Interoperability: Simulation, Health Information Technologies, Medical Devices and Beyond

US Army Medical Research and Materiel Command

19 April 2016

Panel Members

- Dr. Loretta Schlachta-Fairchild (Chair) – JPC1 Medical Simulation and Information Sciences
- Jason Harrington - PMO-MD / USAMMA
- Dr Kevin Kunkler - JPC1 Medical Simulation and Training Program Manager
- COL Dan Irizarry - Joint Project Office for Medical Modeling and Simulation

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Purpose

To increase understanding of the rapidly emerging domain of Medical Device Interoperability (MDI)

- The panel will present:
  - ***Why MDI is important***
  - ***What the Military Medical Device Implications are***
  - ***What the Technology Implications for Clinicians are***
  - ***What the Medical Simulation and Training Implications are***

Medical Device Interoperability

Jason Harrington

PMO-MD / USAMMA

US Army Medical Research and Materiel Command

19 April 2016

Purpose

To increase understanding of Medical Device Interoperability

- Points
  - *Food and Drug Administration Guidance*
  - *Medical Devices Data System (MDDS)*
  - *PMO-Medical Devices / US Army Medical Materiel Agency's approach to Medical Device Interoperability (MDI)*

Food & Drug Administration

February 15, 2011

1. FDA issued a regulation down-classifying MDDS from Class III (High-Risk) to Class I (Low-Risk) ("MDDS Regulation").
   - Class I devices are subject to general controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act)

2. Since down-classifying MDDS, FDA has gained additional experience with these types of technologies, and has determined that these devices pose a low risk to the public

3. FDA does NOT intend to enforce compliance with the regulatory controls that apply to MDDS devices, medical image storage devices, and medical image communications devices

Medical Device Interoperability

Medical Device Data System

1. Hardware or software product that transfers, stores, converts formats, and displays medical device data

2. Intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
   - The electronic transfer of medical device data
   - The electronic storage of medical device data
   - The electronic conversion of medical device data from one format to another format in accordance with a preset specification
   - The electronic display of medical device data

3. MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol

Medical Device Interoperability

Medical Device – Active Patient Monitoring

1. MDDS identification does NOT include devices intended to be used in connection with active patient monitoring

2. Active: Represents any device that is intended to be relied upon in deciding to take immediate clinical action.
   - A nurse telemetry station: Receives / Displays information from a bedside hospital monitor
   - A home setting device that receives and/or displays information, alarms, or alerts from a monitoring device intended to alert a caregiver to take an immediate clinical action

3. Examples of devices not considered “active patient monitors”
   - An App transmitting child’s temperature to parent/guardian from school
   - Display of information such as most recent blood glucose value not intended to be used for taking immediate clinical action or time-lapse between blood glucose measurements

4. Standing FDA classifications for patient monitoring devices

Food and Drug Administration

Center for Devices and Radiological Health (CDRH)

1. Device guidance FDA intends to publish, as guidance-development resources permit each in FY 2015 ("B-list")

2. Final Guidance Topics
   - Finalizing existing draft guidance documents

3. Draft Guidance Topics
   - ***Medical Device Interoperability***

Guidance for Industry and FDA Staff: (Draft 26JAN16)

Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices

1. Manufacturers *should* consider to provide a reasonable assurance of safety and effectiveness of their interoperable medical devices:
   - Designing systems with interoperability as an objective
   - Conducting appropriate performance testing and risk management activities
   - Specifying the functional, performance, and interface characteristics in a public manner such as labeling
2. The use of the word *should* in Agency guidance means that something is suggested or recommended
   - ***But not required***

Food and Drug Administration

MDI Guidance for Industry and Staff (Draft JAN16)

1. FDA intends to promote the development and availability of safe and effective interoperable medical devices

2. Interoperable Medical Devices have the ability to exchange and use information through an electronic data interface with another medical device, product, technology, or system
   - Can be involved in simple unidirectional transmission of data to another device or product
   - Or in more complex interactions such as exerting command and control over one or more medical devices

3. Medical Devices defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act

MDI Guidance for Industry and Staff (Draft JAN16)

1. Draft Guidance does NOT address aspects of compatibility issues with devices' physical connection (e.g. the specifications of the physical connection between two electronic products such as USB, wireless connection, etc.)

2. Draft Guidance does NOT direct that medical devices are to be interoperable

3. Draft Guidance does NOT indicate with which other product(s) a medical device should interoperate

Medical Device Interoperability

PMO-MD / USAMMA and MDI

1. Army Regulation 40-60
   - The Army Medical Department will acquire only U.S. Food and Drug Administration (FDA) or Environmental Protection Agency (EPA) approved products for Soldier use, whenever such approvals would be needed for civilian-use products

2. Department of Defense Instruction 6200.02
   - Personnel carrying out military operations shall be provided the best possible medical countermeasures to chemical, biological, or radiological warfare or terrorism and other health threats. The DoD Components shall make preferential use of products approved by the FDA for general commercial marketing, when available, to provide the needed medical countermeasure

