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# Medical Device Interoperability Reference Architecture (MDIRA)

## Introduction at HL7 FHIR/IEEE Helathcare 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***

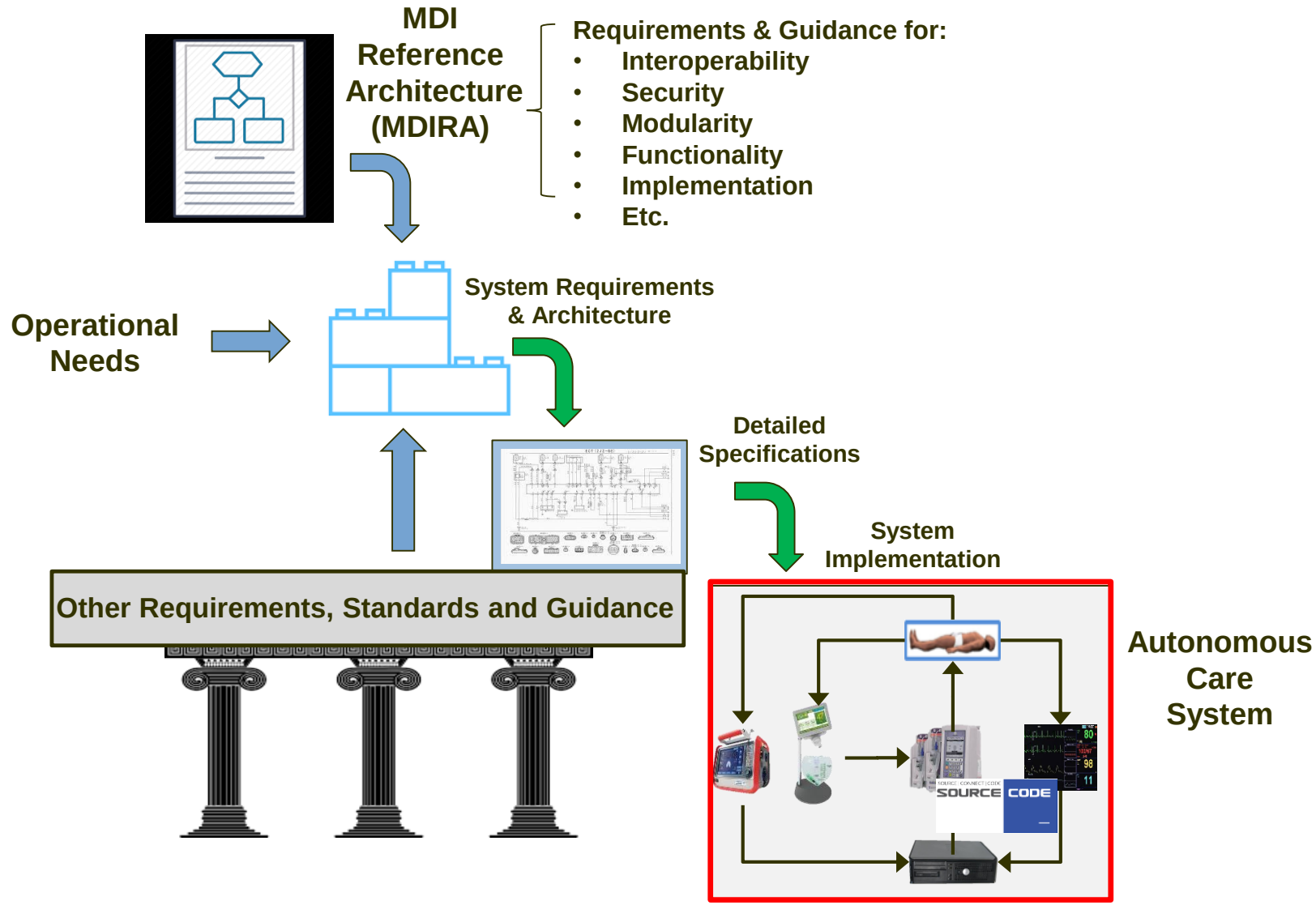
Increasingly human-performed tasks → Increasingly machine-performed tasks

| No autonomy | Technology Assistance | Task Autonomy | Conditional Autonomy | High Autonomy | Full Autonomy |
|---|---|---|---|---|---|
| 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 | Technology decides course of action and executes it without supervision |

