Medical Device Interoperability Reference Architecture (MDIRA)

Introduction at HL7 FHIR/IEEE Healthcare Devices Working Group

17 September 2019 – Revision 2
Objectives

• Introduce MDIRA

• Stimulate discussion on the framing and scope of MDIRA

• Provide foundation for in-depth and focused team collaboration to follow
US Army MRDC MDIRA Research Project

Objectives:
• Advance MDI to improve patient safety through standardization of healthcare delivery
• Identify a collaborative Federal/industry approach in pursuing answers to the questions
• Conduct multiagency/multi partner collaborative research to develop a sustainable framework of autonomous/closed loop prototypes for military health care which are dual use for the civilian healthcare system

Research Deliverables
• Incremental deliverables are expected to support the end deliverables, which are:
• Prototype an overhauled medical device infrastructure that shows a national, sustainable and interoperable medical device technical, clinical and policy framework
• Prototype autonomous, closed loop applications for the following disease processes that are most common for military casualties (and civilian trauma/accidental injuries)
  • Cranio-cerebral trauma
  • Hemorrhagic shock and coagulopathy
  • Septic shock
  • Multi-system organ failure
  • Burns
  • Acute renal failure
  • Pulmonary insufficiency
Future Operational Environment Implications

Military

• U.S. dominance and unobstructed communication are not assured
  – Adversaries are contesting all 5 domains (Air, Land, Sea, Space & Cyberspace), to include electromagnetic pulse (EMP), and the information environment, making casualty treatment and immediate evacuation difficult

• Large numbers of casualties and prolonged care at the point of injury, and in denied environments lacking specialty/skilled medical providers

• Smaller forces fight on an expanded battlefield and in multi-domain operations that are increasingly lethal and hyperactive

• Near-peer states more readily compete below armed conflict making deterrence more challenging

• Dramatically increasing rates of urbanization and the strategic importance of cities also ensure that operations will take place within dense urban terrain

Civilian Needs Mirror Military Needs

• More frequent and volatile weather and human-induced disasters (hurricanes, mass shootings, ebola outbreak etc)

• Need for safe, repeatable, consistent, high quality healthcare delivery regardless of geographic location or staff qualifications (rural/urban hospitals and intensive care units)

• Prolonged care may be needed before evacuation or specialty treatment can occur (Hurricane Maria Puerto Rico 2017)
Medical Device Challenges

MDI Showstopper Issues:
• No plug and play, i.e. cannot swap O2 Sat with another manufacturer
• No standardization of data outputs for devices to interoperate
• Must have the exact make/model to replace a faulty device or system will not work

Interoperability and Integration of Medical Devices for Autonomous Care and Virtual Health are in Early Stages:
• Research needed on treatment decisions with semi-autonomous algorithms in demonstrations and prototypes
• Devices need to be able to “talk” and self-manage in real time on changes in clinical conditions

International and Industry Standards Needed:
• Device data exchanges, interfaces, algorithms
• Standardized methods to provide and improve AI for autonomous care
Future View of Medical Support

Autonomous/Semi-Autonomous/Remotely Operated Medical Devices and Medical Data interacting with Healthcare Providers at hospitals around the globe from Theater and thru Casualty Evacuation to the USA

- Autonomous Critical Care System
- Autonomous Intubation
- Autonomous Cricothyrotomy
- Other autonomous interventional procedures
Proposed Medical Autonomy Levels

**Levels of autonomy**

Increasingly human-performed tasks

- Caregiver(s) performs the task
- Caregiver(s) is involved in task and technology aids and enhances effectiveness
- Caregiver(s) initiates a task and has discrete control over technology that executes it
- Caregiver(s) defines and initiates a task & technology executes the task with caregiver supervision
- Technology decides course of action and executes it with caregiver supervision

Increasingly machine-performed tasks

- Technology decides course of action and executes it without supervision

No autonomy | Technology Assistance | Task Autonomy | Conditional Autonomy | High Autonomy | Full Autonomy

Varying levels of autonomy across tasks
MDIRA Purpose

Requirements & Guidance for:
- Interoperability
- Security
- Modularity
- Functionality
- Implementation
- Etc.

Operational Needs

System Requirements & Architecture

Other Requirements, Standards and Guidance

Detailed Specifications

System Implementation

Autonomous Care System
What the MDI Reference Architecture Can Provide

- Specifies an environment into which combinations of medical devices, some under closed-loop control, can be quickly integrated to meet immediate trauma care needs.
- Provides a common terminology and taxonomy for physical and functional elements.
- Identifies operational interfaces and operational support assumptions.
- Identifies the pertinent interoperability standards as well as requirements (e.g., for medical devices) not yet addressed in the standards (stimulates enhancements to standards).
- Supports development of Reference Implementations of core components.
- Enables an open-systems business model.
Collaboration Benefits

Focus on the difficult cross-cutting research and development challenges to realize military research goals:

• Synergy between designing systems for dual use in the military and civilian sectors that insures uncompromised safety while allowing operators to adapt to changing conditions

• Establish architecture for secure sharing of data use and reuse will facilitate advances in healthcare diagnosis and treatment, as well enhance computational methods to extract new knowledge from these data

• Collaborative efforts are needed to define technical aspects of interoperable platforms, architecture, medical devices, standards and data models that can be used across multiple medical areas