3. PMO-MD recognizes the JAN16 FDA Draft MDI Guidance and continues to monitor its status and significance on industry

Medical Device Interoperability (MDI): Technology Progress, Issues and Simulation Implications

Dr Kevin Kunkler & Dr. Loretta Schlachta-Fairchild
Medical Simulation and Information Sciences
JPC1

Agenda

Agenda
▪ Purpose ▪ Issues related to MDI ▪ Progress due to ICE research ▪ Recommended strategies ▪ Implications for Simulation and Training

Problem: This scenario has not changed in the last 20 yrs

Technologies to reduce error & improve efficiency have not been implemented

- Contextually rich data is difficult to acquire – No clinical BLACK BOX RECORDER
- Medical Devices do not interact with each other (Monitors, Ventilator, IV pumps)

Problem

Current State

All other industries ***except healthcare,*** use Black Box recorders (i.e. aviation, rail, automotive) to collect their systems' performance data

All other industries utilize autonomous, interactive systems (i.e. autonomous aircraft landing systems for pilots, cruise control for cars)

Implications for

Patient Safety
Quality Assurance
DHMSM/JOMIS integration

Medical Errors - in Context

Annual Causes of Death

1. 597,689 Heart Disease
2. 574,743 Cancer
3. *Deaths Due to Medical Errors (210,000-440,000)*
4. 138,080 Chronic lower respiratory diseases
5. 129,476 Stroke
6. 120,859 Accidents
7. 83,494 Alzheimer's disease
8. 69,071 Diabetes
9. 56,979 Influenza &Pneumonia
10. 47,112 Kidney diseases
11. 41,149 Suicide

Equivalent to filling one Arlington Cemetery every year!

Military Gaps for MDI

Theater/Operational Combat Casualty Care Gaps

- Theater care
  - Augment skill level of providers in theater
  - Support prolonged care in place scenarios
- Future: autonomous, unmanned casualty evacuation
- Mass casualty

MTF Gaps

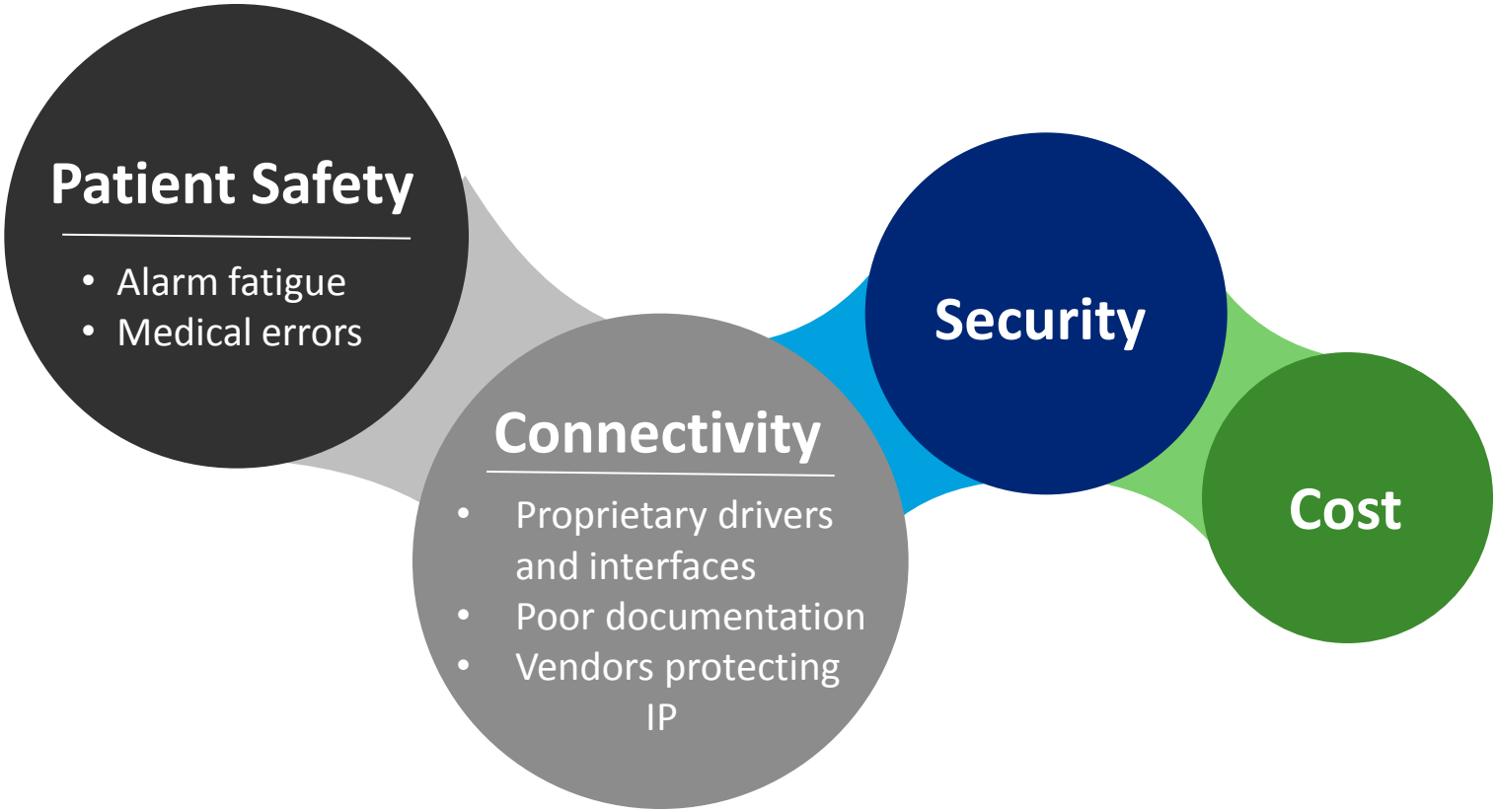
- Joint Trauma Registry (Medical Device data to support best practices)
- Patient Safety
- Smart OR (interoperability between pumps, anesthesia, monitors, etc.)
- Smart ICU/eICU (telemedicine)

