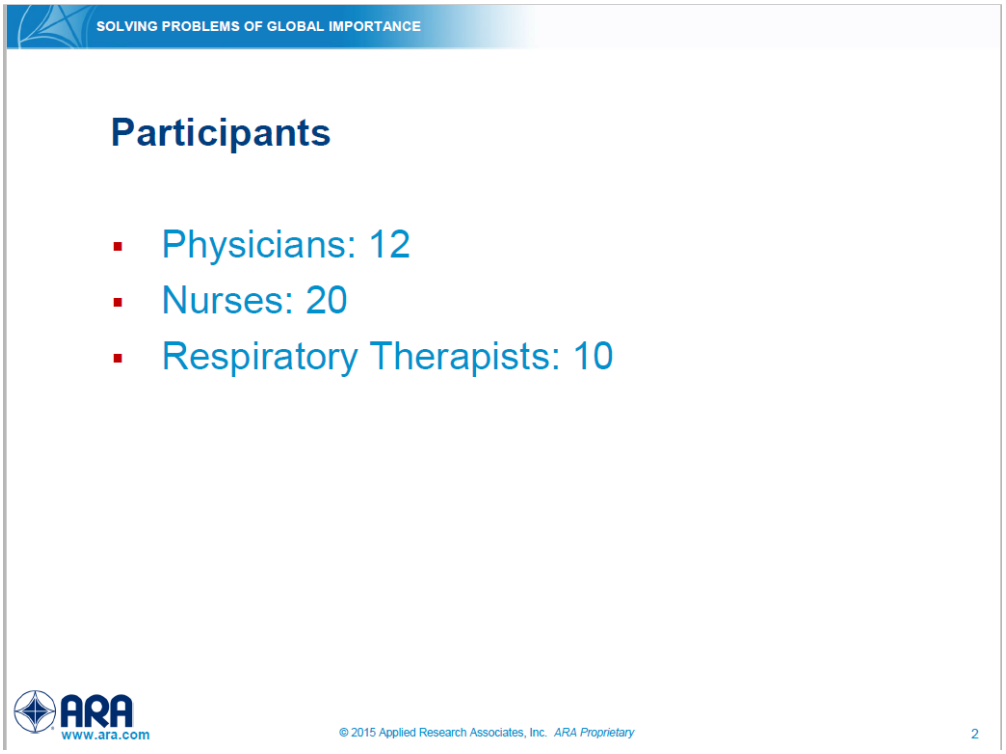
Enclosure (4)

Open Ended Question Responses



## **Coding Structure:** Open-ended Responses

**Developed coding categories based on question and response topics**

**Coded each participant's response for Scenario 1, 2, and Overall, based on coding categories**

- Allowed multiple codes to apply to a given participant response

**Reported within roles (RN, PH, RT) and across roles**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## **Coding Structure:** Open-ended Responses

**Category: CCS difficult/didn't work for me**

- "Nothing"/"no"/NA/blank
- Patient Information (subcodes: ABGs, I/Os, Labs, PEEPS/VDRs, Vent settings/data, Lactate, SFTs, HEM events, BMP, X-ray, IV, General (e.g., 'I need more data'); Other/miscellaneous
- Acronyms/labels/abbreviations
- Screens/windows/scrolling awkward/confusing
- Formats: hard to see, confusing
- Time representation
- Not intuitive/user friendly
- Other/miscellaneous


4 / 22
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## **Coding Structure:** Open-ended Responses

### Category: CCS useful

- Nothing"/"no"/NA/blank
- Info presentation: setup/layout/look & feel, navigation
- Global View
- "Snapshot" of patient
- Trends
- Supports clinical decision making
- Supports teamwork**
- Ability to see team members/roles**
- Tabs
- User-friendly (ease, efficiency)
- Other/miscellaneous

** neither scenario 'called for' these components, but because the system is designed to support them we included them in the coding structure


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## **Coding Structure:** Open-ended Responses

### Additional Codes

- System easy to adopt (yes/no)
- Familiarization (need/want more opportunity to explore and interact )
- Comparative (stated preference for CCS vs. Essentris)
- Not codable (text entry doesn't make sense)


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Open-ended Responses

# Scenario 1 Questions


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## **Scenario 1:** Preparing for Surgery

*A 69-year old male, 96.6 kg with 54% thermal burns to his face, neck, chest, arms and legs, has just been admitted to the unit. He was sent from an outside hospital. The ED team indicates the patient sustained injuries while disposing of old gunpowder that ignited. The patient is hospital Day 4 and is going to the operating room (OR) for his first excision and grafting procedure. He is scheduled as the first case.*

*Set the calendar/clock icon with a start time of 03 Jan 2023 at 8:00 a.m. (0800) and end time of 04 Jan 2023 at 6:00 a.m. (0600 hrs.).*

*Please use the available information to determine whether the patient is ready for this procedure, tell us your recommendation/decision. Then, circle your level of effort for each step on the response sheet.*

- Is the patient's hemodynamic status getting worse?
- Is the patient's pulmonary status getting worse?
- Is the patient's volume status getting worse?
- Is the patient's hemostasis status getting worse?


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## Q. Were there aspects you found difficult to use?

| *Category* | *Ph (12)* | *RN (20)* | *All (32)* |
|---|---|---|---|
| "Nothing"/"No" | 42% | 30% | 34% |
| Patient-specific info (e.g., ABGs, I/Os, labs) | 25% | 45% | 38% |
| Acronyms/labels | 17% | 5% | 9% |
| Screens/windows/scrolling | 8% | 20% | 16% |
| Formats - hard to see; confusing | 8% | 5% | 6% |
| Time representation | 0% | 15% | 9% |
| Not intuitive or user friendly | 0% | 10% | 6% |
| Misc./Other | 0% | 15% | 9% |
| Interested in familiarization | 17% | 35% | 28% |


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## Q. Was there any information you needed for this scenario, but were unable to find?

| *Category* | *Ph (12)* | *RN (20)* | *All (32)* |
|---|---|---|---|
| No | 58% | 55% | 56% |
| Yes – patient-specific info (e.g., ABGs, I/Os, labs, etc.) | 42% | 45% | 44% |


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Open-ended Responses

## Scenario 2 Questions

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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

## **Scenario 2:** New Admission - Nurse

*A 69-year old male, 96.6 kg with 54% thermal burns to his face, neck, chest, arms and legs, has just been admitted to the unit. He was sent from an outside hospital. The ED team indicates the patient sustained injuries while disposing of old gunpowder that ignited.*

*Set the calendar/clock icon, start time to 01 Jan 2023 at 10:00 a.m. (1000 hrs.). Set the end time to 01 Jan 2023 at 10:00 p.m. (2200 hrs.) The patient is 9 hours post burn.*

*Please use the available information to determine whether the patient is ready for this procedure, tell us your recommendation/decision, and write your decision or recommendation on the line next to the question when you are ready.*

- Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same?
- Based on his glucose levels, do you recommend that he be started on an insulin drip (Endotool)?
- Set the calendar/clock icon to a start time of 25 Feb 2023 at 0500 and end time of 25 Feb 2023 at 1200. Based on the patient's lab values, do you think he should be started on CRRT?

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## **Scenario 2:** New Admission - Physician

The nurse calls you about a 69-year old male, 96.6 kg with 54% thermal burns to his face, neck, chest, arms and legs for low urine output. The patient is 9 hours post burn and 7 hours into his hospital admission. The nurse just took over the care of the patient from another nurse who had to leave urgently and is unable to answer most of your questions. You ask to talk with the resident, but the Nurse says that he is downstairs in the ED with another admission.

Set the calendar/clock icon, start time to 01 Jan 2023 at 10:00 a.m. (1000 hrs.). Set the end time to 01 Jan 2023 at 7:30 p.m. (1930 hrs.).

Please use the available information, tell us your recommendation / decision, and write your decision or recommendation on the line next to the question when you are ready.

**What do you want to do?**

- 1-Change the IV fluid rate? If yes, what amount?
- 2-Add albumin or FFP? If yes, what amount?
- 3-Add high dose IV vitamin C?
- 4-Add CRRT? If yes, what prescription?
- 5-Add vasopressors?


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## **Scenario 2:** New Admission - RT

*The patient is a 69-year old male, 96.6 kg with 54% thermal burns to his face, neck, chest, arms and legs who was admitted to the BICU. The patient is on Day 2 of his hospital stay.*

*Set the calendar/clock icon to a start time of 01 Jan 2023 at 2:00 p.m. (1400 hrs.) and an end time of 02 Jan 2023 at 09:00 a.m. (0900 hrs.).*

*Please use the available information, tell us your recommendation, and write your recommendation on the line next to the question when you are ready.*

Based on the bronchoscopy results and current vent settings:

- Do you recommend that the patient stay on the VDR or transition to another ventilator?
- If yes, describe your recommended changes to the ventilator or vent settings?


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## Q. Were there aspects you found difficult to use?

| *Category* | *Ph (12)* | *RN (20)* | *RT (9)* | *All (41)* |
|---|---|---|---|---|
| "Nothing"/"No" | 25% | 25% | 11% | 22% |
| Patient-specific info (e.g., ABGs, I/Os, labs, etc.) | 50% | 45% | 33% | 44% |
| Acronyms/labels | 0% | 0% | 0% | 0% |
| Screens/windows/scrolling | 17% | 20% | 33% | 22% |
| Formats - hard to see; confusing | 8% | 10% | 11% | 10% |
| Time representation | 0% | 10% | 0% | 5% |
| Not intuitive or user friendly | 8% | 0% | 0% | 2% |
| Misc./Other | 0% | 5% | 0% | 2% |
| Interested in familiarization | 17% | 15% | 11% | 15% |


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## Q. Was there any information you needed for this scenario, but were unable to find?

| *Category* | *Ph (12)* | *RN (20)* | *RT (10)* | *All (42)* |
|---|---|---|---|---|
| No | 17% | 50% | 40% | 38% |
| Yes – patient-specific info (e.g., ABGs, I/Os, labs, etc.) | 58% | 30% | 50% | 43% |


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## Detail for "Patient-specific information"

| *Info Type* | *"Difficult to use/couldn't find" (# comments)* | | | | *"Needed for this scenario" (# comments)* | | | |
|---|---|---|---|---|---|---|---|---|
| | RN | Ph | RT | All | RN | Ph | RT | All |
| ABGs | | 2 | | 2 | | 2 | 1 | 3 |
| I/Os | | 2 | | 2 | | 1 | | 1 |
| Labs | 6 | | | 6 | 1 | | | 1 |
| PEEPS/VDR | | | | 0 | 2 | | 3 | 5 |
| Vent (settings/data) | | | 2 | 2 | | | 2 | 1 |
| Lactate | | 1 | | 1 | | 1 | | 1 |
| LFTs | | | | 0 | | | | 0 |
| HEM events | 1 | | | 1 | | | | 0 |
| BMP | | | | 0 | 1 | | | 1 |
| X-ray access | | | 2 | 2 | | | 1 | 0 |
| IV | | | | 0 | | 1 | | 1 |
| Other/Misc. | | | | 0 | 1 | 3 | 1 | 5 |
| General | 2 | 1 | | 3 | 1 | | | 1 |

DRAFT


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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

Overall Questions

## Post- Both Scenarios


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## Q. What aspects of the CCS interface did you find particularly useful?

| Category | Ph (12) | RN (20) | RT (10) | All (42) |
|---|---|---|---|---|
| "Nothing"/"No"/NA/blank | 0% | 0% | 10% | 2% |
| Info Presentation - setup/layout/look/feel/navigation | 83% | 25% | 50% | 48% |
| Global view | 25% | 20% | 20% | 21% |
| Snapshot | 8% | 30% | 0% | 17% |
| Trends | 42% | 25% | 20% | 29% |
| Supports clinical decision making | 0% | 0% | 0% | 0% |
| Supports teamwork | 0% | 5% | 0% | 2% |
| Ability to see team members/roles | 0% | 10% | 0% | 5% |
| Tabs | 8% | 15% | 30% | 17% |
| User-friendly (ease, efficiency) | 33% | 5% | 10% | 14% |
| Misc./Other | 0% | 30% | 10% | 17% |


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## Q. Were there aspects you found difficult to use?

| Category | Ph (12) | RN (20) | RT (10) | All (42) |
|---|---|---|---|---|
| "Nothing"/"No" | 42% | 30% | 30% | 33% |
| Patient-specific info (e.g. ABGs, I/Os, labs, etc.) | 8% | 30% | 30% | 24% |
| Acronyms/labels | 0% | 5% | 0% | 2% |
| Screens/windows/scrolling | 0% | 10% | 10% | 7% |
| Formats - hard to see; confusing | 8% | 5% | 10% | 7% |
| Time representation | 8% | 0% | 0% | 2% |
| Not intuitive or user friendly | 0% | 5% | 0% | 2% |
| Misc./Other | 17% | 10% | 0% | 10% |


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## Q. Would a system like this be easily adopted?

| *Category* | *Ph (12)* | *RN (20)* | *RT (10)* | *All (42)* |
|---|---|---|---|---|
| Yes | 83% | 85% | 90% | 86% |
| No | 17% | 10% | 10% | 14% |


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**Appendix AC.** Trip Report to AISR Scientific Review Conference (Enclosure)

5-7 January 2016

From: Chris Nemeth, PhD
To: Tony Story, CDMRP

Subj: Trip report: AISR Scientific Review Conference Jan 2016

Encl: (1) AISR Science Symposium: A Cooperative Communication System for the Advancement of Safe, Effective, and Efficient Patient Care
(2) System Orientation
(3) Usability Assessment Facilitator Script
(4) System User Response Sheet

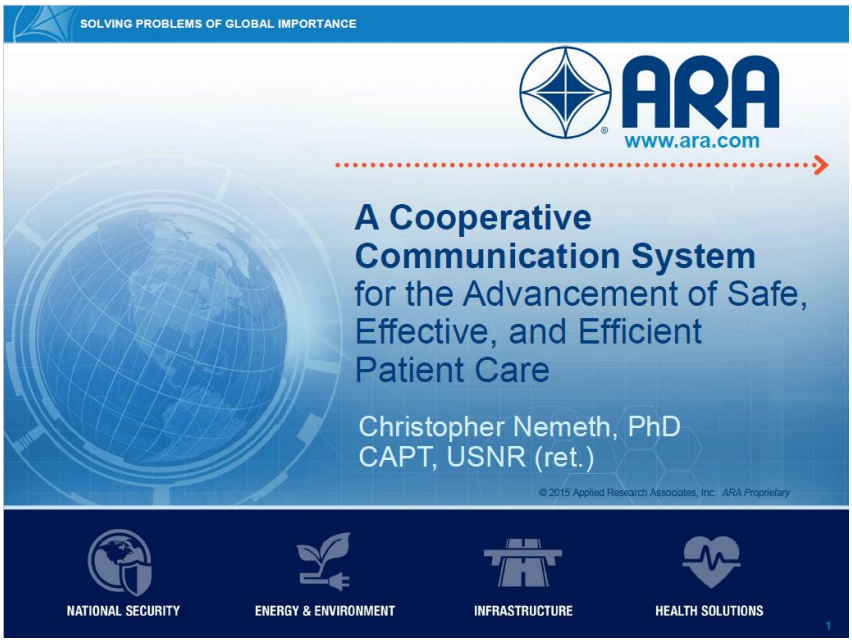
1. On 6 January, Dr. Nemeth visited AISR to give an invited presentation on the CCS to members of the technical staff at their regular Science Symposium.