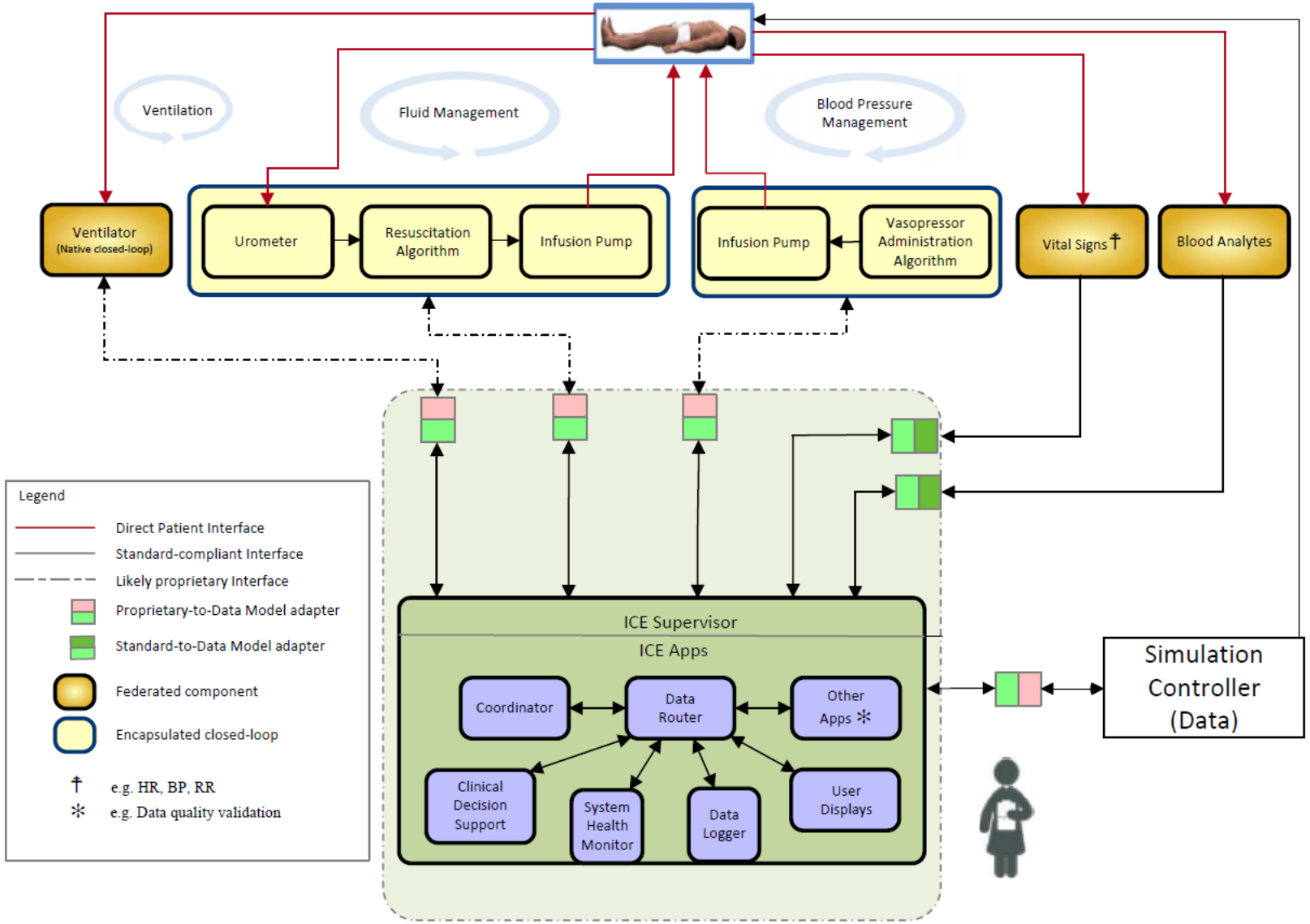
Varying levels of autonomy across tasks




# MDIRA Purpose



# Reference Implementation



# 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