"Provision of data that can guide actions for improvement are the keys that will help us"

TSG Mar 4, 2016

Message for Pt Safety Week Mar 13-19 Mar 2016

MDI Issues


Patient Safety
• Alarm fatigue
• Medical errors
Connectivity
• Proprietary drivers and interfaces
• Poor documentation
• Vendors protecting IP
Security
Cost

Progress due to MDI research

Standards

- System's approach to MDI codified in a standard (ASTM F2761)
- New standards and standard updates to incorporate concepts from ICE (i.e. UL, IEEE, AAMI)

New Communities of Interest

- OpenICE, International Internet Consortium, Underwriters Laboratories, etc.

Early Prototypes

- TBI, Medevac, PCA controlled analgesia, Data Distribution Service, etc.

MDFire

- Proposed acquisition language for MDI considerations
  - Endorsed by Kaiser, Partners, Hopkins, VHA
  - Endorsed by American Society of Anesthesiologists

FDA Coordination

- Medical device safety working group, FDASIA, etc.
- Pre-submission(multiple vendors modular concept)
- FDA final rule on Medical Device Data Systems
- FDA draft guidance on interoperable medical device
- FDA draft guidance on medical device security

Enabling Capabilities

Key Enablers for Innovation

Medical Device Manufacturers must have:
- Open Platforms
- Open Data Models

Interoperability Test Bed

Data logger = medical “black box”
- NIST to offer MD Data Logger to the public in 2016