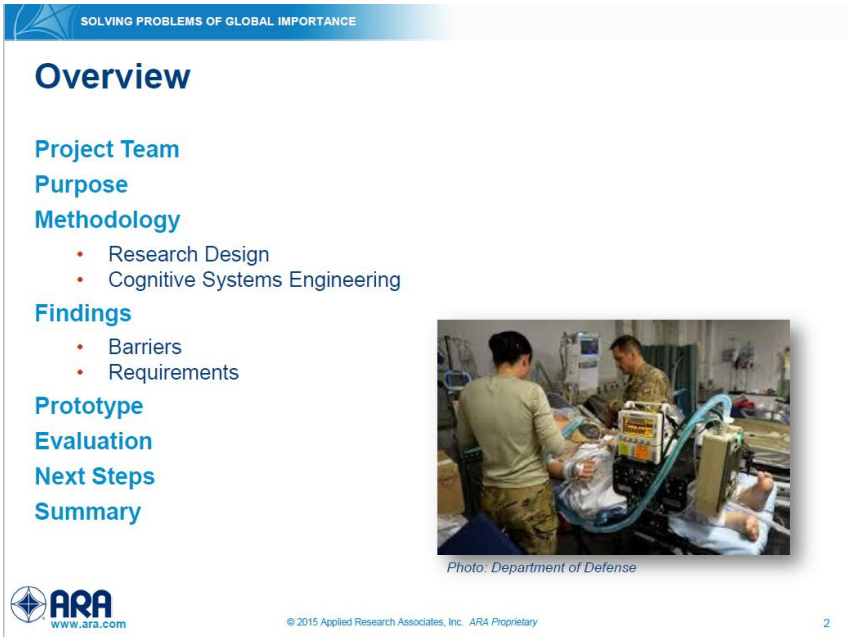
   Along with Mr. Greg Rule, he used the opportunity to conduct a brief usability session with one member of the clinical staff to provide a comparison using Essentris to perform the same scenarios as the November CCS usability sessions. Enclosure (1) is the modified script and Enclosure (2) is the modified response sheet used during the session. Results of the session will be included in the project final report, along with results from the usability and validation assessments.

2. For further information, contact Dr. Nemeth at 937-825-0707, or cnemeth@ara.com.

Enclosure (1)

**Presentation to AISR Science Symposium: A Cooperative Communication System for the Advancement of Safe, Effective, and Efficient Patient Care**



# Project Team

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Cindy Dominguez, PhD
Megan Beck

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Tony Hamilton
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Charlie Fisher
Kyle Foley
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# Purpose

**Hypothesis:** The CCS support for BICU will improve clinician decision making and communication by making patient care more efficient, effective, and less prone to adverse outcomes and misadventures.

**Aims**: Clinical decision and communication support tool that provides:

- Improved clinician decision making, through presentation of salient patient data, and machine learning and communication support
- More efficient, reliable individual and team cognitive work resulting in improved patient outcomes (e.g., reduced length of stay)


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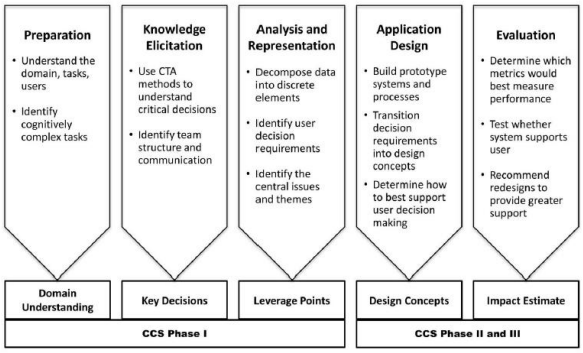
# **Methodology** Cognitive Systems Engineering





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# **Methodology** Research Design

## Year One

- *Literature Review*
- *Observation:* Five week-long visits to the BICU
- *Structured Interviews*: Typically 15-20 per visit
- *Artifact Analysis:* Collection, de-identification, and analysis of information sources
- *Thematic Analysis*: Detection of patterns among and across data elements
- *Participatory design:* Collaboration among ARA and AISR team members to create interface concepts complementary to BICU work practice and culture


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# **Methodology** Research Design

## Year Two

- *Validation interviews:* Review of representations with clinicians to confirm, adjust, and enrich findings (Iterative development)
- *Survey*: Research nurse data collection to answer focused questions, such as requirements priorities
- *Rapid prototyping*: Development of interface design based on Year One data
- *Agile prototyping*: Initial software development, including initial machine learning concepts (e.g., similar patients)


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# **Methodology** Research Design

## Year Three

- *Agile Prototyping*: Comprehensive software development, including machine learning (e.g., similar patients, trends)
- *Usability Assessment*: Determination of CCS suitability for individual decision making, compared with current IT
- *Validation Assessment*: Determination of CCS suitability for team decision making, compared with current IT


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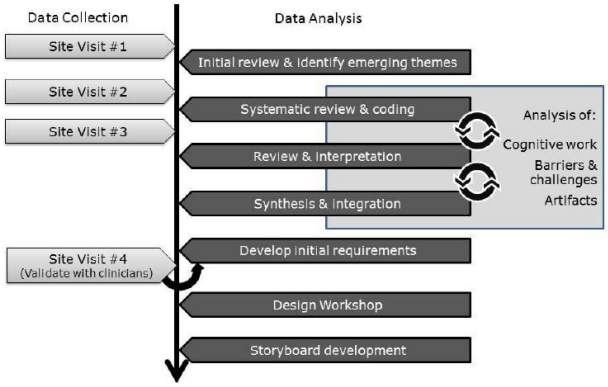
# Data Collection, Analysis





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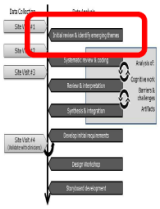
# Review, Emergent Themes



| Example Data Excerpts | Theme |
|---|---|
| *Surgeon and resident talk among themselves, and residents sometimes put in critical orders (e.g. blood). As a nurse I don't know this until I log in and see the note (bedside nurse)*<br><br>*When the Attending changes from week to week, you may find plans reversed from week to week. You end up with a yo-yo effect in the care that is frustrating…. (intensivist)* | Information discontinuity |
| *It is a little tricky to align my goals with staff, which may vary from staff to staff (intensivist)*<br><br>*We have 6 or 8 people working on the problem in their lane. Give it a little time to simmer and then we all come together and sort of talk about it. (Head nurse)*<br><br>*A lot of times with physician orders, there can be multiple consultants, plus attendings that make orders that are contraindicated. If that occurs I will bring it up to the fellow… (LVN)* | Negotiation |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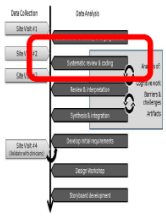
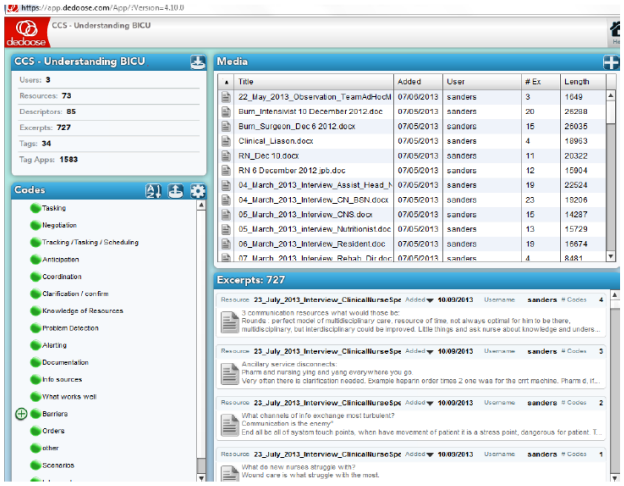
# **Analysis** Systematic Review and Coding







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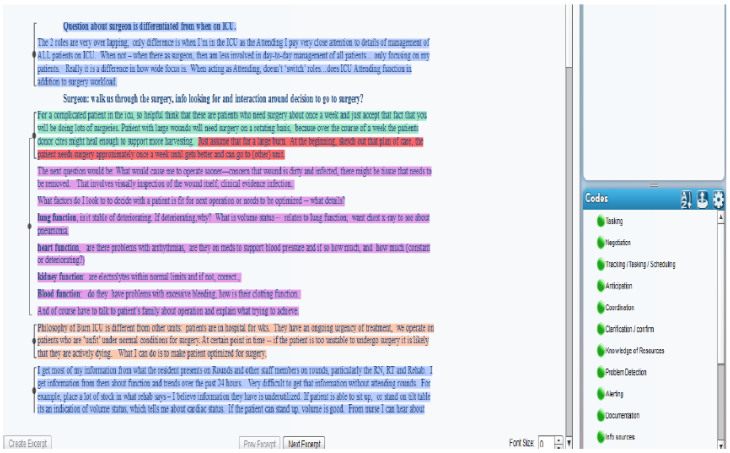
## *Example of a data record in Dedoose*

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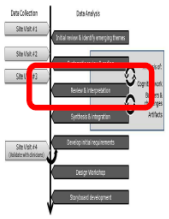
# **Analysis** Review and Interpretation



**Category: Procedural Drag**

**Title: 22_July_2013_Interview_OR-RN.docx**

Additionally, sometimes blood is not ordered early enough, and if we know there is going to be lots of bleeding, then we will sometimes wait and delay the case. In one particular situation, the blood was not in the OR, the anesthesiologist had the patient ready, but the decision was made to wait, to do any incision and grafting. The blood bank was not as quick as we wanted them to be. Usually the anesthesiologist orders blood in Essentris. If the patient in 4east or icu we may need to note. I assume that the majority of our patients are likely to need blood. I will ask about blood when I check in Essentris in the morning and it is not ordered. The anes tech or an OR runner will go get blood in cooler then put it in a fridge in the OR.

**Title: 21May_2013_Nurse_Burn_interview_transcript.doc**

sometimes the on call just doesn't see the importance. Maybe they just want to go through it real quick , but they are very busy and I understand that ICU patients are sick, so often I think they overlook these people that are doing well, in their eyes and they just want to throw over to 4E, but what they really need to do is review all those orders. And I mean, this has been years. I say years, before my time of being hired that they were having issues with these on call residents. You know, where the orders aren't written right for the transfer so I'm going to block the transfer. I'm going to say call on call, hey; I need this, this and this order fixed. And then they came down on us like no, no you can t be blocking transfers you know, but then my orders are inappropriate.

**Title: 21May_2013_Nurse_Burn_interview_transcript.doc**

also what bothers me from pharmacy is doing that many medications in pixes. Something that we are always good at because it is not in stock in our pixes then why don't you send it the day before so that you can always have it in stock and ready to go. So I need to call you every day? And harass you every day for it? Or should you just

**What are the main takeaways?**

**What cognitive activities are the individuals/or team engaging in?**

**What challenges are they facing?**

**What's getting in the way of them doing their work?**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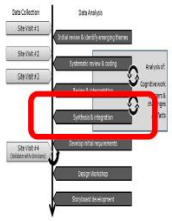
# Synthesis and Integration



**Alerting**

- Bringing issues of concern to one another's attention (i.e., alerting) facilitates team coordination and awareness of patient status.
- Means of alerting across the team depends on level of urgency. E.g. In urgent situations, members of team either bring an issue to someone's attention via F2F communication or via pager.
- Recognition of critical cues/'red flags by members of the clinical team prompts alerting of attending. (and can be missed by those with limited experience)
- Physical presence of physicians in the ICU facilitates alerting.
- Lack of heads-up/alert from others on team and across units prevents ability to anticipate and prepare. (e.g., rec). BICU requires heads-up from other units for patient transfers...when going to CIR, etc.)

**Anticipation**

- Anticipating patient's trajectory, and pre-emptively intervening to head off problems and meet patient needs, is a key cognitive activity performed by clinicians. (needs to be supported by system via develop)
- Morning rounds are a central means for team members to foresee problems and plan treatment.
- Delayed orders obstruct nursing staff, RT, and OT/PT's ability to anticipate and coordinate treatment. (neg: need means to capture and disseminate orders close to real-time)
- Anticipating problems based on pt condition focuses clinician's attention/influences info they attend to. (Residents less able to do this due to limited expertise).
- Common process delays require staff to anticipate patient needs as early as possible so they can begin pushing things through the system.
- Staff use a set of cognitive aids to help them manage expectations and plan their work. (E.g., paper assignment board/charge nurse clip board - tell you who's taking care of what patients.)
- The BICU team anticipates and plans for high pt volume (and associated high workload/staffing needs) based on external factors (e.g., memorial day weekend has high injury potential.)
- Experienced nurses and physicians anticipate novice errors (namely on the part of residents), and intervene pre-emptively to mitigate them.
- Requirements:
  - System needs to support clinician's ability to anticipate patient's trajectory and potential problems.
  - RNs need means to anticipate procedural activities and needs so they can prepare accordingly (otherwise, they don't get this information until surgeon walks into the OR).
  - Need better means to predict staffing needs
  - Need a means to get verbal orders into system at earliest point possible, and means to alert team to changes in orders.

**Tracking, Tasking, and Scheduling**

- Morning rounds are key activity used to develop team's tasking/treatment plans for the day.

**What is getting in the way of efficient, effective patient care and team coordination?**

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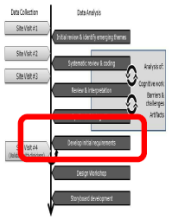
# Develop Initial Requirements



| Comprehensive Integrated View of Patient | | | |
|---|---|---|---|
| **Barrier** | **Needs** | **System Features** | **Impact** |
| **Reliance on clinician to integrate data** | Clinicians need a holistic/macro-view of the patient's trajectory (are they getting better or getting worse over last 24 hrs?) | System should provide trend data on key indicators (e.g., for each of the main bodily systems) | Reduced clinician time to locate data<br><br>Reduced clinician time to synthesize data<br><br>Reduced time to achieve consensus among clinicians |
| **Lack of interoperability among systems** | Minimize staff time spent as the 'system integrators' who move data from one system to another. (addressed in info management category) | System built on a Relational database that has all the info relevant to one patient, so that there is true interoperability: ability of separate systems to cross- populate data, in real time | Reduced clinician time spent entering, moving, repeating, reentering, data.<br><br>Increased time with patients; increased ability to attend to patient issues and needs<br><br>Decrease cognitive workload |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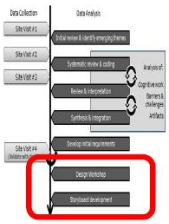
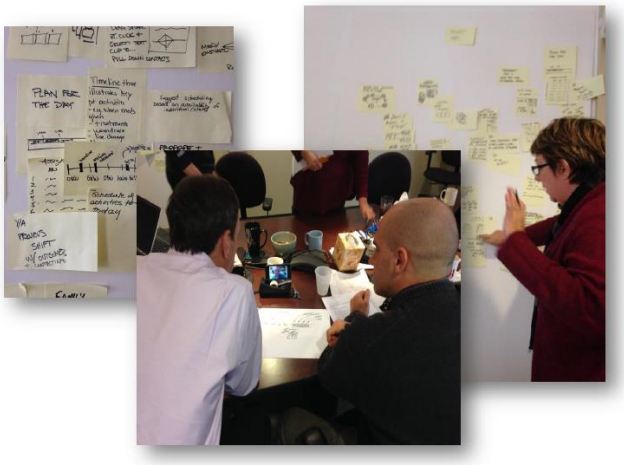
# Analysis to Representation







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# CSE Using Genotypes

***Phenotype**: Clinicians talk among each other, spend a good deal of time writing at terminals*
***Work-around***

***Genotype**:*
*Disconnected databases*
***Source of brittleness***

***Barrier**:*
*No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.*
***Blocks synchronization***

***Requirement**:*
*System shall provide access to a plan of patient care, visible to all care givers responsible for that patient*
***Source of resilience***

***Features**:*
*Current patient status and top-level assessment*
*Goals and goal priorities*
*Changes/updates, such as indication that plan is being updated when one caregiver is working on it*
*Schedule of activities and any changes, timeline*
*Orders and their status*
*Patient's care team identity and contact information*
***Facilitates synchronization***


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# Findings

## Descriptive Model of Cognitive Work

| *Function Unit Members Perform* | *Activities Unit Members Perform* | *Tasks Unit Members Perform* |
|---|---|---|
| **Synchronization** | **Clarification** | Reduce uncertainty<br>Manage ambiguity<br>Manage conflicting agendas<br>Manage communication |
| | **Coordination** | Develop shared awareness of the Patient<br>Get and keep common ground<br>Manage the care plan and treatment goals<br>Coordinate resources |
| | **Negotiation** | Identify alignment, gaps/differences (e.g., agendas)<br>Manage conflicting agendas<br>Manage communication |
| | **Anticipation** | Forward thinking |


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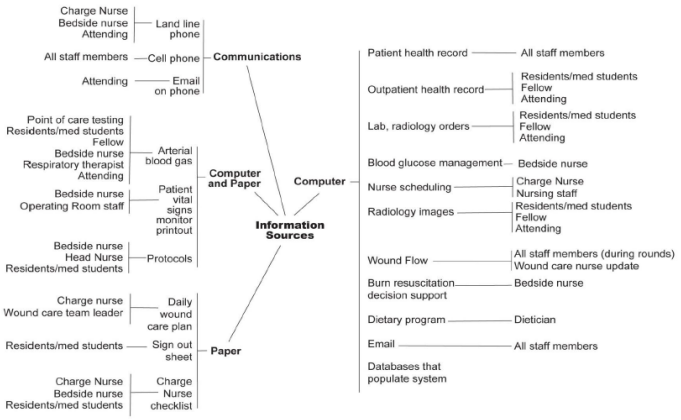
# Findings

## Information Sources





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# Findings

**Problem:** No effective means to synchronize and adapt different aspects of patient care over the course of a shift, across caregiver team.

