Surgical Critical Care Initiative: bringing precision medicine to the critically ill

Eric Elster, MD, FACS
CAPT MC USN
Professor and Chairman
Department of Surgery of the Uniformed Services University of the Health Sciences & the Walter Reed National Military Medical Center

Program Director
Surgical Critical Care Initiative (SC2i)
Addressing a Gap in Surgical Critical Care

**Problem:** Management of battle injured, trauma and surgical patients remains largely dependent upon traditional (visually-guided) clinical decision-making. Currently an 85% solution at 110% cost.

**Solution:** Develop decision support tools using evidence-based clinical data together with cutting-edge science in the understanding of physiological, psychological, and physical factors that govern the body’s response to injury to guide management of surgical care.
95% Solution at 95% Cost

• Focus on developing, translating, and validating biology driven critical care.
• Providing individualized treatment based on the underlying biology
• Dramatically improve patient outcomes while reducing costs.
• Develop Clinical Decision Support Tools (CDSTs) that predict outcome and guide therapy

- Improve Patient Outcome & Quality of Life
- Significantly reduce MHS cost & increase efficiency
- Accelerate return to duty
Immediate response to injury

Assess tissue viability

Immediate response to injury

Assess systemic response

Debridement and Critical Care

Personalized treatment

VTE prophylaxis and therapy

Assess bioburden

SC2i Clinical Decision Support Tools (CDSTs)

Released

In-Development
Getting the right diagnosis is a key aspect of health care

Diagnostic errors persist through all settings of care and harm an unacceptable number of patients

In every research area [...] evaluated, diagnostic errors were a consistent quality and safety challenge

Recommendations (non-exhaustive):

- Ensure health IT used in the diagnostic process provides clinical decision support
- Develop and implement processes to ensure effective and timely communication between diagnostic testing health care professionals and treating health care professionals across all health care delivery settings
- Encourage public-private partnerships among a broad range of stakeholders to support research on the diagnostic process
Structure and Mission

• Launched OCT 2013

• Funded by the U.S. Department of Defense – Defense Health Program (under JPC-6)

• A focused collaboration between DoD research labs, academic centers & industry

• Expanding on prior biomarker research efforts (OEF/OIF) to develop biology-driven Clinical Decision Support Systems (CDSS) for the critically ill

• A goal of developing both device and knowledge products for complex decision support (trauma surgery, orthopedic surgery, transplant surgery, surgical oncology, ICU critical care)
Assay Processing

Critically ill patient
• Complications of critical injury or illness
• Stably injured
• Acutely injured

Event and Time-Driven Collection

T0
T1
T3
T7
1/week until discharge if ‘no event’

Serum:
• Cytokines
• Chemokines
• Proteases
• DAMPs / TLRs
• FACS, PAXgene

Tissue biopsy:
• Wound healing associated genes
• Osteogenesis
• Pathogen specific PCR
• Quantitative bacteriology
• Pathogen Sequencing
• RNA Sequencing

Wound effluent:
• Cytokines
• Chemokines
• Proteases
• RNA Sequencing
Improving clinical outcomes...

WoundDX model input variables:
1- Number of blood products received in the first 24h: 35
2- Number of blood products received at WRNMCC: 17
3- Serum Eotaxin: 51.6 pg/ml
4- Serum IL-1α: 25.7 pg/ml
5- Wound exudate IL-4: 8.0 pg/ml
6- Wound exudate IL-6: 107000 pg/ml
7- Serum IL-7: 27.5 pg/ml
8- Serum MCP-1: 563 pg/ml
9- Use of SeraQuel: No
10- Serum TNFα: 0.621 pg/ml
11- Genitourinary trauma: No

Prediction of outcome:
Dehiscence: 95%
Normal healing: 5%

Wound was closed after 11 days of injury and dehisced
... can substantially reduce costs

- BCA model grounded in 200+ peer-reviewed publications

- Cost-savings across continuum of care:
  - OR → $16,673 per event
  - ICU → $4,100 per day
  - General Ward → $1,210 per day
  - Rehabilitation → $945 per event
  - HAI → $15,667

- Estimated national cost-savings: $3.4B

- Estimated MHS savings over the course of OEF-OIF: $900M
Leveraging Big Medical Data to Deliver Precision Medicine

CLINICAL DECISION SUPPORT SYSTEMS AND COMBAT CASUALTY CARE: REALIZING THE PROMISE OF PRECISION MEDICINE ON THE BATTLEFIELD

Today, the critical care provider uses a limited set of available clinical and physiological data, along with visually-guided decision-making, to dispense therapy. As it relates to the timing of closure for severe extremity wounds, this 'traditional' approach results in failure rates of 15% to 20%.

In the not too distance future (2020), the critical care provider will have access to CDSS capable of integrating and analyzing all relevant medical data to suggest the right treatment, at the right time, for the right patient. This is the very promise of 'precision medicine', a personalize approach to acute care that will have a measurable and positive impact on both clinical outcomes and costs.

TODAY (2015)
- Available data is limited to clinical and physiological factors and is often incomplete
- Traditional, visually-guided, decision-making
- 15% to 20% failure-rate, with associated impact on lengths of stay and resources

TOMORROW (2020)
- Integrate all available and relevant medical data to support the right treatment, at the right time, for the right patient
- Prediction of Wound Healing:
  - Debridement: 95%
  - Normal healing: 5%
- Risk of Invasive Fungal Infection:
  - IFI: 12%
  - No IFI: 88%
- Optimized decisions, with measurable impact on both clinical outcomes and cost
- Accelerate return to duty