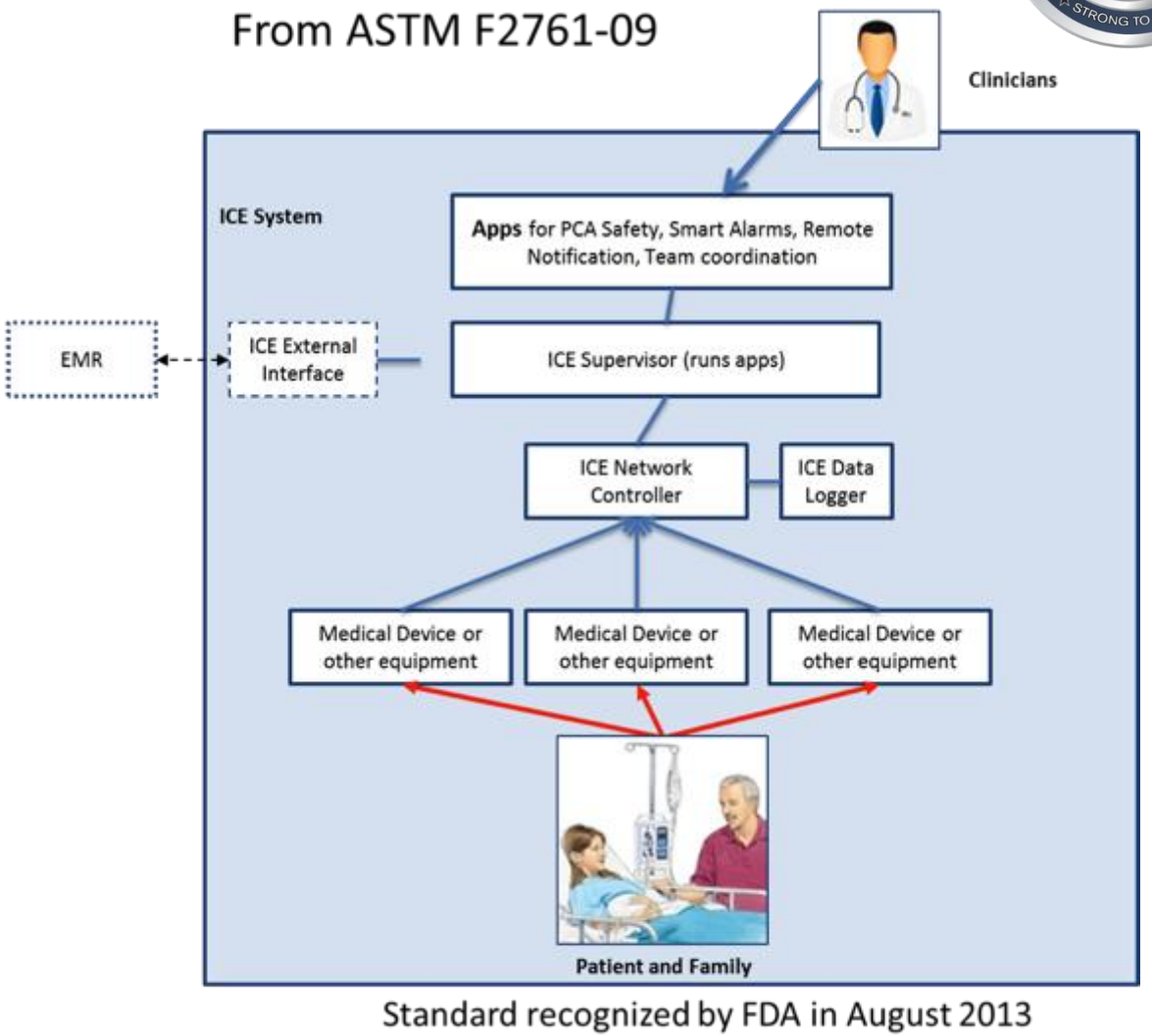
Security

Access to Clinical Environment

ASTM F2761: Integrated Clinical Environment Architecture (ICE)

Logical/functional architecture to address:

- App platform
- Safety and performance of the system
- Security (sandboxing)
- Patient ID-data binding
- Correct time data time stamps
- Data logging for forensic, QA, and liability ("Black Box Recorder")
- Builds on medical device interoperability



Standard recognized by FDA in August 2013

Current MDI Advancement Strategies

MDI Awareness

Inform and educate DHA stakeholders about MDI

- Patient Safety Office
- Quality Assessment
- Interoperability Office
- DHMSM/JOMIS

MD FIRE Language

Work to get DoD/DHA to join endorsing MD FIRE language

Transition Research to Practice

Current research to move to clinical trials in next 2 years

Medical Simulation and Training

Leverage MDI research and advances

Medical Simulation & Information Sciences Research Program

2016 Military Medicine Partnership Day Medical Simulation & Training Intra & Interoperability

Kevin Kunkler, MD, MS

Medical Simulation & Information Sciences Research Program (MSISRP) Portfolio Manager

Chair Joint Program Committee 1: Medical Simulation & Training

19 April 2016

Issues / Gaps

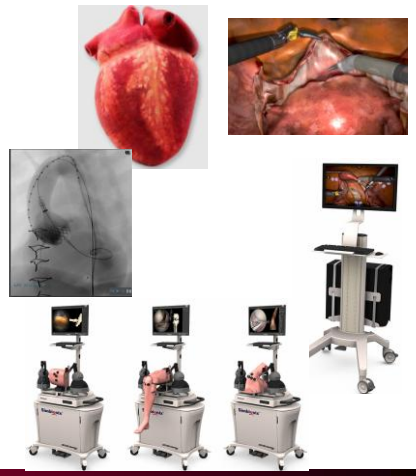
- Interoperability between systems supporting en route care is lacking. A single joint medical system does not exist. Joint medical systems do not provide operational and clinical situational awareness to nonmedical systems. Manager and personnel tracking systems do not interact and are labor intensive.
- Historically, Industry has driven standards within medical simulation and training. This has created vertical (silo) development of systems. Predominately, intra-operability within one's own organization has been developed, tested, and evaluated, but not inter operability.

Company

Company

Company

Company



History: Multiple Technology Approach

A Report of an Integrated Research

Category 1 – PC-based Decision Teaching Tools. The Simulation Technologies for Advanced Trauma Care (STATCare) project, conducted by Research Triangle Institute, Research Triangle Park, North Carolina, is a PC-based, interactive CD-ROM simulator

spectrum of the most commonly encountered trauma conditions. Each scenario requires response to both the overall scene and the physiological condition of the individual patients.

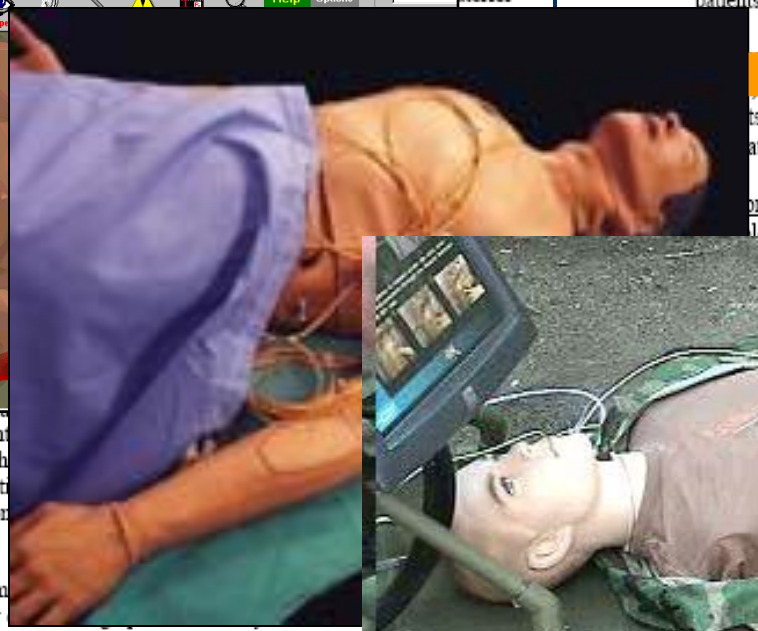
ory 3 – Virtual Workbench Technology. The virtual workbench simulation

and recognized that the current may be severely curtailed in th community to provide alternati EMS systems across the nation medical readiness.