**Requirement:** System shall provide access to a plan of patient care, visible to all caregivers responsible for that patient that includes:

- Current patient status and top-level assessment;
- Goals and priorities for those goals;
- Changes/updates (e.g., indicating that plan is being updated when one caregiver is working on it);
- Schedule of activities and any changes, timeline;
- Orders and their status;
- Identity and contact information for patient's care team.


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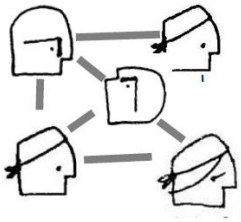
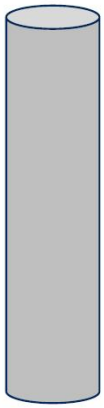
# CCS Elements



**Joint Cognitive System** includes patient, staff, care providers, family & information sources

**Machine learning finds relevant** patterns

**Interface Synthesizes, presents** salient data

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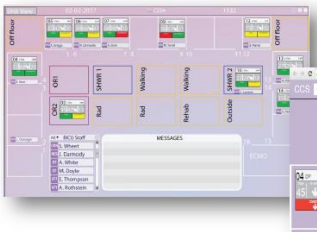
# **Prototype** Unit View

## Information Design



## Software

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# **Prototype** Patient View

## Information Design

## Software

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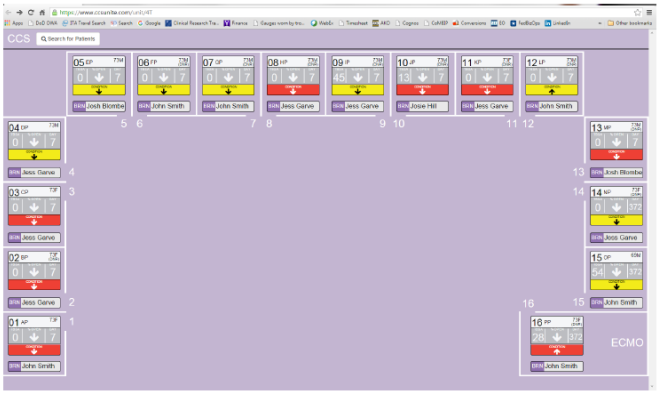
# Prototype




https://www.ccsunite.com/unit/4T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# Prototype

## Comparison with Essentris

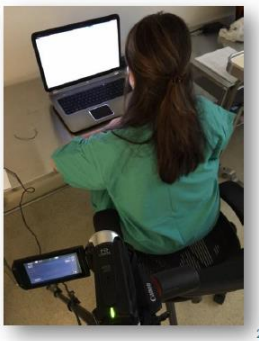
I can find the information I need in CCS **more quickly** than I can using Essentris.

I can find the information I need in CCS **more easily** than I can using Essentris

The CCS system is **easier to use** than Essentris

I would feel **more confident** making future clinical decisions and recommendation using CCS than using Essentris

CCS supports the **way I do my work** better than Essentris.

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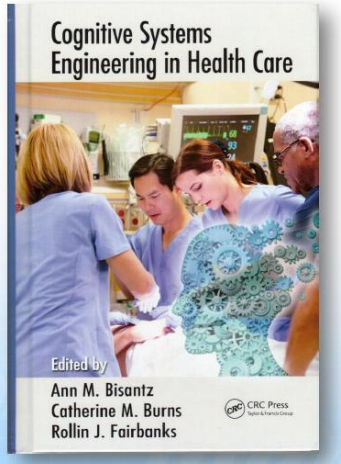
# Publications

**Book chapter (1)**
**Journal paper (2)**
**Proceedings paper (2)**
**Abstract (8)**
**Report (1)**





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# Benefits

**Patient Safety.** Successful implementation of the CCS in the clinical environment has potential to reduce the incidence of medical misadventures.

**Patient care efficiency.** Safety and effectiveness of patient care can be increased by increasing the speed at which clinicians can make accurate clinical decisions.

**Patient care intensity.** Clinicians provided more direct interaction time with patients, by reducing the time burden to find, use needed information.

**Broad applicability**. Can provide the same real time decision support in clinical settings other than military facilities.


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# Next Steps

**Propose bridging project: TRL5 to TRL8**

**Conduct validation assessment**

**Complete prototype**

**Write final report**

*Photo: Department of Defense*


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# Summary

**Research**: Cognitive Systems Engineering methods successfully enabled the team to create an ecologically valid decision making and communication support IT system. JPC-1, TATRC, CDMRP, and USAISR support for publishing was a great help getting word to the professional community.

**Development**: Coordination with USAISR to map data elements from the Essentris healthcare record posed a challenge that the team needed to manage constantly through Year Two into Year Three.

**Administrative**: Institutional Review Board and Defense Health Information Technology security regulations posed challenges throughout the project.

**Transition**: Iterative development through the integration of end users to establish early buy-in is critical for successful implementation.


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SOLVING PROBLEMS OF GLOBAL IMPORTANCE

# Your questions and comments are welcome

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Enclosure (2)

**Usability Assessment: System Orientation**

**System Overview**: In space below document any question the user asked during the system overview (insight into things that are not intuitive in the interface maybe)

Notes from User system training – what questions did they ask? What did we have to explain more (etc.)?

Next, what you have is up to 6 steps for each scenario by role (e.g., Nurse, Attending) broken down by steps in each scenario. You will fill out a 1 page Step sheet for each step in each scenario for each user testing the system. There are now two generic forms – 1 for Surgery and 1 for New Admission.

Scenario 1 for each Step, then three open ended questions on usability Scenario 1. Repeat Scenario 2.

Finally, three open ended questions at the end of the session about CCS overall.

**Recommended Priorities of Note Taking:**

1) **What data element** they search for. (1st in top row, 2nd, in 2nd row, etc). Can use acronym table. Or write out data element.
2) **Observed Problems/Errors** that they encounter. Shorthand terms. Feel free to refine or add to these. Just make sure you both agree. These are based in part on what we saw last week.
    a. **Bad** – can be a system error, not getting data one would expect (e.g., like the time range from last week).
    b. **Diff** – can be a data element that is not where the user expected.
    c.
    d.
3) **Steps** to get data element information – in general was it few (less than 5) or more 5 or greater. You may want to change that rule based on what CCS was designed to do (e.g., 3 steps for the cutoff).

4) **Timestamp –** we start the clock at the beginning, then you just not the current time for each data element if you can. If we can, it would be great to start the video and the room clock at the same time so if you make a note about something we should really look at - that we have a general idea of the time stamp. This might be hard to get and should be dropped.
5) **Perceived difficulty** – Observers rating of whether the user found the info easily or not. Just check the box - did the find the data element – yes, yes with difficulty or no. This can be done for each data element in real time if you can or at the end of each step - when the person is doing the effort question at the end of each Step.

**Scenario 1: Surgery Preparation (Same for Everyone)**

Step 1: Is the patient's hemodynamic status getting worse?

Step 2: Is the patient's pulmonary status getting worse?

Step 3: Is the patient's volume status getting worse?

Step 4: Is the patient's hemostasis status getting worse?

**Scenario 2: New Admission (Different depending on role)**

**3 steps for Nurses, 5 for Doctors, 2 for Respiratory Therapists**

For Nurses:

Step 1: Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same?

Expected: Heart Rate, Blood pressure especially arterial MAP, Fluids-Albumin, LR, Urine output (UOP)]

Step 2: Based on his glucose levels, do you recommend that he be started on an insulin drip (Endotool)?

Expected: Last 24 hours of insulin requirements and blood glucose levels. (Subcutaneous insulin)

Step 3: Set the calendar/clock icon to a start time of 25 Feb 2023 at 0500 and end time of 25 Feb 2023 at 1200. Based on the patient's lab values, do you think he should be started on CRRT?

**Scenario: Prep for Surgery**

| | | | | |
|---|---|---|---|---|
| | Circle Role: Doctor Nurse RT Other: _____ | | | |
| | **Circle Step Number: 1 2 3 4 ___** | | | |
| **List Data Element & Current Time** | **Observed Errors/Problems** | **Notes** | **Num Steps**<br>**0= 1-4**<br>**5 = 5 & up** | **Success** |
| | | | | ☐Found<br>☐Found w diff |

| | | | | |
|---|---|---|---|---|
| Time: | | | | ☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| | | | | ☐Found<br>☐Found w diff<br>☐Did not find |

| | | | | |
|---|---|---|---|---|
| | | | | |
| **Notes: Not tied to a particular data element** | | | | |

**Scenario: New Admission**

| | | | | |
|---|---|---|---|---|
| | Circle Role: Doctor Nurse RT Other: _____ | | | |
| | **Circle Step Number: 1 2 3 4 5___** | | | |
| **List Data Element & Current Time** | **Observed Errors/Problems** | **Notes** | **Num Steps**<br>**0= 1-4 steps**<br>**5 = 5 & up** | **Success** |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| | | | | ☐Found<br>☐Found w diff |

| | | | | |
|---|---|---|---|---|
| Time: | | | | ☐Did not find |
| Time: | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| | | | | ☐Found<br>☐Found w diff<br>☐Did not find |
| **Notes: Not tied to a particular data element** | | | | |

**Post Surgery Scenario Open Ended Questions**

1. Were there any aspects of the system you found difficult to use? If yes, what were they? What made it difficult?

_____
_____
_____
_____
_____
_____

2. Was there any information you needed for this scenario, but were unable to find? If yes, what was it?

_____
_____
_____
_____
_____
_____

3. Any other comments you would like to make at this point?

_____
_____
_____
_____
_____
_____

**Post New Admission Scenario Open Ended Questions**

1. Were there any aspects of the system you found difficult to use? If yes, what were they? What made it difficult?

_____
_____
_____
_____
_____
_____

2. Was there any information you needed for this scenario, but were unable to find? If yes, what was it?

_____
_____
_____
_____
_____
_____

3. Any other comments you would like to make at this point?

_____
_____
_____
_____
_____
_____

**Post Both Scenario Questions about CCS in General**

**Post-Both Scenarios Questions** *(5 minutes)*
**Open-Ended:**

1. What aspects of the interface did you find particularly useful?

_____
_____

_____
_____
_____
_____

2. If yes, which ones and how were they useful?

3. Were there aspects you found difficult to use?

4. If yes, which ones, and what made them difficult?

_____
_____
_____
_____
_____

5. Would a system like this be easily adopted (or integrated into current workflow)? If so why? If not, why not?

_____
_____
_____
_____
_____

6. Are there any additional comments you'd like to share we haven't discussed so far?

_____
_____
_____
_____
_____

Enclosure (3)

**Usability Assessment Facilitator Script 1 January 2016**

---

**I. Introduction and Orientation** *(5 minutes)*

[Introduce self]

Thank you for your time and interest to evaluate this system.

We're interested today to figure out what about the system works well and maybe not so well, to make it better.

We are interested in hearing your thoughts about whether it helps or impedes your work, and how it can better meet your needs as a BICU team member.

None of what we do here will identify you as an individual. We're not evaluating you, just the system

**Consent**

Thank you for indicating your consent on the sign in form. We won't record you or use your name.

We've positioned this video camera to look over your shoulder will only see the screen as you use the system. Is that ok with you?

We'd like to make an audio recording of this session to make sure our notes are accurate. Is that ok with you? [If no: "We can still conduct the session and not record you. Is that okay?]

Please let us know if you'd like to stop at any time.

**Overview of Session**

We will start by asking you to complete a few general questions about your background on the response sheet. We'll also ask you to provide other responses on the sheet as we go along.

We will present you with a clinical scenario and ask you to use the system to perform certain tasks.

As you do, please say aloud whatever's going through your mind. What you're looking for, trying to do, or having trouble with.

When you come to a decision or recommendation, please say it aloud, and note level of effort on the response form

At the end, we'll ask a few questions about your experience using the system.

Do you have any questions before we begin?

**II. Collect Background Information** *(2 minutes)*

We'd like to start by gathering some general background information.

Please use the sheet here to indicate your answers where it says "background" and let me know when you're done.

**III. Scenario Completion** *(two 10 minute scenarios with follow-up questions=30 minutes)*

We would like provide you with a situation and ask you a few questions using this system to find information to make a decision or recommendation.

Picture yourself using the system during your regular clinical work.

Remember to say aloud *everything* that you're thinking. Make comments. Ask questions. Mention any difficulties you're having. Tell us what you're looking for. Any surprises or problems you find.

If you get stuck, or can't figure out how to get the system to do something, feel free to make your best guess of what to do.

**Scenario 1: Preparing for Surgery**

*For Attending Surgeon, Anesthesiologist, Burn ICU nurse*

*Set the calendar/clock start time*

A 69 year old male, 96.6 kg with 54% thermal burns to his face, neck, chest, arms and legs, has just been admitted to the unit. He was sent from an outside hospital. The ED team indicates the patient sustained injuries while disposing of old gunpowder that ignited. The patient is hospital Day 4 and is going to the operating room (OR) for his first excision and grafting procedure He is scheduled as the first case.

Please use the available information to determine whether the patient is ready for this procedure, tell us your recommendation/decision, and circle your level of effort on the response sheet.

1. Is the patient's hemodynamic status getting worse
2. Is the patient's pulmonary status getting worse?
3. Is the patient's volume status getting worse?
4. Is the patient's hemostasis status getting worse?

*After clinician states their decision or recommendation, ask them to complete the following 3 questions also on their system evaluation sheet. Likert-type response format of 1-7 (strongly disagree - strongly agree)*

Please note your response to the Post-Scenario statements on the response sheet.

*Following completion of the Likert-type items above, facilitator will ask the following open-ended questions and note taker will take notes.*

- Were there any aspects of the system you found difficult to use? If yes, what were they? What made it difficult?
- Was there any information you needed for this scenario, but were unable to find? If yes, what was it?
- Any other comments you would like to make?

**********

**Scenario 2: New Admission**

***For Nurse**:*

*Set the calendar/clock*

*The patient is 9 hours post burn.*

Please use the available information to determine whether the patient is ready for this procedure, tell us your recommendation/decision, and write your decision or recommendation on the line next to the question when you are ready.

1. Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same?

2. Based on his glucose levels, do you recommend that he be started on an insulin drip (Endotool)?

   *Set the calendar/clock*

3. Based on the patient's lab values, do you think he should be started on CRRT?

**********

*After clinician states their decision or recommendation for each data element, please ask them to make the post scenario ratings on their response sheet.*

*Following completion of the Likert-type items above, facilitator will ask the following open-ended questions:*

- Were there any aspects of the system you found difficult to use? If yes, what were they? What made it difficult?
- Was there any information you needed for this scenario, but were unable to find? If yes, what was it?
- Any other comments you would like to make?

---

**V. Post-scenario Questions** *(5 minutes)*

In this last section, we would like to ask you about your experience using the system. On the sheet, lease circle the number that best reflects your response.

*Facilitator will finish with these open-ended questions.*

After using this system on two scenarios:

1. Are there any aspects of the interface you found particularly useful?
    a. If yes, which ones and how were they useful?

2. Are there any aspects of the interface you found particularly difficult to use?
    a. If yes, which ones, and what made them difficult?