Representatives from governm simulation training from their using Commercial Off-the-Shelf (COTS) simulators in medical readin their views of the value of simulation in training and their future needs investigators provided details of their ongoing research and highlighte inchoate science. In addition, a number of researchers not funded by identified as on the leading edge of simulation modeling science were the latest work in their respective domains.

The MM and deve

PC-based Interactive Multimedia

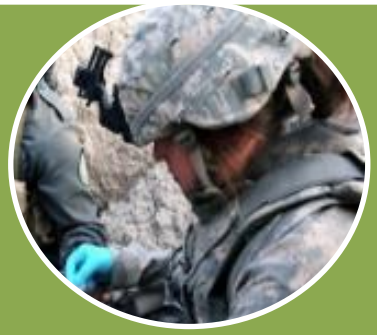


Digitally Enhanced Mannequins

Part-Task Trainers / Virtual

Total Immersion Virtual Reality

Medical Simulation & Training



Combat Casualty Training Initiative

Advancing combat casualty training: emphasis on multi-trauma and mass-casualty scenarios. R&D on tissue appropriate responses; develop High State of combat medical readiness tools; provide resiliency training prior to deployment; & evaluate more efficient and effective ways to deliver team training.

Medical Readiness Initiative

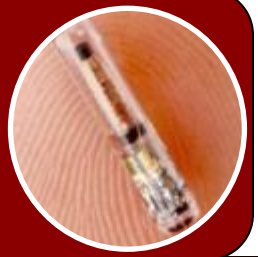
Development of medical training systems & competency assessment for sustained military medical readiness. R&D efforts for ethical, accurate, and appropriate pre-intervention rehearsal models. Efforts in this domain should strive towards measurable outcomes (positive and negative).

Health Focused Initiative

Develop and test self-care technologies patients use, whenever and wherever they choose, to manage personal health and wellness. Advanced user interface and interactive technologies for healthy living, preventative disease management , patient rehabilitation via training.

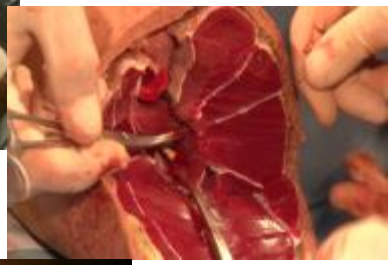
Tools for Medical Education

Transformational open source advanced developer tools to reduce development costs and democratize access to technology. Improve patient safety & clinical outcomes, maximize system & organization-level return on investment, and minimize training burden

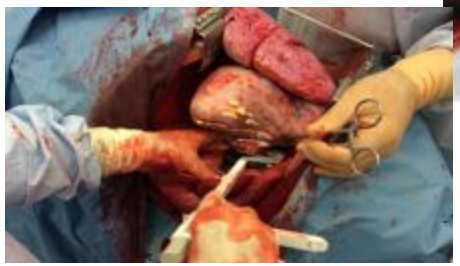


Projects (Examples)

Continuously High State of Readiness



Tissue Fidelity & Physiological Response

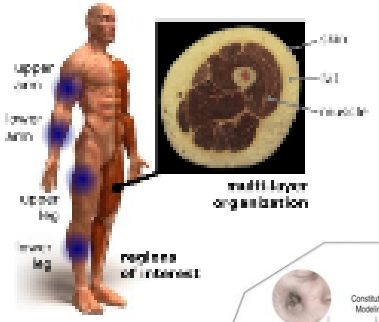


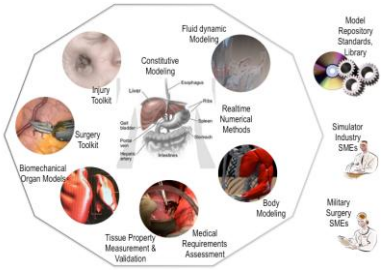
Virtual Reality / 'Serious' Games

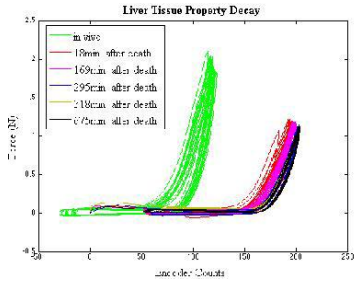
Concepts in the Works

Advanced Modular Manikin

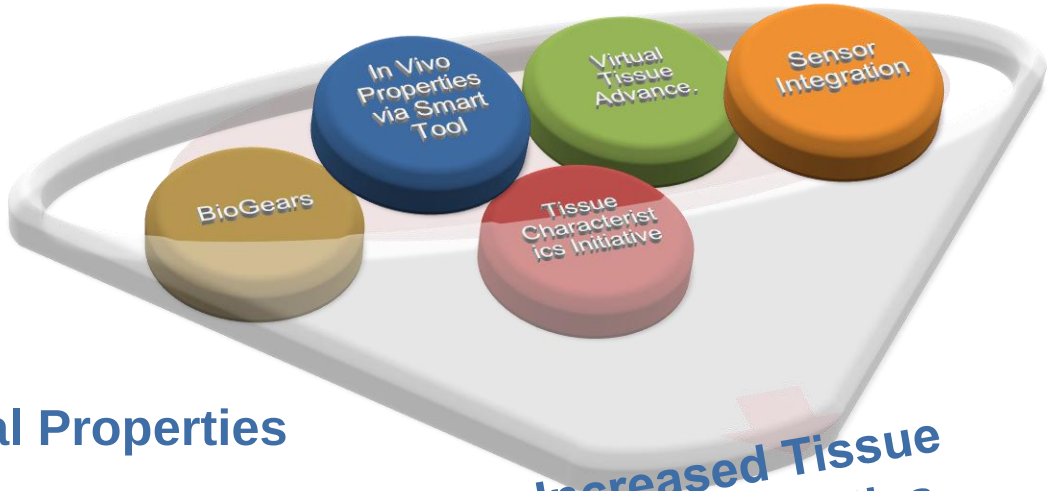
‘Tissue’ Characteristics & Physiological Platforms







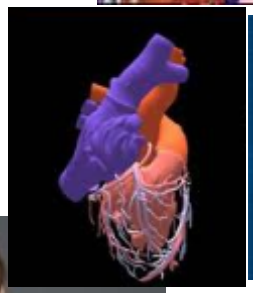
‘Tissue’ Fidelity and Physiological Response