3. Would a system like this be easily adopted (or integrated into current workflow)?
    a. If so why? If not, why not?

4. Are there any additional comments you'd like to share we haven't discussed so far?

**VI. Conclusion** (*1 minute).* Thank for time and dismiss participant

**********

Enclosure (4)

**Usability Assessment**

**System User Response Sheet** Number: _____ Date:_____ Time:_____

---

Background Please circle one response for each:

| | |
|---|---|
| 1) What is your profession? | Physician Nurse Respiratory Technician |
| 2) How many years have you been in this profession? | <1 year 1-3 4-6 7-9 10+years |
| 3) What is your clinical role on the BICU? | Staff Supervisor |
| 4) How many years have you been working on the BICU? | <1 year 1-3 4-6 7-9 10+years |
| 5) How many years have you been using Essentris? | <1 year 1-3 4-6 7-9 10+years |
| | *not comfortable* *very comfortable* |
| 6) On a scale of 1-7, how would you rate your comfort with Essentris? | 1 2 3 4 5 6 7 |

---

Scenario 1

**Preparing for Surgery**

| | Level of effort to answer this question was (circle) *low* *high* |
|---|---|
| Is the patient's hemodynamic status getting worse? | 1 2 3 4 5 6 7 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Is the patient's pulmonary status getting worse? | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Is the patient's volume status getting worse? | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| the patient's hemostasis status getting worse? | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| Post Scenario 1<br>**System Ratings**<br>Please circle the number that best reflects your response. | Strongly disagree | disagree | Somewhat disagree | Neutral<br>Neither agree Nor disagree | Somewhat agree | Agree | Strongly agree |
|---|---|---|---|---|---|---|---|
| I am confident in my decision/recommendation | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The system was easy to use to make this decision | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The system enabled me to quickly find the information I needed | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| was straightforward to find the information I needed to make a decision/recommendation | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| Scenario 2: Nurse<br>**New Admission** | Level of effort to answer this question was (circle)<br>*low* | | | | | | *high* |
|---|---|---|---|---|---|---|---|
| Based on the vital signs and I/Os, what do you recommend for fluids: | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

| | |
|---|---|
| increase, decrease, or remain the same? | |
| We are now at Hour 4 of his hospitalization.<br>Based on his glucose levels, do you recommend that he be started on an insulin drip (Endotool)? | 1 2 3 4 5 6 7 |
| We are now 7 weeks post admission.<br>Based on the patient's lab values, do you think he should be started on CRRT? | 1 2 3 4 5 6 7 |

| Post Scenario 2 System Ratings<br>Please circle the number that best reflects your response. | Strongly disagree | disagree | Somewhat disagree | Neutral<br>Neither agree Nor disagree | Somewhat agree | Agree | Strongly agree |
|---|---|---|---|---|---|---|---|
| I am confident in my decision/recommendation | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The system was easy to use in making this decision | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| The system enabled me to quickly find the information I needed | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| was straightforward to find the information I needed to make a decision/recommendation | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Appendix AD.** CCS Straw Man Comparison, April 2016

**Prep for Surgery,** Scenario 1, Task 1-- Is the patient's hemodynamic status getting worse?

Essentris

| ET | Activity | Verbal protocol |
|---|---|---|
| | Initial screen, vital signs to check his stability; Began scrolling through visible data | He's lightly sedated. On insulin, They stopped vasos, |
| 1:15 | | On ketamine<br><br>I'm looking at vitals-BP, Temp, tidals, blood glucose, pressors, pain meds |
| 1:23 | | He's off vasopressors.<br><br>MAPs are good |
| 1:51 | | Based on vitals, he's ready to go to OR |
| 2:12 | Back to labs | H&H, 10.6 is good, platelets are low |
| 2:44 | | Based on vitals, he's ready to go to OR |

CCS

| ET | Activity | Verbal Protocol |
|---|---|---|
| | Cardiac tab.<br><br>Looking for trends and seeing what's available. HR, BP and temp. | "Interesting that temp is in the cardiac section." |
| 1:20 | Looking at F and C temps, vasopressin. | |
| 1:30 | Looking at CVP | |
| 1:40 | | "Not getting worse. Stable." |

Scenario 1, Task 2-- Is the patient's pulmonary status getting worse?

Essentris

| ET | Activity | Verbal protocol |
|---|---|---|
| 0:27 | Vitals flow sheet | Evaluating sats and respiratory status.<br><br>Resp is 22, O2Sat 98. On vent, 60%, not spectacular. Pressure control mode is not annotated. No spike in resp |
| | | Wish I had ABG |
| | | He's not getting worse |
| 2:30 | Labs. | Go to vent tab to double check. |
| 3:11 | | Pressure control is SINV, check mode notes with pressure support |

CCS

| ET | Activity | Verbal Protocol |
|---|---|---|
| | Respiratory tab. | "Elevated respiratory rate." FiO2. "Is the Pt mechanically ventilated?" "What is BTEXP?" Tidal volume expired? |
| 1:34 | | PEEP is 8. |
| 1:37 | Found vent settings | . |
| 1:49 | Found bronch findings | |
| 1:54 | Went to vent history. Found it went from pressure control | |

| | | |
|---|---|---|
| 5:02 | | I would look at ABG |
| 6:35 | | Pulmonary status is getting worse. I'd re-verify from the notes though. |

| | | |
|---|---|---|
| | to spontaneous pressure control with pressure support. | |
| 2:19 | Looked at ABGs. | Said "it looked empty." |
| 2:37 | | "I don't think we are getting worse." |

Scenario 1, Task 3-- Is the patient's volume status getting worse?

Essentris

| ET | Activity | Verbal protocol |
|---|---|---|
| | I/Os | Already looked at vitals, H&H are good. Looking at total in/out and urine out for foley |
| 1:10 | | Significant drop, but overall positive |
| 3:07 | Labs | BUN, creatinine, been pretty much the same. Summary screen indicate ins and outs. Main issue, can see high and low, but not clear on status |
| 4:15 | | Volume is the same, not getting worse |

CCS

| ET | Activity | Verbal Protocol |
|---|---|---|
| | Renal tab.<br><br>Looked at I's and O's, fluids. Noted Pt had some PO intake | . "I don't know if this is tube feeding or meds." I see ketamine. Pt has a foley. |
| 0:39 | Looking for I's and O's | "out more than in." |
| 1:03 | | "Pt is getting better." "Not sure if this is a shift. I'm assuming the time on the graph is a shift." |
| 1:45 | | "Large dump of urine. " |
| 1:51 | | "This is not a total." |
| 2:13 | Looking at net I and O's. | "It's positive. It's only telling me now. It's not enough time in the view. They need to change the time view so it's not just a 24 hour period." Need yesterday (day prior)." |
| 3:32 | | Need hours or dates changed to see a whole week. That would be more helpful." |
| 4:04 | | "Not getting worse." |

**New Admission**, Scenario 2, Task 1--Based on the vital signs and I/Os, what do you recommend for fluids: increase, decrease, or remain the same?

Essentris

| ET | Activity | Verbal protocol |
|---|---|---|
| | *Vital signs,* | Having issues with Levofed, |

CCS

| ET | Activity | Verbal Protocol |
|---|---|---|

| | | |
|---|---|---|
| | *notes* | on-off<br><br>MAPS no change<br><br>Off hypotensive<br><br>Start albumin at 75<br><br>MAP improved |
| 1:30 | | Have to increase fluids to verify with labs and I/Os |
| 2:20 | I/O's | Steadily increasing LR<br><br>He's "in resuscitation" |
| 3:25 | | Output increasing 30.12 next day.<br><br>Definitely increase fluids, don't need labs. |

| | | |
|---|---|---|
| | Renal tab | Looking at I's and O's. |
| 0:27 | Looked at fluids | "I've got LR at 1,000. Albumin, so this must be active resuscitation." |
| 0:47 | Looked at urine output. | "Not enough." |
| 0:57 | Cardiology tab | "I'm looking for hemodynamic status. HR is down." |
| 1:40 | Looked at temperature | |
| 1:52 | Looked at BP. | "I can't scroll." |
| 1:58 | Looked at MAP, pressors. | |
| 2:19 | Looked at CVP. | "Not trending." |
| 2:29 | Looked at lactate. | "Up in fluids, H&H is concentrated." |
| 2:48 | | "I would go up on fluids" |

Scenario 2, Task 2-- Based on his glucose levels, do you recommend that he be started on an insulin drip (Endotool)?

Essentris

| ***ET*** | ***Activity*** | ***Verbal protocol*** |
|---|---|---|
| | Vital signs | Evaluate blood glucose at least 180 |
| 0:53 | | Yes, I would add glucose |

CCS

| ***ET*** | ***Activity*** | ***Verbal Protocol*** |
|---|---|---|
| | Endo/GI | |
| 0:12 | | [Reiterated protocol for starting insulin drip.] |
| 0:16 | | "Yes, start insulin drip." |

Scenario 2, Task 3-- Based on the patient's lab values, do you think he should be started on CRRT?

Essentris

| ***ET*** | ***Activity*** | ***Verbal protocol*** |
|---|---|---|
| | | |
| | | I will go through urine output, BUN, creatinine |
| 0:47 | I/O's | Looking at output, low 40s |

CCS

| ***ET*** | ***Activity*** | ***Verbal Protocol*** |
|---|---|---|
| | Renal tab<br><br>Looking at urine output, BUN, creatinine, potassium and | |

| | | |
|---|---|---|
| | | Total I/Os 7k in<br><br>No putting out much. |
| 1:30 | | I'm already thinking CRRT |
| 2:22 | Labs | K is climbing<br><br>BUN and Creatinine |
| 2:45 | | Yes, I would start.<br><br>Lactate isn't available, I would look at ABG |

| | | |
|---|---|---|
| | phosphate. | |
| 1:03 | | "Not yet. Do not start CRRT." |

**Appendix AE.** Trip Report to AISR Validation Study, June 2016

APPLIED RESEARCH ASSOCIATES, INC.

19 June 2016

From: Christopher Nemeth, PhD
To : Mr. Tony Story, CDMRP
Cc : Jose Salinas, PhD, Army Institute for Surgical Research

Subj : Trip report : AISR Validation Assessment 8-15 June 2016

1. Executive Summary. Applied Research Associates, Inc. (ARA) is under contract W81XWH-12-C-0126 to the U.S. Army Medical Research & Material Command's (USAMRMC) Congressionally Mandated Medical Research Program (CDMRP). The Cooperative Communication System is intended to be part of a joint cognitive system that allows the healthcare team to remain connected to an individual patient and to each other across time and space as the team delivers patient care. In addition to the improved communication among providers, this project explores the potential to provide relevant information to support clinician decision making.

We planned for and conducted the validation assessment to leverage the foundation data collection, analyses, and prototype development by:

- Determining how well the prototype version of the CCS graphical user interface (GUI) supports team cognitive work.
- Comparing team performance using the CCS with performance while using Essentris
- Discovering how team members use the CCS messaging feature

2. ARA Staff. Research personnel on this trip included Christopher Nemeth, PhD, Dawn Laufersweiler, Tony Hamilton, and Greg Rule.

3. Activities. The validation assessment would follow task scenarios, and collect quantitative data (e.g., time to complete task) and qualitative data (e.g., subjective report on ease of use). Findings would be used to compare team performance using the CCS compared with the current Essentris EMR. All information would be collected in accordance with IRB-prescribed procedures. Two teams of three BICU clinicians (attending physician, resident and nurse) would participate in two 4-6 hour clinically relevant scenarios (sepsis, ARDS) held over two days on the unit using either the CCS or Essentris.

Mr. Hamilton arrived a day earlier than planned to resolve issues created by a BAMC IT update that temporarily made the CCS unavailable for use. Ms. Laufersweiler, Mr. Rule and Dr. Nemeth used the coding scheme they had developed and practiced to document team activity and also documented team comments during post-scenario session reviews.

b. USAISR Meetings. Dr. Nemeth and Mr. Rule met with Dr. Salinas on 8 June to discuss plans for the CCS transition to development.

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4. Results. The ARA team collected observer notes for each role that noted the kind of cognitive activity that was observed (e.g., information searches, decisions). We also collected post-scenario team comments and a brief survey that each participant completed to report on their scenario experience that day. The ARA team also recorded team activity on video through each scenario to serve as a back-up in case of questions that observer notes could not answer.

5. Further work. Next steps for the project are:

- Analyze the quantitative and qualitative data at ARA offices 27 June-1 July
- Draft findings section for the CCS project final report
- Translate findings into manuscript for submission the journal *Critical Care Medicine*

6. For further information, contact Dr. Nemeth at 847-869-3621, or cnemeth@ara.com.

**Appendix AF.** CCS Validation Assessment Research Team Field Guide, May 2016

**Research Design**

Clinicians will be asked for their consent to participate in this validation assessment of the CCS interface while they perform team based patient care during two simulated clinical scenarios. Participants will be recruited to participate in one of two clinical teams. Each team will consist, at a minimum, of one attending physician, one bedside nurse, and one resident, who will also interact with other multidisciplinary care team members on the BICU service. At the beginning of the session, the clinical team will be oriented to the scenario.

Two teams will be formed from those who consent. Each team will engage in two simulated scenarios lasting up to 8 hours each using either the current Essentris-based health record alone or Essentris with the CCS prototype to access and view clinical data. The first scenario is the team's response to a patient's potential infection (sepsis). The team must evaluate whether the fictional patient is becoming septic and how to treat it. The second scenario is the team's response to a critically ill patient with severe ARDS who may be a candidate for Extra Corporeal Membrane Oxygenation (ECMO).

On the day after orientation, the clinicians will perform one of the scenarios using the CCS in the morning, then the other scenario not using the CCS in the afternoon or the following day. The Facilitator will introduce scenarios during "change of shift" handoffs to scenario participants. The clinical team will be asked to use either standard of care information sources, or standard of care information sources plus the CCS to make clinical decisions and care for the patient. The scenario participants will interact with the simulated patient data over a period of about six hours. Observers will take notes throughout the session. The Simulation Monitor will note clinical team decisions and advance the scenario "clock" to the next simulated patient data set. After the scenario begins, the scenario participants will be expected to review the available simulated patient data and make appropriate decisions based on the information provided. The scenarios are structured to require specific sets of anticipated clinical decisions.

| | |
|---|---|
| Scenario 1<br><br>Abdominal Sepsis | • initiation (delivery) of antibiotic therapy,<br>• decision to perform diagnostic procedure (i.e., diagnostic peritoneal lavage or exploratory laparotomy),<br>• decision to perform exploratory laparotomy or transition to palliative care,<br>• communicate with the family/patient's decision maker |
| Scenario 2<br><br>Severe ARDS | • initiation (delivery) of antibiotic therapy,<br>• paralyze the patient,<br>• order the rotaprone bed,<br>• initiation or decision not to initiate inhaled nitric oxide therapy,<br>• consult the ECMO service, decision to cannulate or forgo cannulation for ECMO<br>• communicate with the family/patient's decision maker |

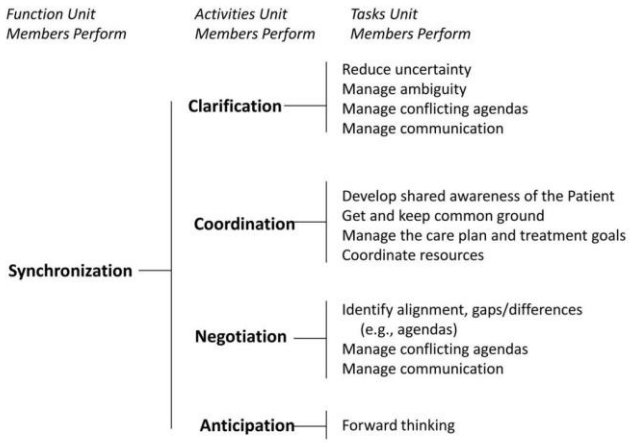
When the participants encounter a decision point, the Observer will document details, including what decision is made, who participates in the decision from the core team and extended clinical staff, what information they use to make the decision, and how long it requires them to identify the information

and complete the decision making process. The scenario will proceed to the next step based on the decision made regarding the care and treatment of the simulated patient. The scenario team will complete the exercise while performing their normal clinical duties on the floor.

At the conclusion of the scenario, the Facilitator will ask members of the scenario team several subjective questions about their experience. They will repeat the process using the alternate scenario the same day or the next day.

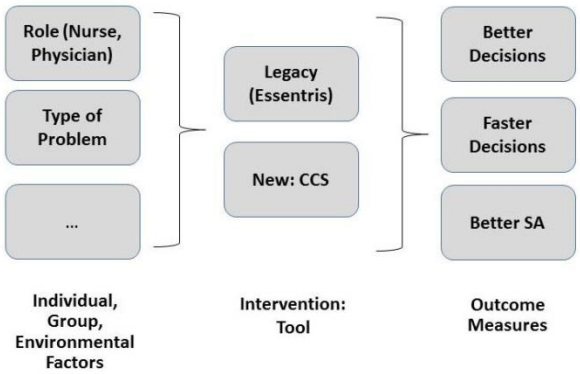
**Observation**

During Phase One, the team identified tasks BICU care providers performed that reflect macro-cognitive activities. The descriptive model included Clarification, Coordination, Negotiation, and Anticipation. The research team will observe clinical team activity during the validation assessment to document macro-cognitive activities. Our goal will be to reflect team cognitive activity as the scenario proceeds. In the notes section, particular points of comparison will matter between the Essentris and CCS scenarios. What does the team do:




- When they need to find/compare information?
- When there is a need to communicate?
- When they need to check trends/patient history?

The guide is organized to focus attention on how the use of either Essentris or CCS changes outcomes. Are outcomes (e.g., efficiency, situation awareness) better or faster using either system and in what way?



**Outcome Measures**

Improvements to clinician cognitive work will be manifest in ways we can observe and document. Our observations need to be sensitive to activity related to these four measures.

- Salience—CCS presents important patient information
- Shares awareness—CCS makes important trends evident
- Efficiency—CCS composite view enables clinicians to act more decisively, sooner
- Collaboration—CCS messaging enables clinicians to build consensus, sooner

| Process, Code | Example | Definition, Macrocognitive Activity |
|---|---|---|
| **Search (S)** | "I'm looking for X.. I'm looking for Y and Z info."<br><br>"Where is… Y information?"<br><br>(as long as they are asking for information from the system. | Searching for information in a system (not from a person).<br><br>*Uncertainty management*-Efforts to overcome when something is unknown or not understood.<br><br>*Developing mental models*- Mental imagery and event comprehension, based on abstract knowledge and domain concepts and principles. |
| **Perceive patterns (P)** | "I wonder if it's X kind of thing that's happening." | Person is able to put information together to perceive patterns, describe possible future states, and possible scenarios. Fitting data from search with mental models.<br><br>*Sense making*- Diagnosis of how current state came about and anticipation of how it will develop.<br><br>*Mental Simulation and Storytelling*-Enacting events and pondering how they may lead to possible futures. |
| Collaboration<br><br>**Clarification (C)**<br><br>**Question (Q)** | Two types of actions:<br><br>Clarification: [Push]"I have information."<br><br>[Pull] "Do you have information?"<br><br>Integration-Merges information | Coordinating between two or more people (within and outside the team).<br><br>*Coordination*- How team members sequence actions to perform a task.<br><br>*Maintaining common ground*-- Ongoing maintenance and repair of a calibrated understanding among team members |

| | | |
|---|---|---|
| **Integration (I)** | with info someone else has | |
| **Decide (D)** | Order entry for either diagnosis (figuring out what the problem is) or therapeutic intervention (care plan). | Document when orders are entered.<br>*Problem detection*- Ability to notice potential problems at an early stage.<br>*Planning*--Changing action in order to transform a current state into a desired state.<br>*Naturalistic Decision Making*- Reliance on experience to identify a plausible course of action and use of mental simulation to evaluate it. |

We will use an activity analysis format to keep brief but meaningful notes. The challenge will be to keep the notes simple yet also recognizable. Our records should reflect who did what and when. We've assembled a table to help each observer to keep track of that information as the scenario plays out. The table is organized to reflect that with a column for time, role (Nurse, Resident, Attending, RT/PT), activity, and notes. Rather than write out terms, it's easier to use codes. We've added unique cods next to each of the macro-cognitive terms that can be jotted into the "code" column. It will help to keep the table handy for reference.

CCS Validation Assessment Observer:_____ Page: ____

Research Team Field Guide Day/Scenario:_____

| Time | Who | Code | Note |
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Crandall, Klein and Hoffman (2006) described the following macro-cognitive activities:

| **Activity** | **Description** |
|---|---|
| Naturalistic decision making | Reliance on experience to identify a plausible course of action and use of mental simulation to evaluate it. |
| Sense making/ situation assessment | Diagnosis of how current state came about and anticipation of how it will develop. |
| Planning | Changing action in order to transform a current state into a desired state. |
| Adaptation/re-planning | Modification, adjustment or replacement of a plan already implemented. |
| Problem detection | Ability to notice potential problems at an early stage. |
| Coordination | How team members sequence actions to perform a task. |
| Developing mental models | Mental imagery and event comprehension, based on abstract knowledge and domain concepts and principles. |
| Mental simulation and storyboarding | Use of mental models to consider the future, enact a series of events, and ponder them as they lead to possible futures. |
| Maintaining common ground | Ongoing maintenance and repair of a calibrated understanding among team members |
| Managing uncertainty and risk | Coping with a state or feeling in which something is unknown or not understood. |
| Turning leverage points into courses of action | Ability to identify opportunities and turn them into courses of action. |
| Managing attention | Use of perceptual filters to determine the information a person will seek and notice. |

**Appendix AG.** CCS Machine Learning Validation Report

APPLIED RESEARCH ASSOCIATES, INC.

## Validation Report for the Cooperative Communication System Machine Learning Use-Cases

Oct 31, 2016

Contract: W81XWH-12-C-0126

ARA developed three Machine Learning Use-Cases for CCS:

| | |
|---|---|
| **Wellness Trajectory** | Provides a time-series score reflecting the patients overall condition. A wellness score is a real number between 0 (indicating near death) and 1 (likely ready to discharge from the BICU). |
| **Patient Cohorting** | Provides a ranked set of historic patient records intended to give a clinician insight for the treatment of the current patient by reviewing reverent examples of previous care and outcomes. |
| **Problem Recommender** | Provides a set of potential medical problems indicated by performing simple Natural Language Processing (NLP) on the notes data in the heath record so as to cue clinicians to consider these possibilities. |

In machine learning, we often use expert classification to train our computational models (i.e., supervised learning). This requires an expert to generate a labeled training set that the model then learns to apply to new (i.e., test set) data. In these cases, validity is established by executing the model on an expert labeled testing set and measuring the results. In the case of these three CCS ML Use-Cases, we did not have a labeled data set. All of our data were copied and cleaned directly from the electronic medical records system (Essentris). Addressing these use cases with this sort of data required us to use a combination of analytics, and unsupervised and supervised machine learning. Unfortunately, this complexity prevents us from validating by using a split of the data as a test set, because there is no split of the data that contains the correct answers.

To address these challenges, our methodology for validation incorporates both SME input for a small set of analytic comparison values and rules for face validity of the outputs. Given constraints on SME time, these data are woefully insufficient to train/re-train the models, which would be desirable. When feasible, we compare our ML-produced results against those that use alternative automated reference methods and evaluate consistently. Due to having no accredited models for these use-cases or this context, results here offer guidance for development but they do not strictly validate the performance of our models. We detail our validation process for each independently in the next three sections.

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## Wellness Trajectory Validation

Wellness is a subjective term and the degree of wellness within the context of a BICU is not a universally agreed upon measure. There are several existing methodologies (such as SOFA and APACHE 2) that have been used to manually quantify the probability that a given patient will die based on historic cases in general ICUs. We are essentially developing similar measures using machine learning and other analytics and focusing on modeling a set of historic BICU patients. Our methods are intended to be exclusively informed by, and executed using, available raw health record data without human intervention.

Our ML approach for this use-case consisted of using the last two days of a patients stay as a representation of the extremes of wellness. The final days of patients with the disposition of deceased were used as examples of an extremely low wellness level (notionally 0.0), while discharged patients final days were assumed to have been high wellness (notionally 1.0). We trained a set of ML classifiers on these samples, and performed 10 fold cross validation on each model (see analytic validation below). Each classifier used a different ML strategy and we ensemble their results to establish the final Wellness Score for each patient for each day of their stay.

There are three significant challenges in validating this use-case:

1. There is no standard for a correct wellness score, particularly one bound by our ranges. It is therefore not possible to train our model on labeled cases. To resolve this, our models are derived from data in each historic patient's last 48-hour window and labeled based on the final disposition of the patient. Without training data for known interim values, our models infer a probability for each disposition in any time window. In validation, we will need to check if this scale reasonably approximates the subjective estimates of clinicians.
2. Our models are developed exclusively using an IRB approved 2-year patient data set specific to the Burn ICU. This limited data set introduces the risk that our models are not sufficiently general. In validation, we must be sensitive to the fact that in our BICU data, there is limited diversity in presenting problems, and every patient is actively cared for throughout their stay. Only a small percentage of the patients pass away during stay, which biases predictive models.
3. Our models only use available data in the health record; no additional information is to be provided. While more flexible, this approach does not leverage the depth of medical knowledge an expert would and therefore may not capture the nuances of individual cases. In validation, we must watch for cases where medical experts would infer condition information that is not explicit in the data.

## Validation Methodology

We performed validation on the entire stays of 320 patients. Only 4.4% of those patients died during their stay in the BICU (Table 1). The length of their stay averaged 12.8 days (min <1 day, max 123 days), a complete histogram of stay by disposition is in Figure 1.

Table 1. Summary of Patient Final Disposition for Wellness Trajectory

| | n | n% | Avg. Stay |
|---|---|---|---|
| DECEASED | 14 | 4.4% | 8.3 days |
| DISCHARGED | 306 | 95.6% | 13.0 days |
| | **320** | **100%** | **12.8 days** |

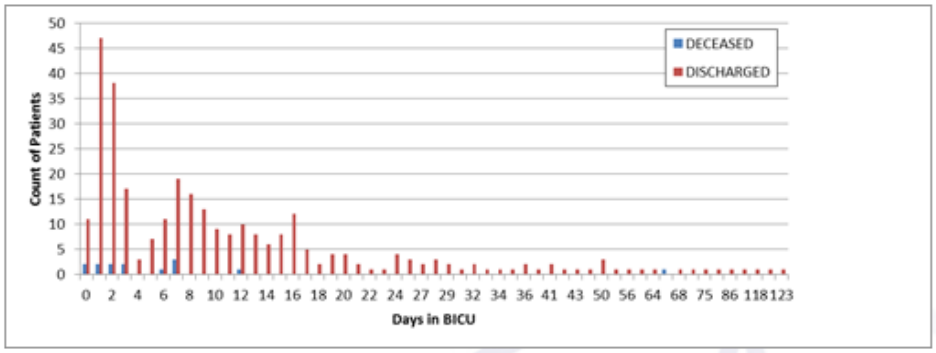



Figure 1. Histogram of the number of patients (by final disposition) and the duration of their stay (in days) in the BICU.

## Methodology for Domain Expert Validation

We selected a cohort of 5 patients from our IRB-approved data set for assessing wellness trajectories with a SME by filtering patients with BICU stays of at least 20 days (we needed multiple diverse points within each patient stay), had data daily, and controlled for final disposition (Table 2).

Table 2. Patients used for Expert Assessment for Wellness Trajectory.

| | Duration | Disposition |
|---|---|---|
| **Patient A** | 18 days | DISCHARGED |
| **Patient B** | 57 days | DECEASED |
| **Patient C** | 15 days | DISCHARGED |
| **Patient D** | 22 days | DECEASED |
| **Patient E** | 37 days | DISCHARGED |

After consenting, we elicited 3 assessments (randomly within in the early, middle, and late portions in their stay) for each patient from the SME. The SME was free to use their own judgement in assessing wellness, but our SME modeled their assessments after the Phases of Illness Paradigm (POIP) approach with subjective adjustments. We quickly discovered that the manual process for evaluating Wellness is extremely time-consuming. It required 6 hours of SME time to elicit 15 data points, which prevented us from gathering a larger sample for validation. The major reason for this was that the EMR data was not presented in a manner amenable to retrospective analysis. Our expert had to manually

search for data, make assumptions, sometimes try to recall the situation, and read clinician notes to try to decode what was occurring in historic data. Progressively within this collection, our SME started prioritizing using the flexibility of the CCS portal to view larger spans of time graphically and perform more selective queries into the EMR when necessary to clarify the meaning of the data they were viewing. We wrote down the final assessment for each patient/time combination. Due to time and availability constraints, we focused on a single SME and are unable to perform inter-rater reliability assessments.

### Methodology for Analytic Validation

In addition to our Wellness Condition model, we implemented a Modified SOFA score. We modified SOFA in two ways: (1) to accommodate automation using the data available in the EMR, (2) we normalized the scale and inverted it (SOFA is normally a measure of sickness not wellness). Our modified SOFA algorithm serves as comparisons for our validation process.

We calculated the Mean Absolute Error (MAE) for both our ML and Modified SOFA algorithms by differencing the condition points from SME provided assessments:

$$MAE = \frac{1}{|x|}\sum_{x} ABS(alg_x - sme_x)$$

Strategies with a lower MAE more closely match the SME assessments and are considered superior. The magnitude of the MAE is consistent with the normalized Wellness values.

### Cross Validation for ML Classifiers

Internally to our code, we train 12 different ML models on the automatically generated labeled training set from the final 3 days of each patient's stay. This data set includes 3254 features based on the various data elements discovered in the EMR, their counts, first derivative, and variance for each day. In practice this feature set is sparse as most patients do not have most values for most days. We ensemble these models to run against data significantly different from the training set (i.e., all non-terminal times when the patient falls somewhere between discharge and deceased). However, we can use traditional ML validation approaches to assess the quality of the individual ML models. We used Weka, which is a collection of machine learning algorithms for data mining tasks (http://www.cs.waikato.ac.nz/ml/weka/), to execute 10-fold Cross Validation of these models. When repeated, Weka splits the data set into training and test sets (a fold) and averages the evaluation of the test set across all folds. Our training set includes 1250 samples from multiple patients. A smaller MAE indicates a classifier that more closely models the data (over many folds).

## Results for Wellness Trajectory Validation

In patients A (Figure 3) and B (Figure 4), our Wellness Trajectory and Modified SOFA significantly overestimated wellness relative to the SME's assessment. Patient C (Figure 5) was closer but still underestimated. Our Wellness Trajectory model produced results similar to the SME for Patients D (Figure 6) and E (Figure 7). We assessed the difference between SME-elicited wellness estimates, and generated values and computed mean absolute error (which are already normalized)

Table 3. Mean Absolute Error (MAE) relative to SME assessment.

| | Wellness Condition | Modified SOFA |
|---|---|---|
| **Patient A** | 0.37 | **0.30** |
| **Patient B** | **0.38** | 0.40 |
| **Patient C** | **0.13** | 0.28 |
| **Patient D** | **0.07** | 0.36 |

| | | |
|---|---|---|
| **Patient E** | **0.13** | 0.31 |
| | **0.22** | 0.33 |

ARA's Wellness Condition values were most often closer to the SME values than the Modified SOFA scores. Both methods tended to be overly optimistic about the patient's condition relative to the SME, with our Wellness Condition above the SME in 80% of the points. Our model likely overestimates because the training data set for our ensemble of models only includes 4.4% deceased patients, so the base rate for disposition is significantly in favor of being discharged. Since the BICU frequently intervenes on the behalf of their patients this optimism in the model is not unfounded. Secondarily, our models are based on terminal dispositions, so they do not characterize issues that are serious only if left untreated (but are never left untreated) as detrimental to wellness.

Modified SOFA is a pure formula based analysis performed for general ICU use and includes a wider range of issues than might be found in the BICU patients. Our approach to normalizing each of the component scores gives credit for not having high sickness levels in each component. Since a patient is unlikely to be at the most sick level concurrently for every component score and still be alive, these normalized scores tend to overestimate wellness.

*Cross Validation Results.* The MAE for the 12 individual classifiers via 10-fold cross validation indicates that each model is reasonably accurate (Figure 2. MAE using 10-fold Cross Validation for each model in the Wellness Condition ensemble.Figure 2). The mean MAE was 0.05 (min 0.02, max 0.06, sd 0.01) Correctly classified instances averaged 95.8% (min 93.6%, max 98.2%, sd 1.6%) across models. However, given the disproportionate number of patients being discharged alive, these rates reflect a bias towards classifying cases as discharged.

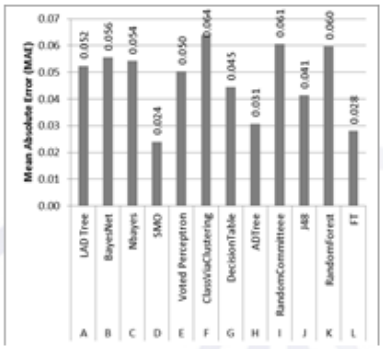


Figure 2. MAE using 10-fold Cross Validation for each model in the Wellness Condition ensemble.

*Notice: In the following graphs, wellness trajectory scores are computed for all days where the EMR contains any data. In some cases, data is entered into the EMR for patients that have already been discharged. These may reflect entry from notes, charts, or pending lab results. Each method makes its own determination when there is sufficient data to make an assessment.*

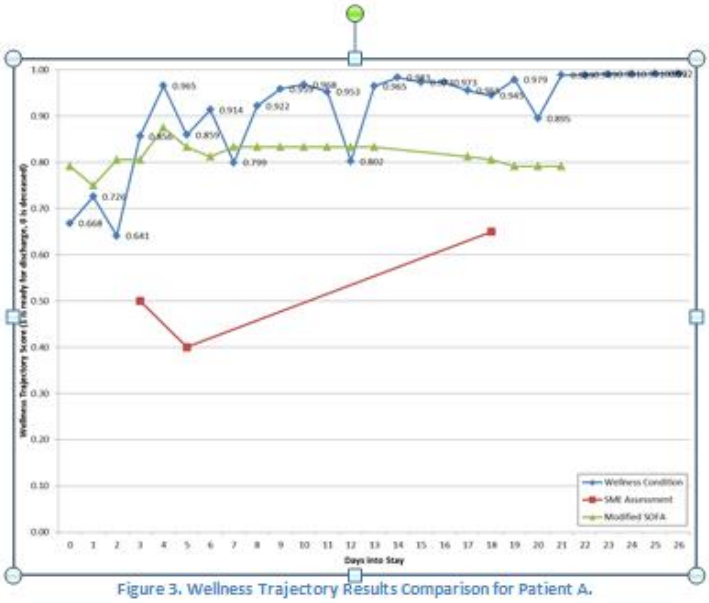



Figure 3. Wellness Trajectory Results Comparison for Patient A.

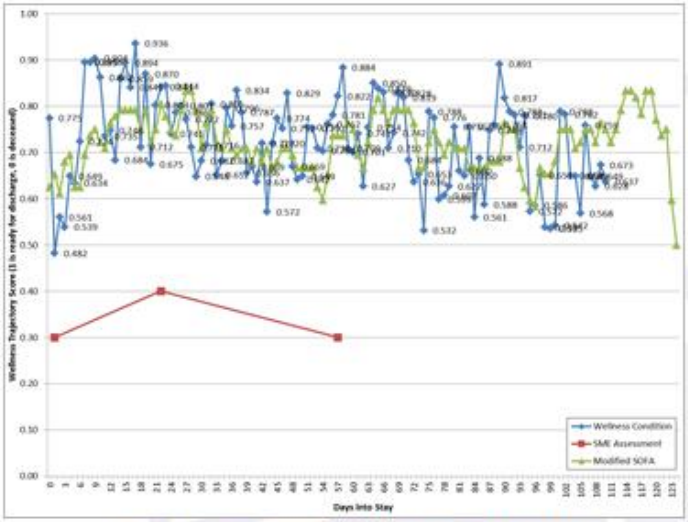



Figure 4. Wellness Trajectory Results Comparison for Patient B.

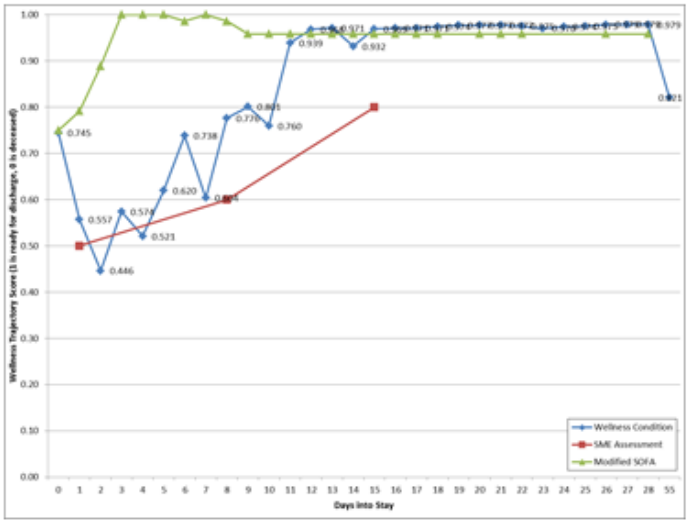



Figure 5. Wellness Trajectory Results Comparison for Patient C.

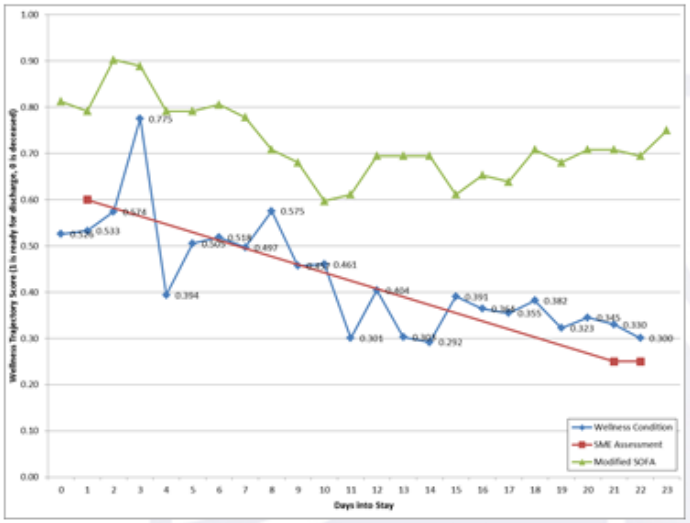



Figure 6. Wellness Trajectory Results Comparison for Patient D.

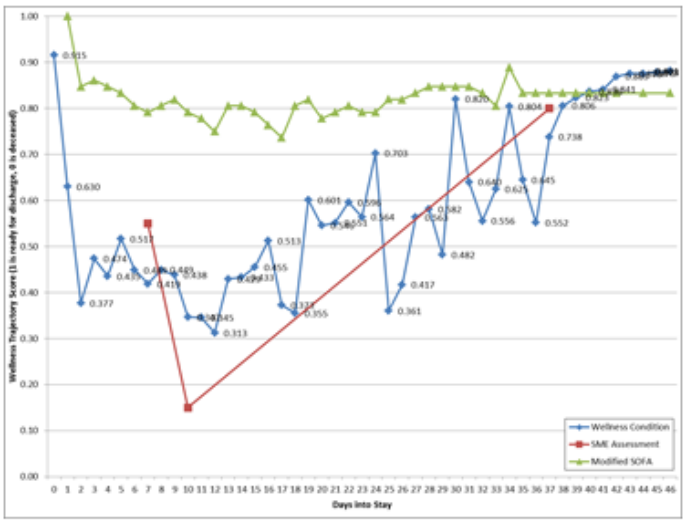



Figure 7. Wellness Trajectory Results Comparison for Patient E.

## Patient Cohorting Validation

Patient cohorts are used to identify historic cases that may be of value for decision making in the subject case. There are many ways to cohort, and different methods result in different cohort compositions. Ideally, the cohort selection process would be directed towards identifying cases to support a specific decision-making situation. We were directed to analyze the raw EMR data, which was not labeled for any decision context or with examples of cohorting from which to train our models. In this research, we developed several models assessing how similar a pair of patients' data are at some point in time, and how similar their stay up to that point in time is to other patients' full-stay. We believe there is benefit to each, and they are detailed below:

**Window-based** We compare one patient at one time interval (8hrs), with all other historic patients at all of their equivalently sized time intervals. This identifies the extent to which patient A at time A' is similar to patient B at time B', for all patients and all time windows. This is particularly useful for comparison of immediate/short-duration conditions. We computed windowed similarity by comparing available data in and near the time interval and statistically determining how likely two patient's values are to being drawn from the same population (incorporating Student's T-Test). The key factor in ML tailoring of these windows is learning the weights to apply to each feature, we developed three weighting models:

- **Simple Mean** – This considered each feature to be equivalent.
- **Expert Directed** – This model increase the relative weights for features indicated by an SME to be the most important for cohorting.
- **PCA Derived** – This model uses weights that were determined through a Principal Component Analysis (PCA) to be the most significant for differentiating patient samples. PCA translates data into a multidimensional space based on Eigenvectors (EVs), and our weighting of factors is determined by the most significant EVs.

**Temporally Aligned** We additionally compare one patient to another over the course of their entire stay in the BICU, where similarity is computed between temporally ordered sequences of windowed comparisons (using any of the above methods). This identifies patient history similarities and is expected to be useful for full admission condition comparisons because it identifies the extent to which patient A has maintained similarity to patient B over the course of their stay to date. We evaluate two methods for grouping

- **Full Stay Aligned** – This considered each feature to be equivalent.
- **Full Stay Clustered** – This model prioritizes collective similarity by grouping similar patients, so recommended cohorts are mutually similar.

In the validation, we will compare the effective of each approach. It should be noted, that NONE of our methods focus on the traditional demographic approach to cohorting. In fact demographics are not considered at all, introducing a risk in making comparisons against domain expert's subject opinion which may consider these factors significant.

## Validation Methodology

Due to time requirements it was infeasible for an SME to manually determine equivalent cohorts based on direct temporal windows similarity. However, our SME identified two key factors for face validity based on our graphical user interface (GUI): (1) at the specific time of comparison, similar patients should have similar Wellness Conditions and (2) the slope of their Wellness Trajectory should be similar to indicate they are going in the same overall direction.

Cohort identifications include the following information:

- Patient being evaluated
  - Time window being considered (is whole patient record for Full Stay)
- Cohort patient under consideration
  - Time window being considered (is whole patient record for Full Stay)
- Similarity score – which is between 0-1 with 1 being the most similar possible

For analysis, we compare every 8hr window for every historical patient to every other 8hr window for every other patient and produce a similarity matrix. We drop similarities below .1 to reduce the overall data set. This results in a very large data set of weighted comparisons.

*Point MWAE.* We calculated a Mean Weighted Absolute Error (MWAE) by differencing the Wellness Condition points for each patient (x at time tx, and y at time ty) and multiplying it by the similarity score. These are then averaged over all patients and time windows for each variation of the cohorting algorithm.

$$PMWAE = \frac{1}{|x,y,tx,ty|} \sum_{x,y,tx,ty} similarity(x,tx,y,ty) * ABS(Wellness(x,tx) - Wellness(y,tw))$$

Combinations that result in a lower MWAE indicate that the cohorts produced mode closely match the SME rule that wellness should be similar.

*Slope MWAE.* We similarly calculate a Mean Weighted Absolute Error (MWAE) by performing a linear regression on the Wellness trajectory and differencing each patient's slope (x and y) and multiplying it by the similarity score. These are again then averaged over all patients and time windows for each variation of the cohorting algorithm.

$$SMWAE = \frac{1}{|x,y|} \sum_{x,y,tx,ty} similarity(x,tx,y,ty) * ABS(Slope(WT(x)) - Slope(WT(y)))$$

Combinations that result in a lower MWAE indicate that the cohorts produced mode closely match the SME rule that wellness should be similar. A better method would focus the slope calculation on the times series leading up, but not exceeding to the comparison windows. However, due to time constraints, this is future work.

## Results for Cohorting Validation

The MWAE results for both point and slope-based evaluations demonstrate that the Expert Directed weighting performs best with respect to the SME evaluation rules. This is not terribly surprising given that the EMR contains a considerable amount of very noisy data, and our SME has been active in research for useful wellness measures. This does however show the importance of combining expert domain knowledge with ML analysis. For Point MWAE rates ranged from 0.012 (Full Stay Aligned - Expert Directed) to 0.036 (Full Stay Aligned – Simple Mean). Table 4 shows Simple Mean performed worst in every case suggesting that much of the data in the EHR not useful in finding cohorts with similar degrees of wellness. Numerically, one would expect PCA Derived to find good feature weights, however picking the features that best differentiate patients may not be consistent with finding those relevant to overall wellness.

Table 5 shows the Slope-based MWAE and again suggests Expert Directed feature weights are the most appropriate for cohorting patients. Because we used slopes for the entire patient stay, the results of windowed and aligned strategies were indistinguishable (there are differences in lower digits).

Table 4. Mean Weighted Absolute Error for Wellness Points for each combination of windowing and alignment.

| Point MWAE* | Window Only | Full Stay Aligned | Full Stay Clustered |
|---|---|---|---|
| Simple Mean | 0.031 | 0.036 | 0.025 |
| Expert Directed | 0.015 | **0.012** | 0.014 |
| PCA Derived | 0.024 | **0.019** | 0.022 |

*one way ANOVA p-value < 0.05

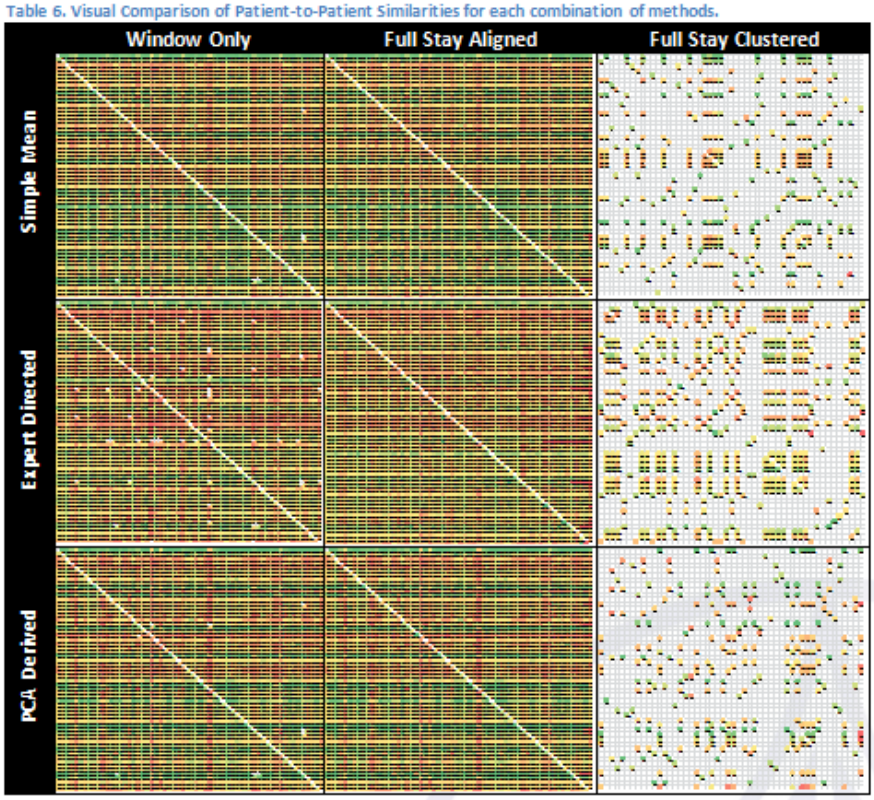
Table 5. MWAE for Wellness Trajectory Slow for each combination of windowing and alignment

| Slope MWAE | Window Only | Full Stay Aligned | Full Stay Clustered |
|---|---|---|---|
| Simple Mean | **0.006** | **0.006** | 0.010 |
| Expert Directed | **0.003** | **0.003** | 0.005 |
| PCA Derived | **0.005** | **0.005** | 0.007 |

The key differences between methods can be seen in the similarity matrices of Table 6. First windowed patient to patient comparisons are asymmetric due to handling of missing data. For example, if your patient does not have lab results but the historic potential cohort does, this will not be counted against the similarity match. However if you have lab results and the historical cohort does not, this does decrease similarity. The primary difference between the Window Only and the Full Stay Aligned is aggregation of the best comparisons resulting in an > 80% reduction in data size and somewhat less extreme values. This is obscured in the similarity matrices because each block is the average of all comparisons between that set of patients (for which there is only 1 in the aligned case).

The clustering approaches dramatically reduce the number of cohorts by prioritizing similar groups of patients and dropping comparisons with all others. The intent of this approach was to attempt to mine classes of patients and present them as cohorts. This method performed slightly better than Window Only in Point MWAE but slightly worse in Slope MWAE. Notice Full Stay Clustering drops ~97% of the comparisons (the resolution of these matrices is lower than the others and it is more spare).

Table 6. Visual Comparison of Patient-to-Patient Similarities for each combination of methods.




## Problem Recommender Validation

Problems are high level clinically relevant concepts that reflect adverse states of patent; for example: "Sepsis". Our Problem Recommender analyzes at the clinical notes data using NLP and attempts to identify and isolate these concepts so that they can be called out to the clinical care team. This is informed by a SME-generated list of terms that were drawn from the experience of clinically relevant problems in the BICU. Specifically, we process the text in notes entries to identify concepts and incidences of the use of these concepts. This process simply extracts existing information for us in providing semantic context for understanding changes in wellness, predicting future issues from cases, and determining reasons why one cohort may be superior to another.

## Validation Methodology

Aside from algorithmic testing and face validity of results, there are not significant measures of accuracy for this use-case. In reviewing problems in the GUI, our SME noticed correspondences between the problem labels and changes in the Wellness Trajectory. We would anticipate that the existence of a problem should correspond to a dip in Wellness.

We will assess the correspondence of problem concepts in the notes and dips in the Wellness by measuring the delta in Wellness Trajectory for from 1 day prior to 1 day after the detection time. Instances where the problem and dip co-

occur will be marked as a positive correspondence. Instances where the problem concept is detected but there is no dip in wellness are marked as negative correspondences. We will compute the ratio of positive correspondences to concept detections.

$$CR = \frac{positive\ correspondences}{concept\ detections}$$

We have 320 patient records that contain 1337 detected problems. Our analysis shows that 64.9% of the problem concepts detected in the clinical notes are entered on the day of admission. This suggests that either the relevant data for on-going clinical assessments is not being searched correctly or that clinicians are less likely to document problems in text as the patient stays progress. One repercussion of this is that there are fewer examples with full data from which to learn models of various problems. A second issue is that there is no history of wellness on the first day from which to detect a dip, so we will eliminate all day 0 detections from our analysis.

## Results of Problem Identification

We computed the detections (some instances co-occur on the same day and were merged) and correspondences. Overall, 59.6% of the problems corresponded to dips in the Wellness Trajectory. Table 7 details the problems detected (ordered by total counts of occurrences after the first day). These may be conservative as the mention of problem concepts in terms of prevention and mild problems may not show as dips. Conversely, dips may occur for reasons other than the problem detected.

Table 7. Problem concepts detected and the correspondence ratio (CR) for dips in Wellness.

| Concepts | Detections (>day 1) | CR |
|---|---|---|
| All Concepts | 312 | 59.6% |
| edema | 139 | 60.4% |
| constipation | 65 | 64.6% |
| pneumonia | 32 | 68.8% |
| diarrhea | 29 | 48.3% |
| thrombosis | 18 | 55.6% |
| sepsis | 16 | 56.3% |
| arthritis | 10 | 50.0% |
| hepatitis | 7 | 57.1% |
| cholecystitis | 5 | 80.0% |
| tracheobronchitis | 4 | 50.0% |
| gastritis | 3 | 66.7% |
| osteomyelitis | 3 | 66.7% |
| pancreatitis | 2 | 50.0% |
| endocarditis | 1 | 100.0% |
| erythremia | 1 | 100.0% |
| paraplegia | 1 | 100.0% |
| sciatica | 1 | 0.0% |
| serositis | 1 | 100.0% |

## Summary

The ML capability in CCS offers innovative analytics that that show promise for improving diagnostic and therapeutic decision making in the clinical setting. Despite challenges in data access limitations, noisy and missing data in the EMR, and SME time limitations for labeling of historic data, this first-ever research study demonstrates the potential for machine learning to extract meaningful patterns without the need for human intervention for the three key use-cases of wellness trajectory, cohort identification, and problem recommendation. Future research incorporating larger scale data sets and more rigorous validation will help to make these ML approaches more robust and better calibrated to SME judgments.

**Appendix AH.** Confirmation of Contract Deliverables Receipt (August 2016)

August 25, 2016

USA MED RESEARCH ACQ ACTIVITY
820 Chandler St
Fort Detrick, MD 21702-5014

Attention: Lance Nowell, Contract Specialist

Reference: Contract No. W81XWH-12-C-0126

Subject: Confirmation of Contract Deliverables Receipt

Dear Mr. Nowell,

On behalf of the Critical Care Systems Research Task area at the US Army Institute for Surgical Research (USAISR), I am acknowledging receipt of the following contract deliverables under the Cooperative Communication System (CCS) contract No. W81XWH-12-C-0126.

a. Phase 2, Task 2.5: CCS code had been delivered to USAISR for implementation in the ISR Development environment pending final approval of the technology transition plan.

b. Phase 3, Task 3.5: Draft CCS Technology Transition Plan.

If you have any questions or require additional information, please contact me at 210-539-0806 or at the following email: jose.salinas4.civ@mail.mil.

Sincerely,

Jose Salinas, PhD
Task Area Manager
Critical Care Systems Task Area
US Army Institute of Surgical Research

**Appendix AI.** CCS Transition Plan

In accordance with Task 3.5, CCS Clinical Implementation and Transition, ARA and USAISR have identified the transition requirements and finalized the technology transition plan for the completed prototype CCS.

Our transition plan has three main themes: maturation, generalizability, and transition.

*a. Maturation:* Three capabilities must be completed that the initial CCS research identified as requirements for clinical work but were beyond the scope of the initial project: data entry, scheduling, checklists, machine learning algorithm refinement, and medical device integration.

*Data entry*. The CCS project team identified entry of patient data as an essential aspect of routine care yet was not permitted to enter data to the Essentris EMR. A data entry widget will make it possible for clinicians to enter data in the context of the CCS information design. Making data entry possible in the context of an individual patient's information will make data entry more efficient and accurate. This will require close coordination with the developer of the new EMR, e.g., Cerner, mediated by the Program Executive Office, Defense Healthcare Management Systems (PEO DHMS).

*Scheduling*. The ability to plan staff assignments will inform the CCS Care Team widget to connect those on shift to each patient. During the CCS project, the team identified Schedule Anywhere software as the best match for unit needs but was not allowed to include it, as research funds could not be used to acquire an operational product. In fact, the feature proved so valuable to clinicians that AISR purchased the contract using operational funds and began to use it separately from the CCS.

*Checklists*. Compliance is an important aspect of clinical work. The checklist widget will provide any unit's Charge Nurse with needed guidelines and requirements than can be used to ensure unit compliance appropriate to each individual patient's care plan.

*Machine Learning*. Refine and further validate machine learning predictive and pattern recognition capabilities.

*Device Integration*. Work with DHA and AISR to use AISR's Integrated Data Exchange and Archive (IDEA) server to transfer data from medical devices to CCS.

*b. Generalizability:* The CCS must be proven effective in multiple environments by implementing it in a clinical setting other than the AISR Burn Center such as an MTF, CSH, or VA facility. We anticipate three milestones:

1. Perform field study at an alternate MTF. Develop a tailoring plan for CCS to operate in that setting
2. Install, evaluate CCS with the JOMIS./Cerner EMR system at the field site (CHS)
3. Report on results of CCS implementation at the field site

*c. Transition*

1. The activities across each phase will align the CCS so that it is prepared for entry into the Decision Gate process. We anticipate three milestones:
    a. Complete a Materiel Development Decision (MDD)
    b. Develop and submit material needed to initiate FDA approval process
    c. Submit a Decision Gate presentation and report

**Plans and Strategy for Translation, Implementation, and/or Commercialization**

This proposed effort is structured to take the current prototype CCS from a technology readiness level (TRL) 5 based on current system capabilities, to a TRL of 6, which is suitable for entry into Decision Gate and Advanced Development for clinical trials. The requirements for CCS are based on the Combat Casualty Care (CCC) Initial Capabilities Document (ICD) and the EMR requirements established by Defense Health Agency (DHA).

The CCS was presented to the Capability Development and Integration Directorate (CDID) to be considered for a full Integrated Product Team (IPT). Once approved, a requirements memo will be generated to enable commissioning of an IPT and MDD. This will support further development of CCS functional aspects in the deployed field medical setting, integration with JOMIS, and validation in a CSH.

For advanced development transition to the MTF, PEO DHMS will need to issue a requirements directive regarding the integration of CCS into the Cerner EMR. This will enable CCS development to integrate with the EMR and bedside medical equipment, and CCS validation in an alternate MTF.

Milestone 1: The project team will prepare and present a Materiel Development Decision (MDD) request for CCS to secure permission to proceed with the transition process. Based on the current technology readiness level (TRL), we will request entry into Decision Gate at a Milestone B. However, we will be prepared to proceed at a Milestone A based on IPT direction.

Milestone 2: After a successful MDD the CCS will begin coordinating for FDA clinical trials to validate the system for full clinical use. These clinical trials will be scheduled at a number of MTFs throughout the DoD. These trials will be coordinated to proceed in parallel with the deployment of the new Cerner EMR as the CCS will be designed to interface with that system to support current DoD medical IT requirements. The CCS team has already begun to coordinate with the Mayo Clinic Project AWARE team to leverage their experience with gaining Class 2 clinical device approval in civilian hospitals. The AWARE system is also already integrated with the Cerner EMR in multiple civilian hospitals. Through a cooperative research agreement, we will enable AWARE capabilities to be integrated with CCS in MTFs, while AWARE will be integrated with CCS capabilities for civilian commercial healthcare use.

Completion of the clinical trials and full FDA approval will authorize the CCS to operate as a clinical decision support system and Class 2 medical device. The CCS software will then be packaged and delivered to the USAISR and PEO DHMS, including all source code under a government-wide limited license. This will permit the DoD to manage and alter the code for use in MTFs without contractor involvement (unlike previous and current EMR software). The CCS will be delivered to MTFs through the DHA Medical IT program office. The field version of the CCS will be deployed to CSH and field medical units in coordination with the JOMIS deployment. ARA will retain control over the software for commercialization and sales to civilian hospitals and be available under contract to provide software support and future improvement on an as-needed basis to the DoD. However, PEO DHMS will retain full rights to build on and improve the code for use in the DoD.

**Significance and Uniqueness**

The CCS directly supports the two primary goals of PEO DHMS:

- Modernize the Military Health System (MHS) electronic health record (EHR)
- Establish seamless medical data sharing between the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the private sector

Multiple features the CCS offers make it a unique and desirable interface for medical data, regardless of the data sources.

*a. Common Operating Picture (COP) for clinical data in real time*

Access to and visualization of clinical data will be consistent at all MTFs and field hospitals.

Clinical data can be updated in real time from bedside patient monitors, local data management systems, and the centralized EMR. This leads to better decisions based on current, accurate data and reduced potential for medical errors.

*b. Reflects clinical mental models*

The CCS is the result of three years of intense collaboration among human factors researchers, information designers, developers and clinicians. Usability assessment results confirm it accurately reflects clinician mental models. The system supports a clinician's ability to access and use medical data without compromising the data management needs of the administrative and coding functions hospital managers require for reporting and compensation.

*c. Directly support clinical work processes*

CCS Year One research identified seven requirements that are essential to cognitive work that are present in the CCS.

*Patient Identifier:* Simple graphic with key condition trend and data enables the BICU staff to scan among and across patients and recognize care needs at a glance.

*Unit View.* Organized as a BICU floor plan, the view includes an patient identifiers and facilitates resource allocation and prioritization, care planning and coordination.

*Patient View.* Presents all salient, data related to the patient in a single window organized by body system using a "parent-child" tab/window format.

*Tasking, Messaging, and Alerting.* Real time message correspondence among care team members supports the development and maintenance of common ground.

*Checklists.* An interactive list of quality measures makes it possible for the unit's Charge Nurse to ensure that essential evidence-based care is accomplished.

*Scheduling.* Staff assignment to the unit, and to each patient care team, improves unit efficiency by matching care resources to needs.

*Order Management.* Lists all orders from treatments to diagnostic tests, to minimize uncertainty about diagnostic and therapeutic plans, status, and results.

*d. Tailorable to Clinical Roles, Individual Preferences*

The Patient View can be customized by the user to change what data are displayed and how they are shown. Salient information is available and evident, because views are based on role and task requirements. Variables can be displayed graphically, in either a line graph, or table. This also makes the creation of relational information displays possible by showing meaningful combinations such as a "cardiovascular," "cardiopulmonary," or "cardio-renal" that may help clinicians answer questions about patient condition or treatment effects.

*e. Autodidactic system*

The CCS ML feature makes it possible to identify patterns such as trends, comparable patients and care regimens, and metadata on how clinicians use the system so the CCS can evolve as the unit does.

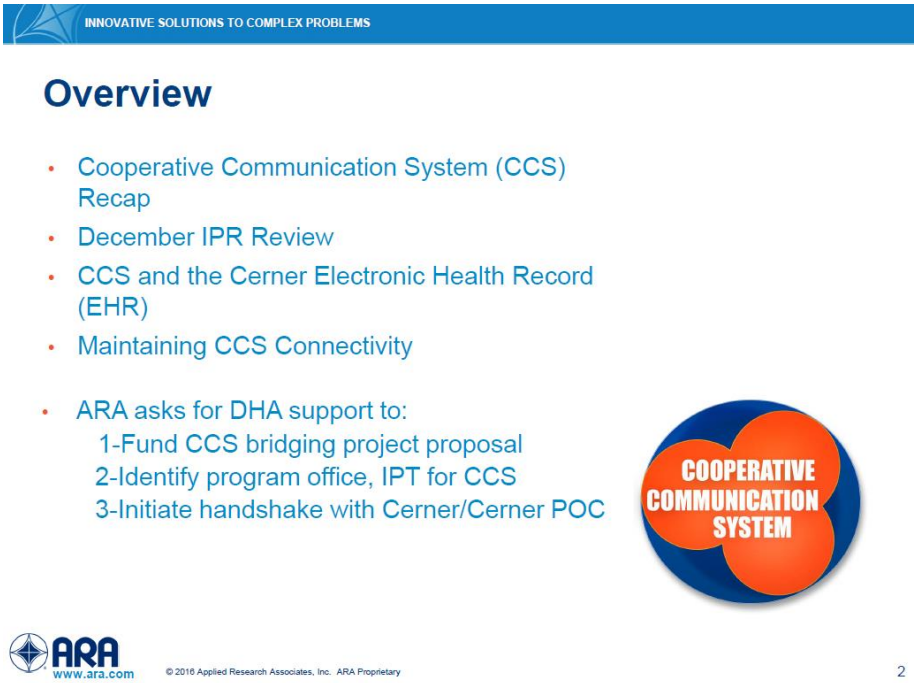
*f. Accelerated Expertise*

Machine learning algorithms detect and offer patterns that would otherwise go unnoticed, particularly by inexperienced clinicians. Clinicians who are assigned to operational medicine but who are unfamiliar with it will receive the necessary support to make decisions "like an expert." This leads to faster turn-around for more diagnostic, treatment decisions.

*g. Interoperability*

Because the CCS is platform agnostic, it can assemble and present salient data from any number of information sources including EMRs, databases, and medical devices. It can extract data from an EMR and available bedside monitors for display in a coherent clinician-centered view. It can also feed data back to the underlying EMR for storage. The AISR has developed the Integrated Data Exchange and Archive (IDEA) Server to support in-house medical device monitoring needs as part of the clinical projects within its research and intensive care units. The Fast Health Interoperability Resources (FHIR) standards will also provide a perfect standard to drive inter-device communication between monitors, the EMR, and CCS.

**Appendix AJ.** Transition: Cooperative Communication System (Aug 2016)



# Cooperative Communication System (CCS)

The CCS is a real time decision and communication support IT system based on clinical mental models and work processes.

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# Decision & Communication Support Matters

| | |
|---|---|
| 34,000 of 540,000 ICU annual deaths attributable to diagnostic error | Winters B, Custer J, Galvagno SM, Jr., Colantuoni E, Kapoor SG, Lee H, Goode V, Robinson K, Nakhasi A, Pronovost P *et al*: Diagnostic errors in the intensive care unit: a systematic review of autopsy studies. *BMJ Qual Saf* 2012, **21**(11):894-902. |
| Information chaos contributes to poor situation awareness and high mental workload which impairs memory, decision making, judgment, execution of decisions | Beasley, JW, Wetterneck, TB, Temte J, Lapin JA, Smith P, Rivera-Rodrigues AJ, Karsh BT. Information chaos in primary care: implications for physician performance and patient safety. J Am Board Fam Med, 2011 Nov-Dec;24(6):745-51. doi: 10.3122/jabfm.2011.06.100255. |
| After visiting 23 high-functioning medical teams, Dr. Sinsky [AMA VP of Professional Satisfaction] said she had found that 70% to 80% of physician work output could be considered waste, defined as work that doesn't need to be done and doesn't add value to the patient. | Beresford, L. (2015, 23 Oct) AMA's Christine Sinsky, MD, Explains EHR's Contribution to Physician Burnout The Hospitalist. http://www.the-hospitalist.org/article/amas-christine-sinsky-md-explains-ehrs-contribution-to-physician-burnout/ |


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## December IPR Review

- *Will the CCS get its information from the EHR? How will CCS enter data into the EHR? (GPM3)*
- *What steps remain for CCS to pull/push information from the EHR or other devices? (GPM3)*
- *What is your plan to integrate the CCS with Cerner? (GPM3)*
- *Is CCS an application, or does it include hardware? (GPM6)*
- *Will CCS be FHIR compliant? (GPM6)*
- *How will CCS visualization of critical care patient information complement, supersede, or otherwise integrate with Cerner visualization?*
- *How will clinicians use CCS and Cerner/EMR? (GPM6)*


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## Data Transfer Between CCS and Cerner EHR

*Will the CCS get its information from the EHR? How will CCS enter data into the EHR? (GPM3)*

- Through an HL-7 bridge, CCS can function platform agnostic, able to exchange information from the Cerner EHR as well as other devices and databases
- Machine learning (ML) algorithms can fuse data from multiple sources, just like the interface it can pull data from the EHR and reason about it.
- Outputs from ML can be added into the EHR as notes or potentially existing fields.
- ML can also can track how clinicians use the CCS interface, enabling it to better learn how information is used and evolve its presentation in response to clinician use patterns, typical needs, and opportunities
- Data can be entered in the CCS when we are approved to develop the data entry feature


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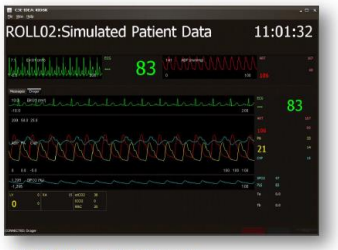
# CCS Link to Cerner EHR: Steps Remaining

*What steps remain for CCS to pull/push information from the EHR or other devices? (GPM3*

- Complete the data entry feature (not possible during research phase)
- Link CCS to Cerner through an HL-7 bridge
- Install and refine AISR's Integrated Data Exchange and Archival System (IDEA) module
- Map devices to the IDEA module
- Review device mapping through IDEA/CCS




*IDEA Clinical Client screen*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# How the CCS Can Integrate with Cerner

*What is your plan to integrate the CCS with Cerner? (GPM3)*

CCS Integration Plan will include several steps from planning to connectivity setup & testing, functional testing, integration testing and production:

- Setup a meeting with Cerner's integration team (Interface, Security, HIPPA, Policy)
- Identify available inbound and outbound interfaces
- Define key initiatives, milestones, workflow and schedule
- Document Cerner's interfacing policies and procedures, including encryption to ensure HIPAA compliance, protecting patient data
- Get data documentation and sample messages, API calls and data structure formats
- Perform final data mapping review and acceptance with Cerner


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# The CCS Can Comply with FHIR

*Will CCS be FHIR compliant? (GPM6)*

- CCS is not proprietary, so ARA can ensure FHIR (Fast Healthcare Interoperability Resource) compliance
- CCS use of HL-7 architecture for FHIR standard will enable platform independence
- ARA has experience with getting software CCHIT (Certification Commission for Healthcare Information Technology) certified
- Dr. Goldman is a colleague and we would welcome the opportunity to talk with him
- The Army Institute of Surgical Research (AISR) testing facility can rapidly adopt standards and ensure compliance


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# CCS Visualizes Salient Data

*How will CCS visualization of critical care patient information complement, supersede, or otherwise integrate with Cerner visualization?*

**CCS integrates with Cerner** by:

- Integrating multiple data sources into a common view and automatically populating the Cerner EHR instead of requiring manual entry
- Enabling the system to evolve as equipment, needs, and opportunities evolve

**CCS complements Cerner** by:

- Translating EHR data into clinically relevant information design
- Finding meaningful patterns in data through machine learning
- Making it possible to tailor views to clinical roles, individual preferences
- Supporting team consensus and common ground through messaging
- Learning from clinician use of the CCS and propose improved information designs, representations
- Cutting need tor clinician training to a small fraction of time and cost
- Matching clinician trend  to use phones, tablets, etc , to support work


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# How Clinicians Use the CCS

*How will clinicians use CCS and Cerner/EHR? (GPM6)*

**Upon Opening CCS a Clinician will:**

- View a unit status with patient IDs including trends from CCS ML (current)
- View status for assigned patients, with salient data from Cerner (current)
- Read and update notes on patient from Cerner database (current)
- Correspond with care team (shown in CCS) through CCS messaging (current)
- After patient exam, enter notes and orders in CCS, populating Cerner (prospective)
- Brief patient condition using CCS [patient view], with Cerner data (current)
- View patient trends (using CCS ML), based on data from Cerner (in progress)

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# How Clinicians Use the CCS

*How will clinicians use CCS and Cerner/EHR? (GPM6)*

**CCS provides a Clinician with**:

- A single software interface to view all patient data
- A single view of patient and unit data through the CCS interface

**CCS will provide a Clinician with**:

- A single entry point for data exchange data with Cerner and other applications
- A reduction in data-entry requirements
- Access to data from multiple sources, systems, and devices
- Self-learning interface that improves data display based on actual clinician use


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ORIGINAL INVESTIGATION

ONLINE FIRST | HEALTH CARE REFORM

# Electronic Health Records and Clinical Decision Support Systems

## *Impact on National Ambulatory Care Quality*

*Max J. Romano, BA; Randall S. Stafford, MD, PhD*

**Background:** Electronic health records (EHRs) are increasingly used by US outpatient physicians. They could improve clinical care via clinical decision support (CDS) and electronic guideline–based reminders and alerts. Using nationally representative data, we tested the hypothesis that a higher quality of care would be associated with EHRs and CDS.

**Methods:** We analyzed physician survey data on 255 402 ambulatory patient visits in nonfederal offices and hospitals from the 2005-2007 National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey. Based on 20 previously developed quality indicators, we assessed the relationship of EHRs and CDS to the provision of guideline-concordant care using multivariable logistic regression.

**Results:** Electronic health records were used in 30% of an estimated 1.1 billion annual US patient visits. Clinical decision support was present in 57% of these EHR visits (17% of all visits). The use of EHRs and CDS was more likely in the West and in multiphysician settings than in solo practices. In only 1 of 20 indicators was quality greater in EHR visits than in non-EHR visits (diet counseling in high-risk adults, adjusted odds ratio, 1.65; 95% confidence interval, 1.21-2.26). Among the EHR visits, only 1 of 20 quality indicators showed significantly better performance in visits with CDS compared with EHR visits without CDS (lack of routine electrocardiographic ordering in low-risk patients, adjusted odds ratio, 2.88; 95% confidence interval, 1.69-4.90). There were no other significant quality differences.

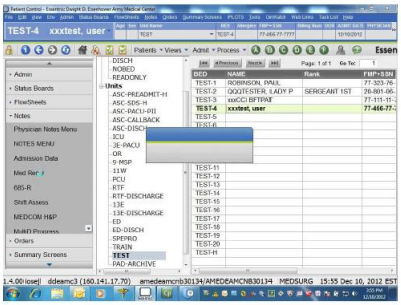
**Conclusions:** Our findings indicate no consistent association between EHRs and CDS and better quality. These results raise concerns about the ability of health information technology to fundamentally alter outpatient care quality.

*Arch Intern Med. 2011;171(10):897-903.*
*Published online January 24, 2011.*
*doi:10.1001/archinternmed.2010.527*





# CCS Would Save DoD Money and Time




**CliniComp Essentris EHR**
Weeks of training

**Apple iPhone**
No training

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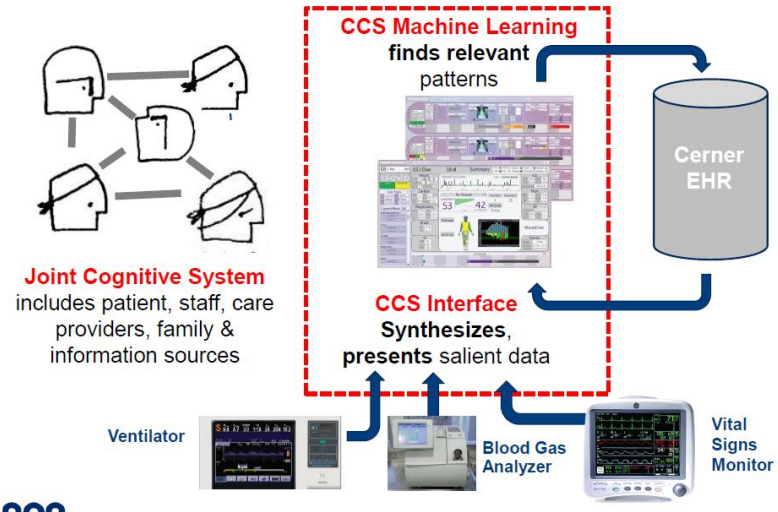
## CCS & Cerner EHR





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## ARA Would Maintain CCS Connectivity

We are well-qualified and experienced with ongoing technical support for government systems, including SEI CMMI Level 3.

We stand ready to assemble and manage a similar team of technically qualified professionals to support CCS connectivity. The support team will be set up to:

- **Monitor** - Track new device additions within the system
- **Develop** – Provide an efficient methodology to map data sources to the CCS from all available data repositories (Cerner, legacy systems, Softmed, Spacelabs, Meditech, Epic, etc.)
- **Evaluate** - Verify the relationship performs to specification prior to implementation
- **Implement** - Install the new device on the CCS interface


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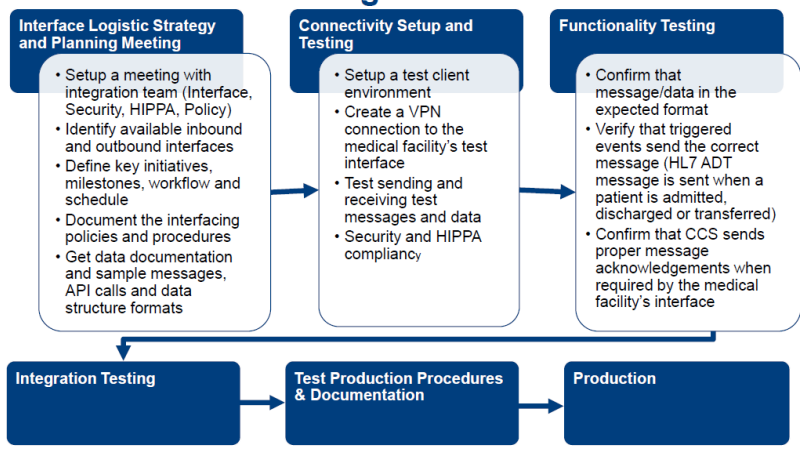
# How ARA Would Integrate the CCS





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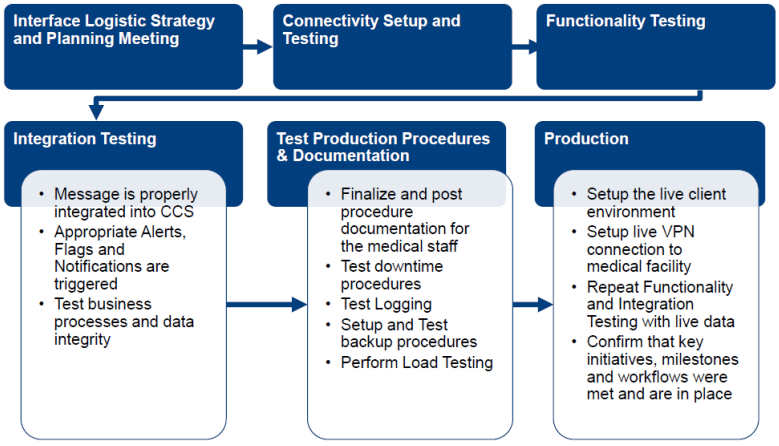
# How ARA Would Integrate the CCS





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# ARA is Ready

**Capable Development Team:**

- 3 Database Administrators and Architects
- 4 Software Architects
- 12 Developers and 4 Testers

**Understands Essential Technologies:**

- Multiple Applications that interface with multiple data structures
  - Excel, XML, JSON, PostgreSQL, SQL server, Oracle
- Interfacing and importing External Data sources
  - RADM, NMRS, SKED, MPTE

**Experienced with EHR Interfacing:**:

- Two of our team members have over 25 years combined experience designing and implementing EHRs and interfacing with hospital software systems, through the use of HL7 interfaces and web services
- Cerner, Epic, Meditech, eClinicalWorks and GE


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# Summary

- We have responded to each question the IPR posed in December
- CCS and the Cerner EHR complement each other
- CCS interface is a match for clinical cognitive work
- ARA can maintain CCS connectivity with Cerner EHR, devices, and other data sources
- ARA is qualified and ready to transition the CCS to development

**ARA asks for DHA support to:**

1-Fund CCS bridging project proposal
2-Identify program office, Integrated Product Team for CCS
3-Initiate handshake with Cerner/Cerner POC


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# CCS Requirements and Transition Plan

**ARA proposes a bridging project to develop functional requirements for TRL 6.**

- Feature maturation (data entry, scheduling, checklists, ML, device integration)
- Clinical generalizability (create, test interface in additional setting)
- Preparation for transition (apply for FDA device certification)

**CCS (TRL5) can be ready for an MDD within 12 months if needed**

- Entry into Decision Gate depends on bridging work to address remaining functional requirements to reach TRL 6
- Operational fielding to Level III MTF (CSH) possible through CDID

**The CCS directly supports the goals of PEO DHMS**

- Modernize the Military Health System (MHS) electronic health record (EHR)
- Establish seamless medical data sharing among the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the private sector


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# We welcome your comments and questions

**Christopher Nemeth, PhD** Principal Investigator
**Gregory Rule, PE** Project Manager

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**14. Acronyms**

Acute Respiratory Distress Syndrome ..... ARDS
Army Medical Research & Material Command's .. USAMRMC
Application Programming Interface ..... API
Applied Research Associates, Inc. ..... ARA
Amazon Web Services ... ..... AWS
Burn Intensive Care Unit ..... BICU)
Clinical Decision Support Systems ..... CDSS
Charge Nurse Rounds ..... CRN
Cognitive Systems Engineering ... ..... CSE
Cognitive Task Analysis . ..... CTA
Cooperative Communication System ..... CCS
Combat Support Hospital ..... CSH
Continuous Renal Replacement Therapy ... ..... CRRT
Defense Health Agency .. ..... DHA
Do Not Resuscitate ..... DNR
Defense Business Information Technology ..... DBIT
Department of Defense ... ..... DoD
Eigenvectors ..... EVs
Electronic Medical Record ..... EMR
Event Sequence Alignment and Clustering ..... ESAC
Extra Corporeal Membrane Oxygenation .. ..... ECMO
Federal Information Processing Standard .. ..... (FIPS
Forward Surgical Team .. ..... FST
Graphical User Interface . ..... GUI
Intensive Care Unit ..... ICU
Information Assurance .... ..... IA
Information Technology . ..... IT
Information Assurance .... ..... IA
Institutional Review Board ..... IRB
Joint Program Committee ..... JPC-1
Mean Weighted Absolute Error ... ..... MWAE
Multivariate Analysis of Variance ..... MANOVA
Military Treatment Facilities ..... MTF
Machine Learning ..... ML
Natural Language Processing ..... NLP
No-Cost Extension ..... NCE
Period of Performance .... ..... PoP
Phases of Illness Paradigm study . ..... POIP
Principal Component Analysis .... ..... PCA
Resilient Health Care Network .... ..... RHCN
Scientific Systems Company Inc. ..... SSCI
Sequential Organ Failure Assessment ..... SOFA
Situation Awareness ..... SA
Structured Query Language ..... SQL
Standard Operating Procedures .... ..... SOPs
Systematized Nomenclature of Medicine -- Clinical Terms ..... SNOMED CT
Telemedicine & Advanced Technology Research Center ... ..... TATRC
United States Army Institute of Surgical Research . ..... USAISR
U.S. Army Medical Research & Material Command's ..... USAMRMC