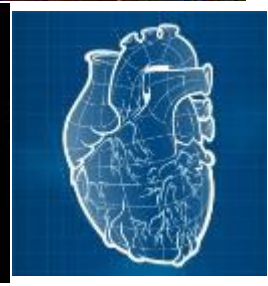


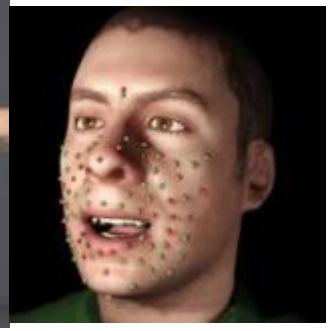
Material Properties

Increased Tissue Characteristics

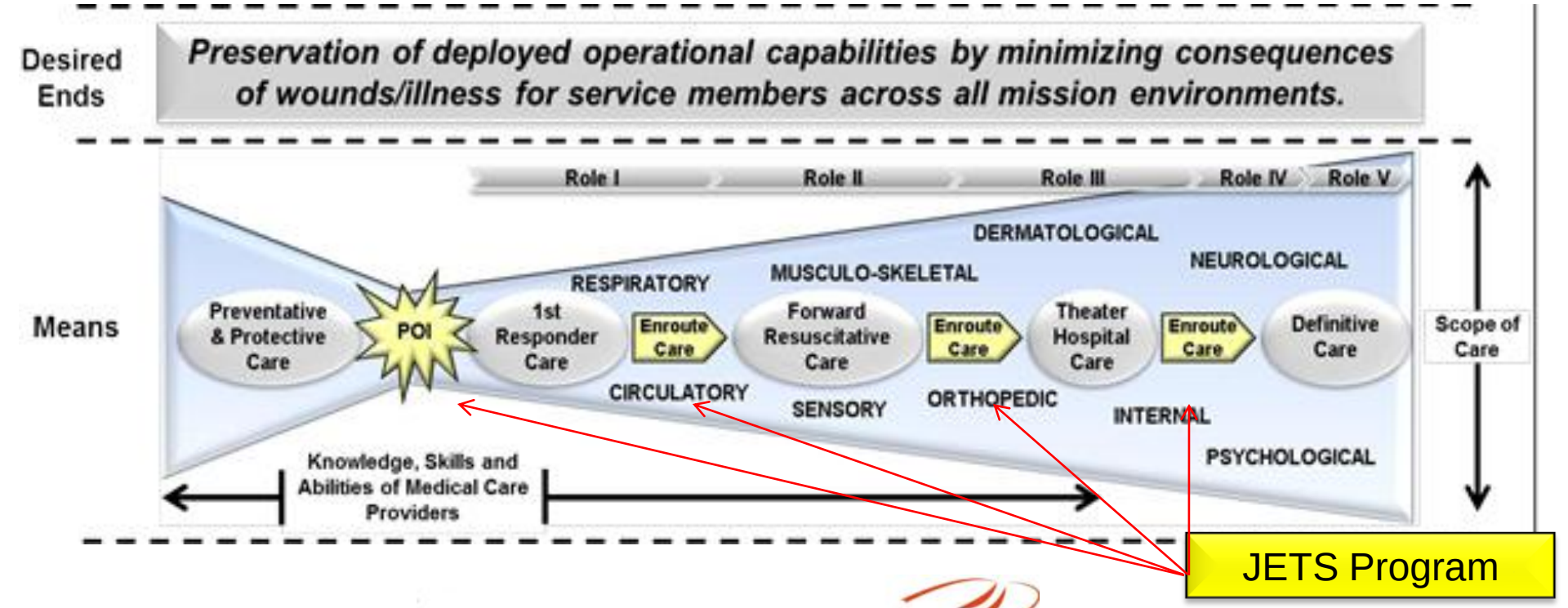
Virtual Reality Models





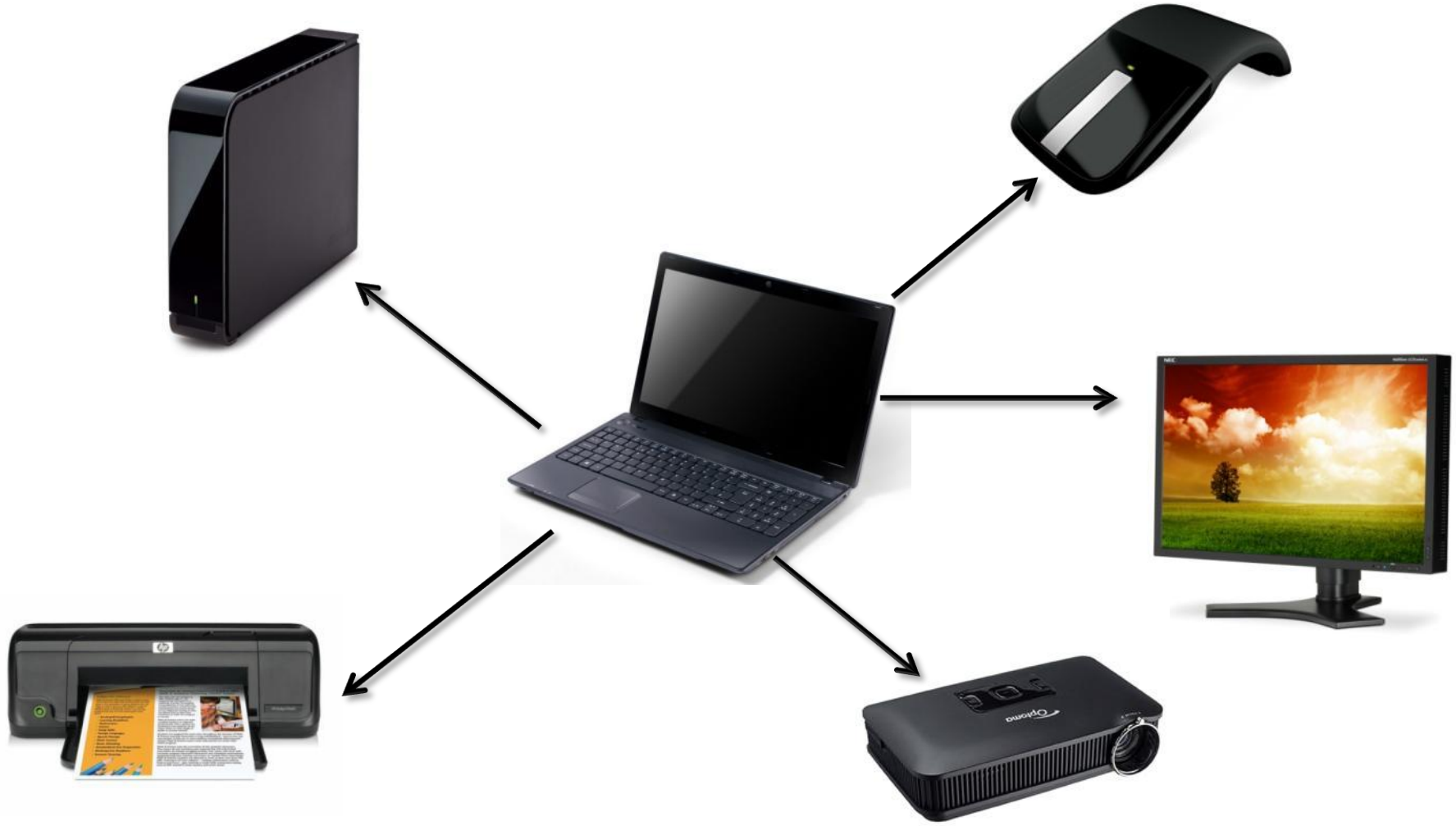


Joint Evacuation Training Simulation System



Advanced Modular Manikin Concept

Intra operability

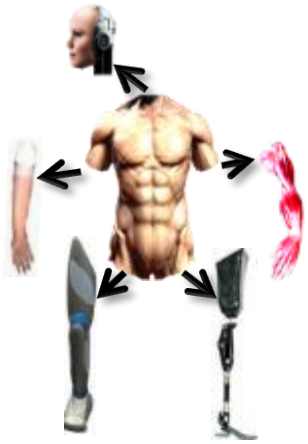


AMM Concept (Cont)

AMM Concept (Cont)

AMM Concept (Cont)

Concept of Intra & Inter Operability



AMM (Intra-operable): Core with Peripherals, Peripherals to Core, and even Peripherals to Peripherals

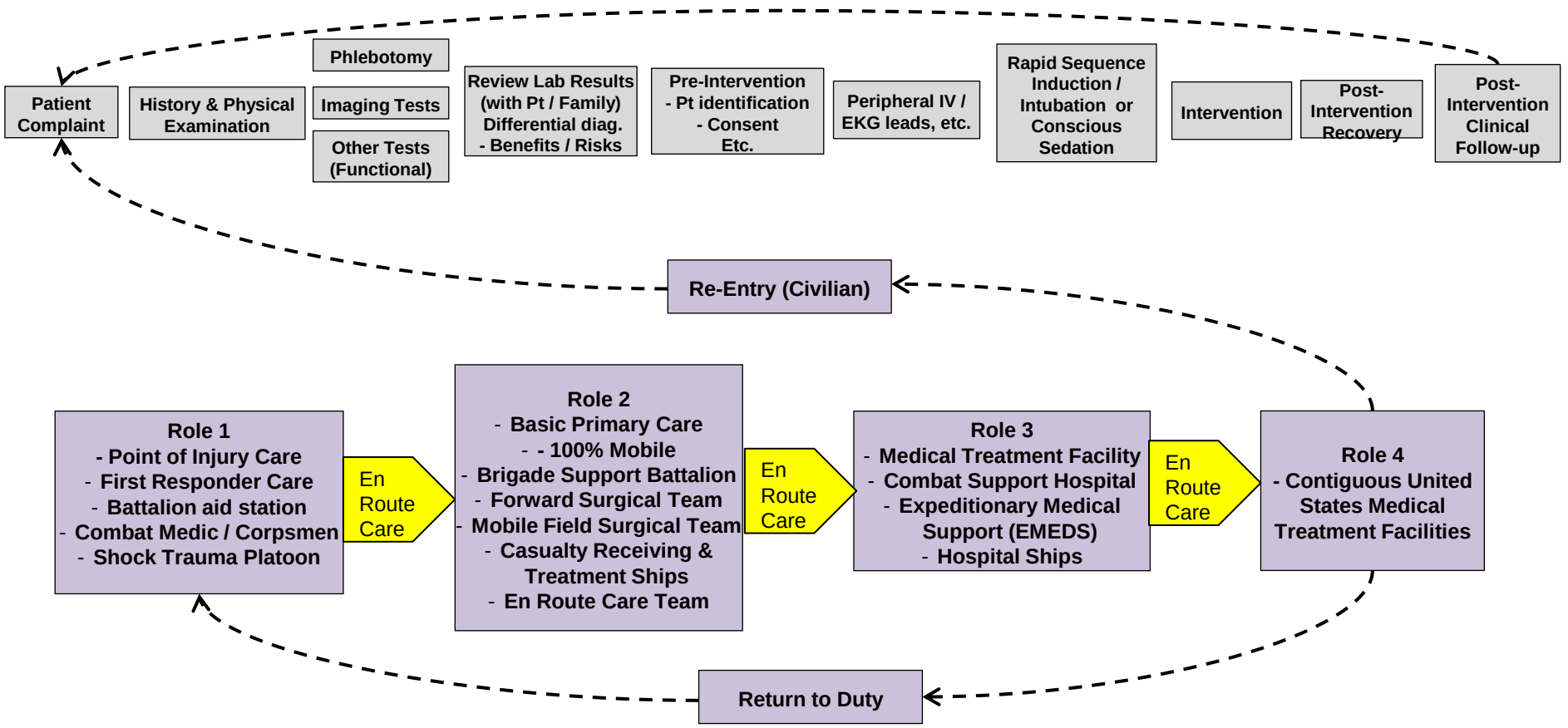
Also Core to 'System'

Physiology Engine: Organ/Tissue system with Organ/Tissue system. Physiology of 'entire' human system.

Integrate Physiology Engine into AMM

Training using Simulation > Crossing over to Reality

Success: 'Start to Finish'



Sim Training Translation to Real Medicine

Challenges (viewed another way > Opportunities)

- Organization(s) assisting in documenting current ‘standards’; more importantly designing future standards for the next century
  - Who will lead, regulate (enforce) and maintain these standards
- Use (integrate) real instruments into medical simulation systems (NOTE: Safety issue)
  - Proof of concept already demonstrates real devices ‘communicating’ within simulation systems
- Securing the System (particularly personalized data / info)
- Next century vision of the capabilities / functionalities that defines a System of System (for medical simulation)
- Need to think ‘small’; ‘large’, and ‘multi-dimensional’
- What else?

Questions?

For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil