Medical Device Autonomy and Data Interoperability in Support of Multi Domain Operations (MDO)

Live, Online Technology Demonstration

November 18, 2022

Important Note

- This slide deck was presented to support a live virtual demonstration on November 18, 2022, 1:00-3:00 PM ET.
- Key outcomes and messages from the project are not detailed in these slides and are contained in the associated 1:50 video recording available online:

  https://www.youtube.com/watch?v=bgaS9nSLwAg

Contact for issues with video links or edits to this slide deck: jmgoldman@mgh.harvard.edu

Meeting Opening

Alice Isenberg, PhD, MITRE

Agenda

Item	Topic	Speaker	Time
1	Meeting Opening	Alice Isenberg, PhD, MITRE	1:00 – 1:05
2	Introductory Comments	Matthew Quinn, Chief Science Officer, TATRC	1:05 – 1:15
3	Overview of Today's Demonstrations	Julian M. Goldman, MD, MGH	1:15 – 1:30
4	Demonstrations	Multiple Parties at multiple sites	1:30 – 2:10
5	Presentations of key technologies and enabling research	MGH, MITRE, DocBox	2:10 – 2:45
6	Q&A, Closing Remarks, & Next Steps	Matthew Quinn, Chief Science Officer, TATRC	2:45 – 3:00

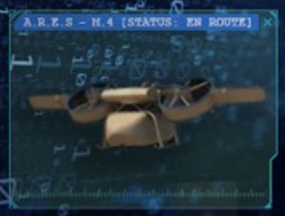
Letter from
COL Jeremy Pamplin, Director, TATRC
read by
Matthew Quinn, Science Director, TATRC

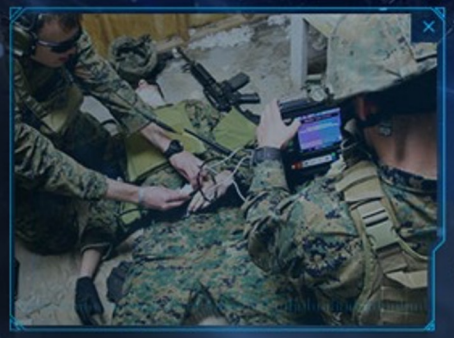
This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=96

Introductory Comments

Matthew Quinn, Science Director, TATRC

This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=341





MISSION

To fuse data, humans, and machines into *trustworthy* solutions that optimize warfighter performance and casualty

VISION

Automating casualty care to maximize medical decision space

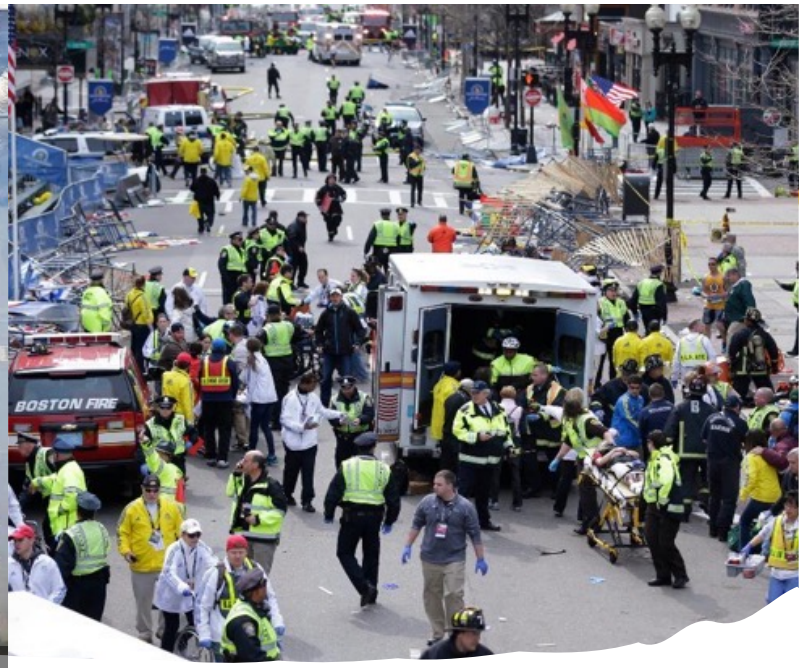
Objectives for Today

- Illustrate the use and value of medical device, telemedicine, data analytic, and visualization technologies working together using open standards and a device-agnostic platform to expand capability and capacity of response for large numbers of casualties/patients using fewer human resources in MDO and during military/civilian disaster events

- Demonstrate how the Device Interoperability and Autonomy Coordinating Center (DIACC) and use of the “Playbook for Threat Modeling Medical Devices” has accelerated the pace and progress of solution development, availability for use, and identification and mitigation of technical, cyber and clinical risks

- Identify key follow-on efforts to capitalize on this work

Boston Marathon Bombing, 15 April 2013



Las Vegas Shooting, 1 October 2017

MASCAL Events

TATRC

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Common to all?

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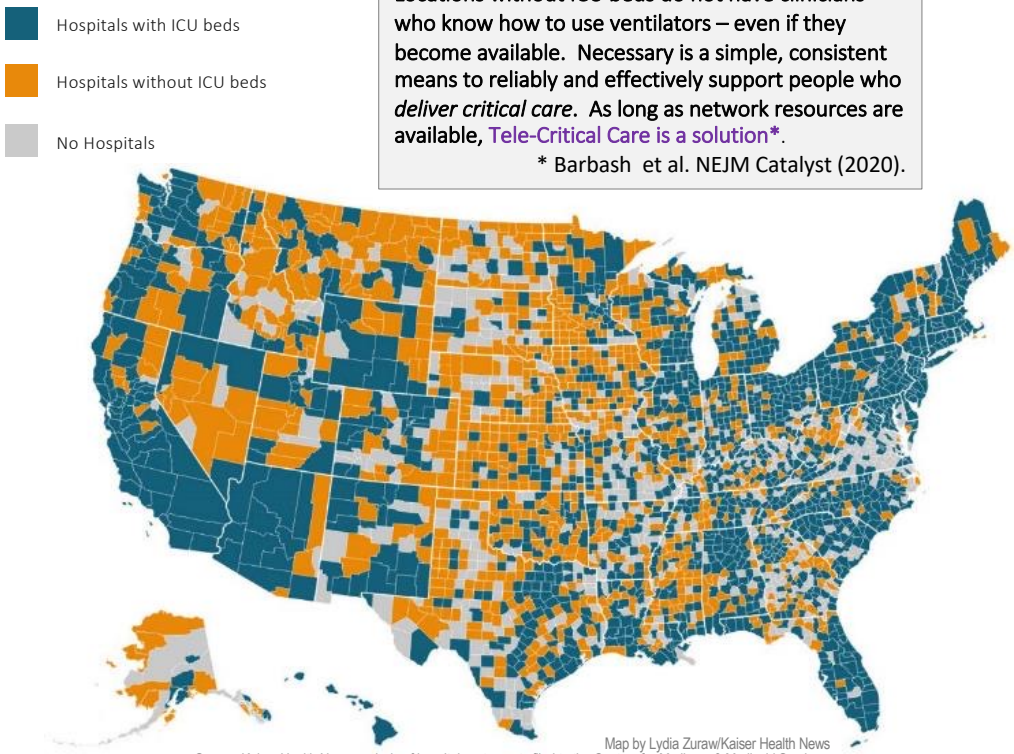
Resource Limitations

- *Equipment*
- *Medications*
- *Medical Devices*
- *Time*
- *Experts*

The Critical Care Problem

A BIG Problem: Where there are no ICU beds, there are no critical care trained clinicians!

- Half of all U.S. counties **lack Intensive Care Unit (ICU) beds and critical care (CC) trained clinicians** to manage severe COVID-19 patients.
- The COVID pandemic has demanded unprecedented CC capacity.
- Tele-critical care (TCC) **expands both the capability and capacity of nurses and physicians**, who lack experience in critical care, to provide this care.
- **TCC has been demonstrated to improve patient outcomes in both rural and urban medical centers**, especially when no CC trained physicians are locally available.



Locations without ICU beds do not have clinicians who know how to use ventilators – even if they become available. Necessary is a simple, consistent means to reliably and effectively support people who *deliver critical care*. As long as network resources are available, Tele-Critical Care is a solution*.

* Barbash et al. NEJM Catalyst (2020).

Map by Lydia Zuraw/Kaiser Health News

Source: Kaiser Health News analysis of hospital cost reports filed to the Centers for Medicare & Medicaid Services

https://khn.org/news/as-coronavirus-spreads-widely-millions-of-older-americans-live-in-counties-with-no-icu-beds/

Objectives & Lines of Effort (LOE)

LOE 1

» The NETCCN digital health ecosystem connects clinicians across traditional boundaries to optimize access to expertise at the point of need thus increasing capability and thus capacity of the system.

LOE 2

» Adding the ability for remote experts to deliver *hospital like* capabilities without local expertise improves local standard of care and outcomes.

LOE 3

» Collecting all the data and making it usable at scale enables 1) better care & situational awareness at echelon & 2) optimal resource allocation

"The committee commends… TATRC… for the rapid development and deployment of… NETCCN… and… encourages the Defense Health Agency to fully leverage this…to accelerate current and future digital health and telehealth applications throughout the military health system."

– 2022 NDAA (Senate Armed Services Committee Letter)

"I wish we had this in Iraq"

2021 FedHealthIT Innovation Awards

DISRUPTIVE TECH SUMMIT

Government Innovation Awards

NETCCN Participation in Military Exercises

SOF PCC 2021
CyberQuest 2021
CAPSTONE Field FTX 2021
47th CSH Field Exercise 2021
Defender Pacific 2021
Operation Bushmaster 2021
Operation Gunpowder 2022
Project Convergence 2022
AEWE 2023 (planned)

	Civilian	Military*	Total
Unique Deployments/Exercises	61	> 7	**> 68**
Total Remote Experts	65	> 43	**> 108**
Total Local Care Givers	>390**	> 295**	**> 685**
Total Encounters***	1235	> 900	**> 2135**
Total Unique "Patients"****	1061	> 60	**> 1121**
Patient Days[V]	5470	> 60	**> 5530**

Multi-Domain Operations (MDO): The Tyranny of Distance and Peer Adversaries

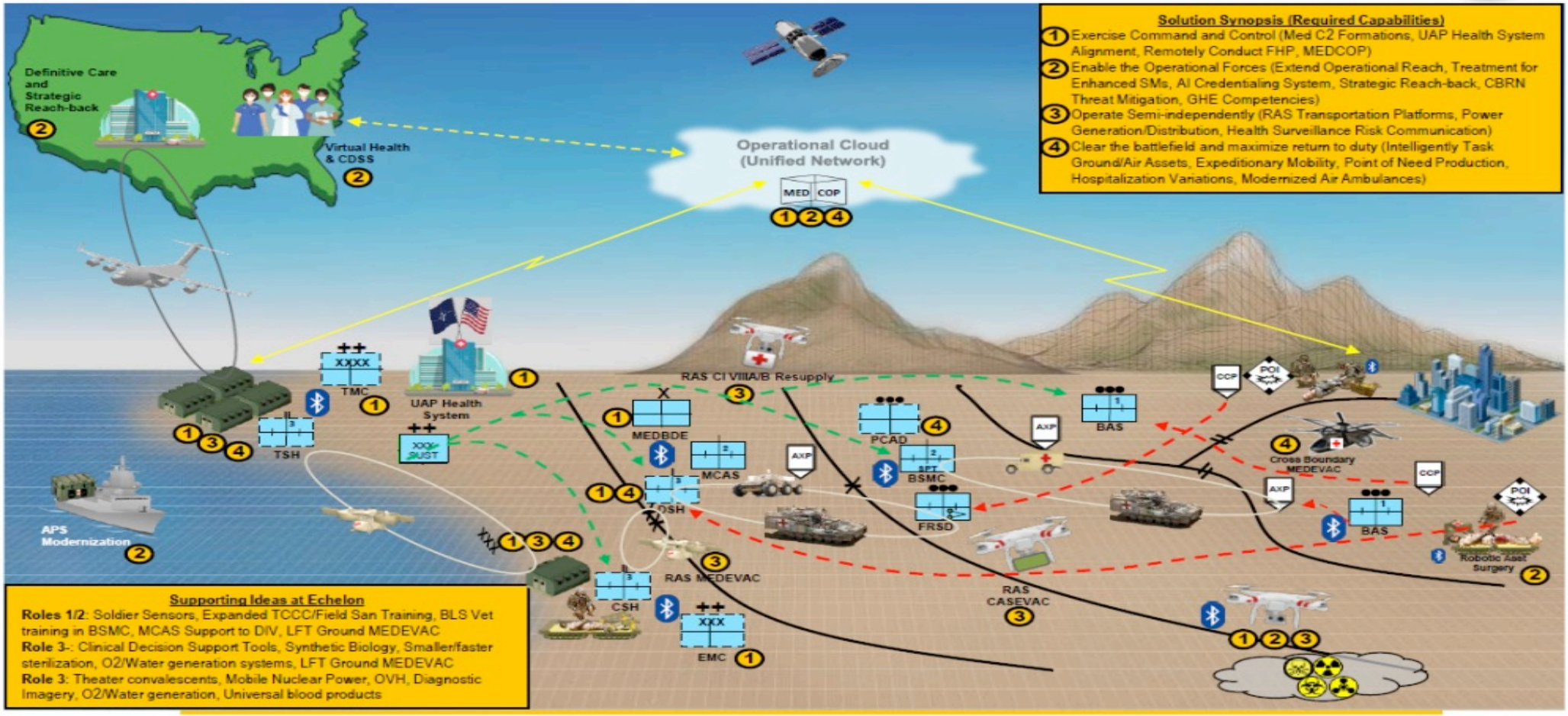
Context		Problem
Long, delayed or unavailable evacuation	=	resource consumption
Dispersed operations	=	diluted resources, delayed supply
Deep fires	=	need for mobility
Devastating weapons, large scale	=	more casualties
New technologies (AI, synthetic biology, nanotechnology, robotics, directed energy, hypersonic, -omics, etc.)	=	creative unknowns…

Source: Natural Earth

Prolonged Care

Massive Casualties

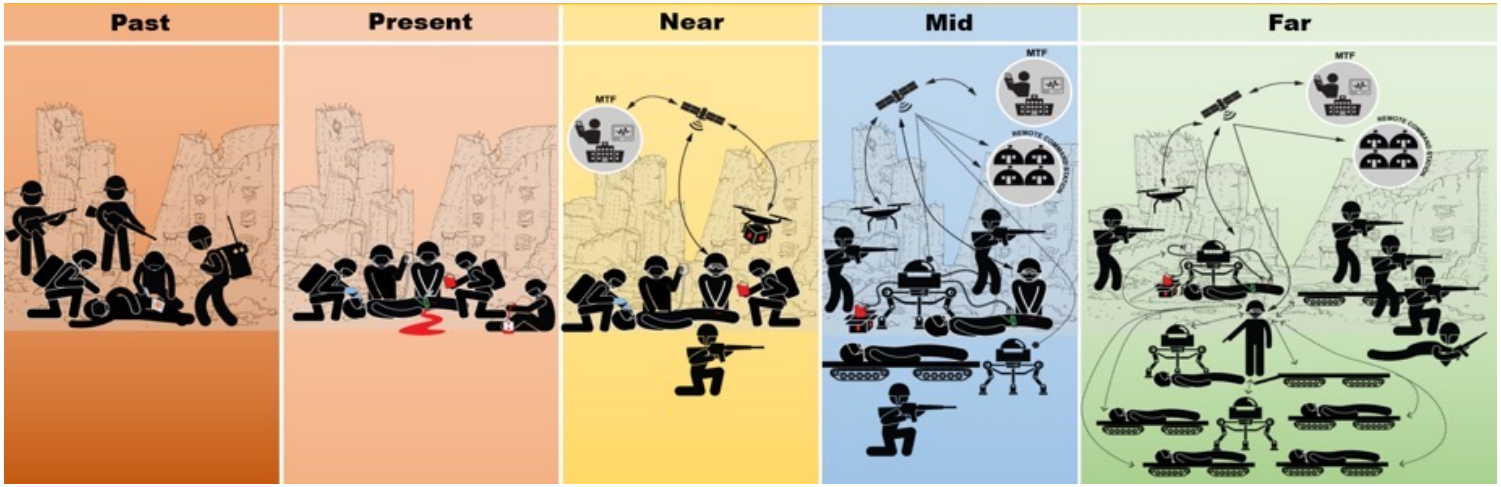
Future AHS Concept 2035



The Journey to Optimized Human-Machine Teaming

Solutions for MDO

1. Reduce Casualties
2. Increase Caregiver Capability and Capacity



Human-machine teams increase caregiver capability and capacity through decision support, autonomous/semi-autonomous, and robotic systems that work together using common controllers in networked and/or locally connected interfaces.

*N.B. size and configuration of robots, drones, and evacuation vehicles are notional and do not reflect teaming, future miniaturization, or multi-purpose functionality

"The AHS' current acquisition and modernization processes are antiquated and unable to keep pace with the current threat environment… Cohesive integration of AHS systems into battlefield networks through a system of systems approach will require increased coordination with diverse battlefield governance. Given the Joint nature of warfare, common data standards and message formats will inform the development of a continuous, seamless link between administrative and tactical systems through the continuum of DoD, VA, civilian hospitals, and coalition partners."

Army Medical Modernization Strategy (2022) - LTG James M. Richardson

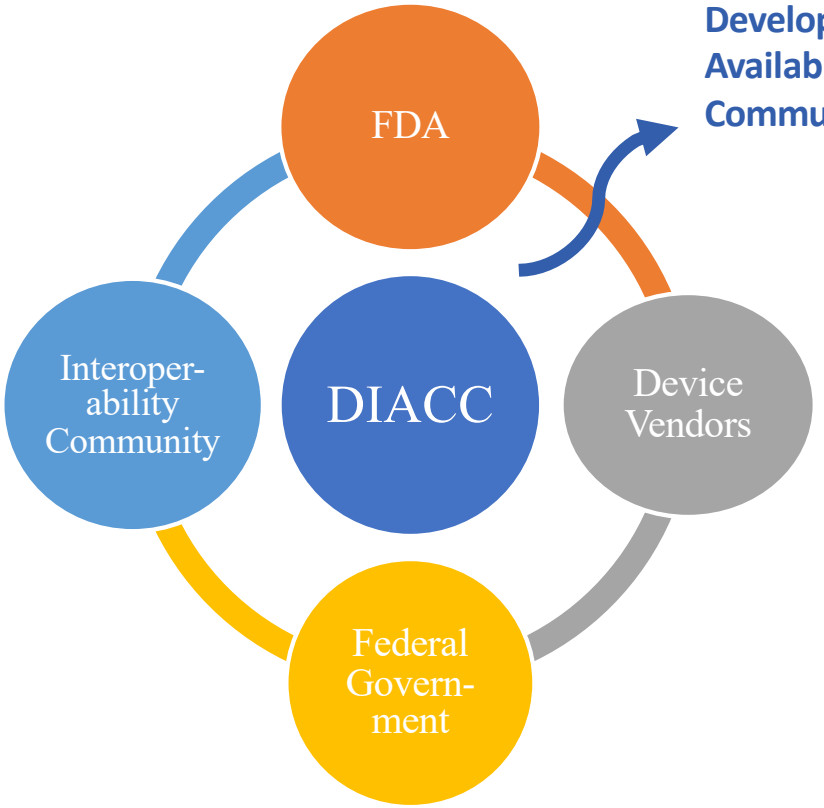
A Tale of Two Approaches

Device Vendor → Product

Device Vendor → Product

Device Vendor → Product

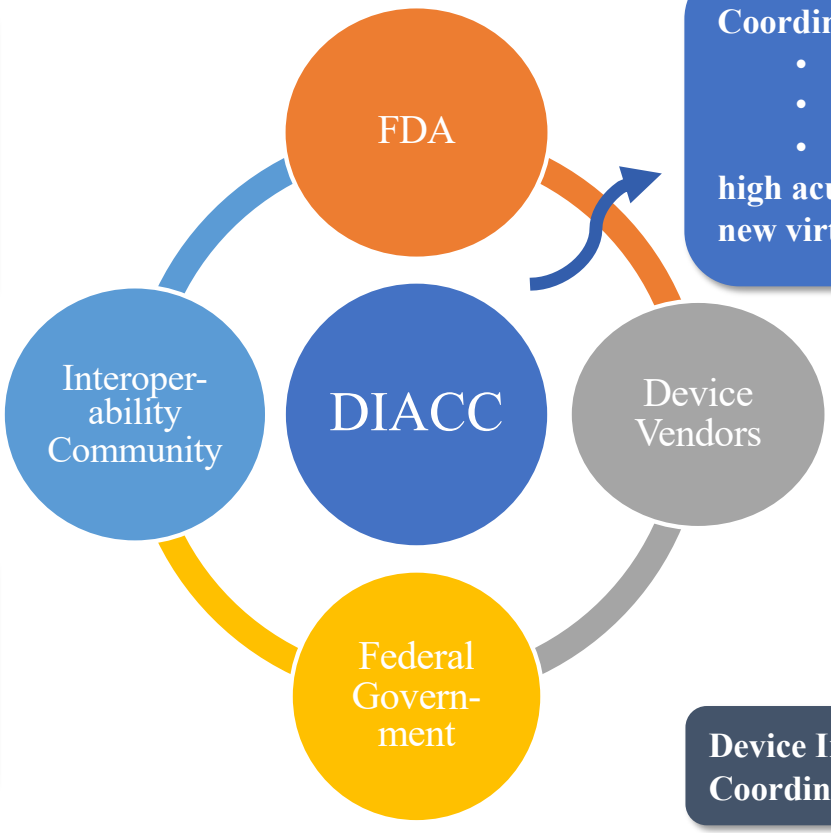
vs.



Collaboratively Developed Products Available to the Community

A Tale of Two Approaches: The DIACC Approach

The DIACC has:
- Safe, collaborative space with objective leadership, sensitive to proprietary concerns
- Unique opportunities created by the CARES Act, EUAs, and FDA guidance to expedite innovation



Coordinated development & testing of:
- integrated
- remotely-controllable
- standards-compliant

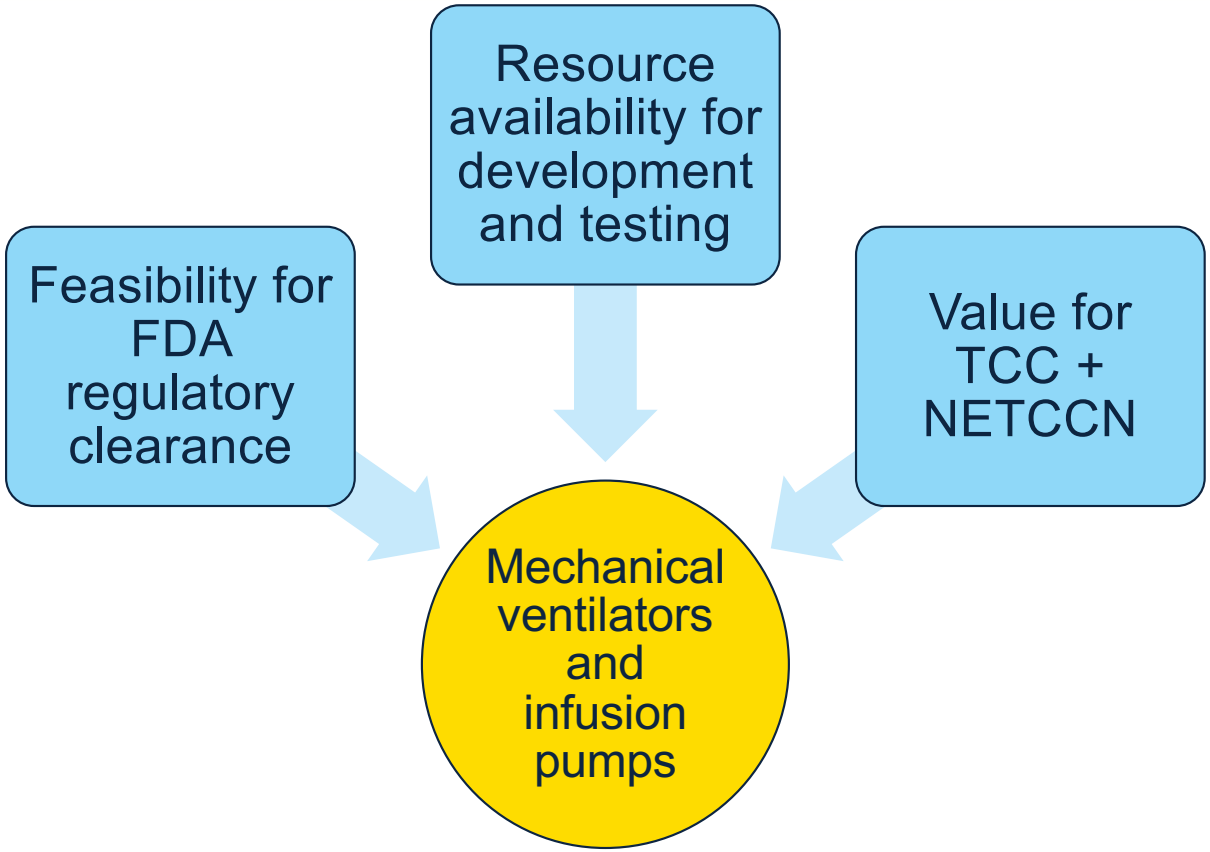
high acuity medical devices that provide new virtual health capabilities.

Work includes:
- Standards use
- Similar workflows
- Similar use cases
- Risk management assessments

Device Interoperability and Autonomy Coordinating Center (DIACC)

TATRC

Decision Framework for Selection of Medical Devices with Data Integration & Device Control in NETCCN



Conclusions

- Thank you to all of the participants and attendees in today's demo!
- We have made tremendous progress in a short amount of time by working differently and working together
- Please think about how the standards-based system-of-systems that we're demonstrating today can be applied to other challenges in MDO and beyond

This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=976

Demonstration Overview

Julian M. Goldman, MD
Massachusetts General Hospital

Background

Remote Control was prototyped during Ebola[1] (2014)

WCVB

BREAKING NEWS: Coronavirus crisis in Massachusetts: The latest map and data

RECOMMENDED

- Couple holds special adoption ceremony over Zoom
- Massachusetts men arrested in connection with smuggling ex-Nissan executive out of Japan
- Restaurant opens for last time because of pandemic's toll on business
- Gov. Charlie Baker visits Braintree company converted to producing protective equipment
- AR-15 stolen from Maine state trooper in 2018 recovered in Boston
- Police find body of missing former WWE star Shad Gaspard
- Coronavirus crisis in Massachusetts: The latest map

Local researchers testing remote control Ebola care

Researchers hope prototypes will soon be in medical centers

WCVB Updated: 7:09 PM EST Nov 6, 2014

Kelley Tuthill

SOURCE: Kelley Tuthill/WCVB

BOSTON — If a television can have a remote control, why can't a medical device?

Watch the report

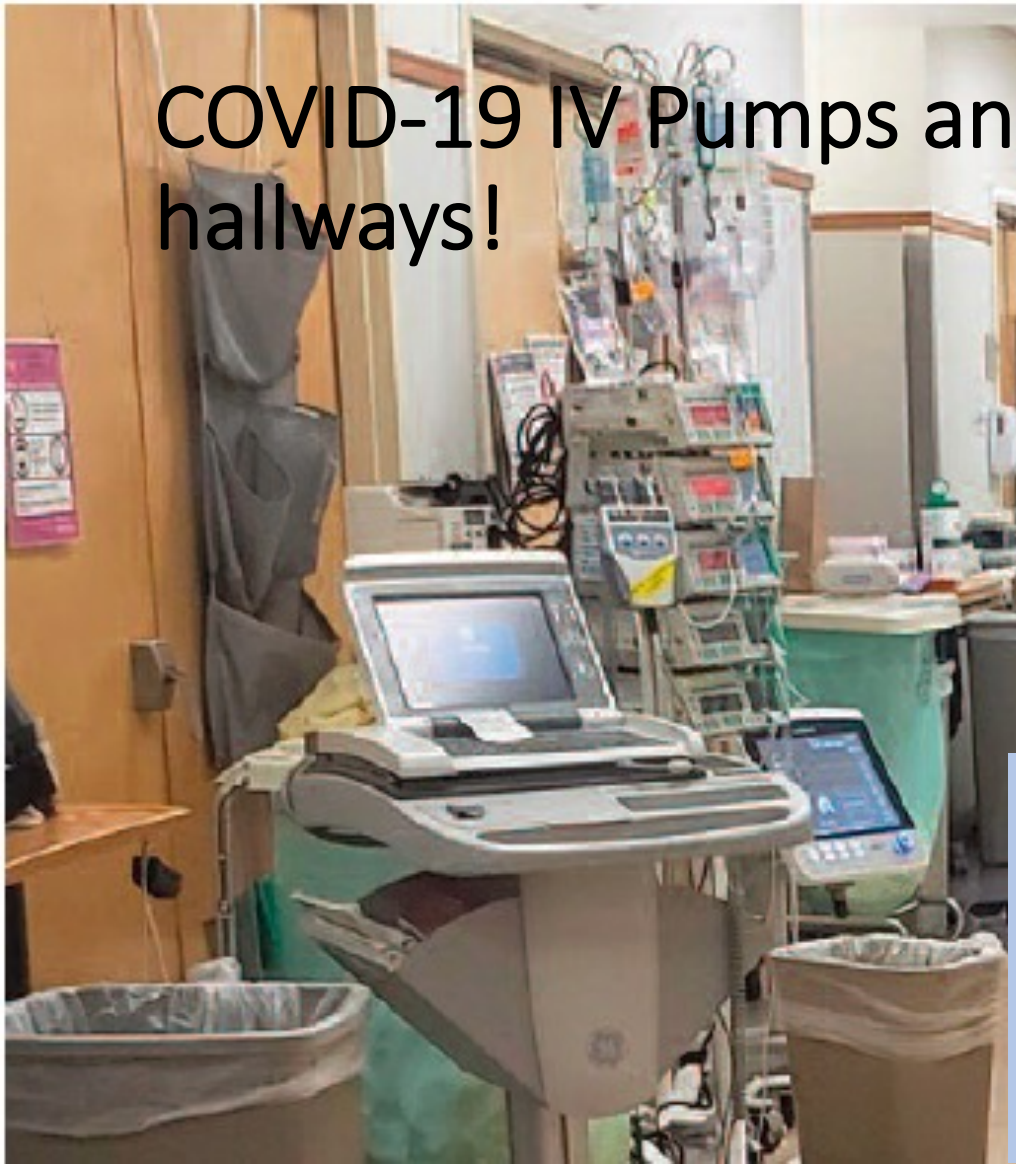
Proof of Concept: Remote Ventilator Control and Data Visualization

Enables:

- More rapid response to urgent patient needs
- Reduce room entries
- Reduce PPE usage
- Assess patient more quickly
- Initiative with NSF Smart America Closed-Loop Healthcare[2]

1. https://www.wcvb.com/article/local-researchers-testing-remote-control-ebola-care/8211393# in MGH MD PnP lab
2. https://www.nsf.gov/discoveries/disc_summ.jsp?cntn_id=132204

COVID-19 IV Pumps and Ventilators placed in hallways!



Typical ICU during COVID-19:

- IV pumps in hallways for access
- Vent control panels in hallways (when possible)
- Cannot hear other device alarms outside of room
- Must don PPE to enter room and adjust settings (20-40 min to don and doff)

Trajectory of the NETCCN/MDIA/DIACC portfolio

- March - May 2020 - Research portfolio inception
- December 2021 – First technology demonstration of NETCCN smartphone apps, remote control of ventilators and infusion pumps, pervasive interoperable data infrastructure

  https://vimeo.com/channels/tideremotecontrol
- August 10, 2022 – CPAM – Cross Platform Application Module pervasive interoperable data pipeline for Virtual Critical Care operations and analytics

  https://www.youtube.com/watch?v=DYviSp9Orhs

First Demonstration Presented on December 17, 2021

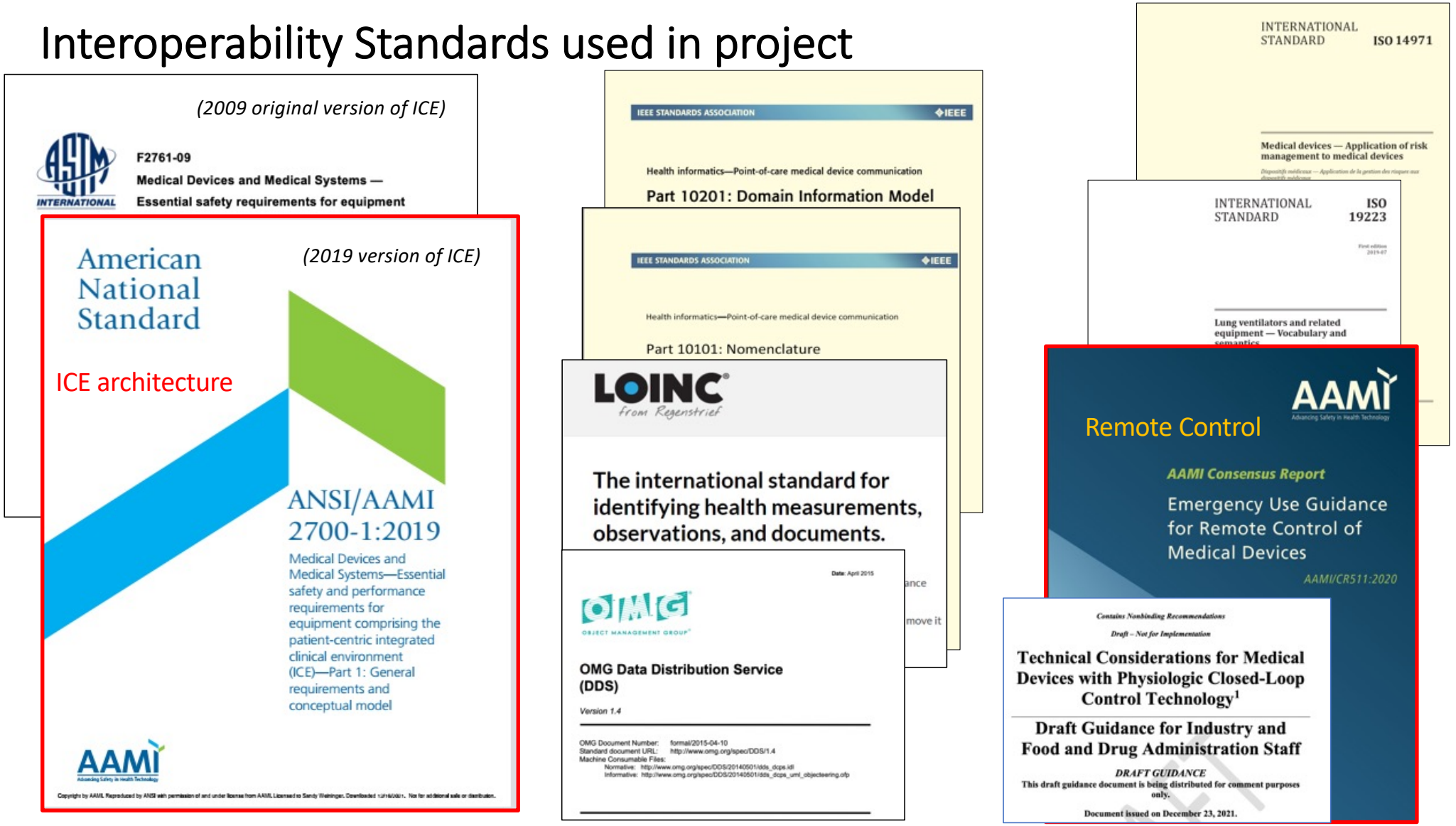
- Live simulations of clinical scenarios in which remote control of medical devices and interoperable data could improve patient care
- Connected sites in first technical demonstration:
  - Madigan Army Medical Center, JBLM, WA
  - Massachusetts General Hospital, MD PnP Lab, Cambridge, MA
  - Nihon Kohden OrangeMed, Santa Ana, CA
  - Thornhill Medical, Toronto, Canada

Live simulations presented on
December 17, 2021 available online:

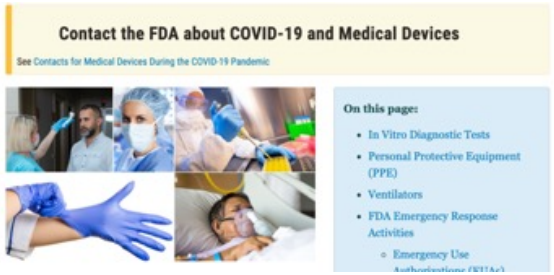
1. Far remote control from MGH MD PnP Field Hospital* (Cambridge) to Nihon-Kohden Community Hospital (California) https://vimeo.com/665473382
2. Far remote control by MD @Madigan AMC during patient evacuation via ambulance (Toronto, Canada) https://vimeo.com/665476662
3. Remote control of ventilator and IV pump (Cambridge) to optimize care https://vimeo.com/665484469
4. Remote control from MD PnP Field Hospital observation area (Cambridge) https://vimeo.com/665487966
5. Situational awareness dashboard (from all sites to Waltham, MA) https://vimeo.com/665490502
6. Teleguidance (from Fort Mill, SC) of point-of care-ultrasound to MD PnP lab https://vimeo.com/665494677

*Note: These are fictitious hospital names and simulated patients. Geographic locations are accurate.
Some remote-control capabilities demonstrated today are under development and not yet intended for clinical use.

Interoperability Standards used in project

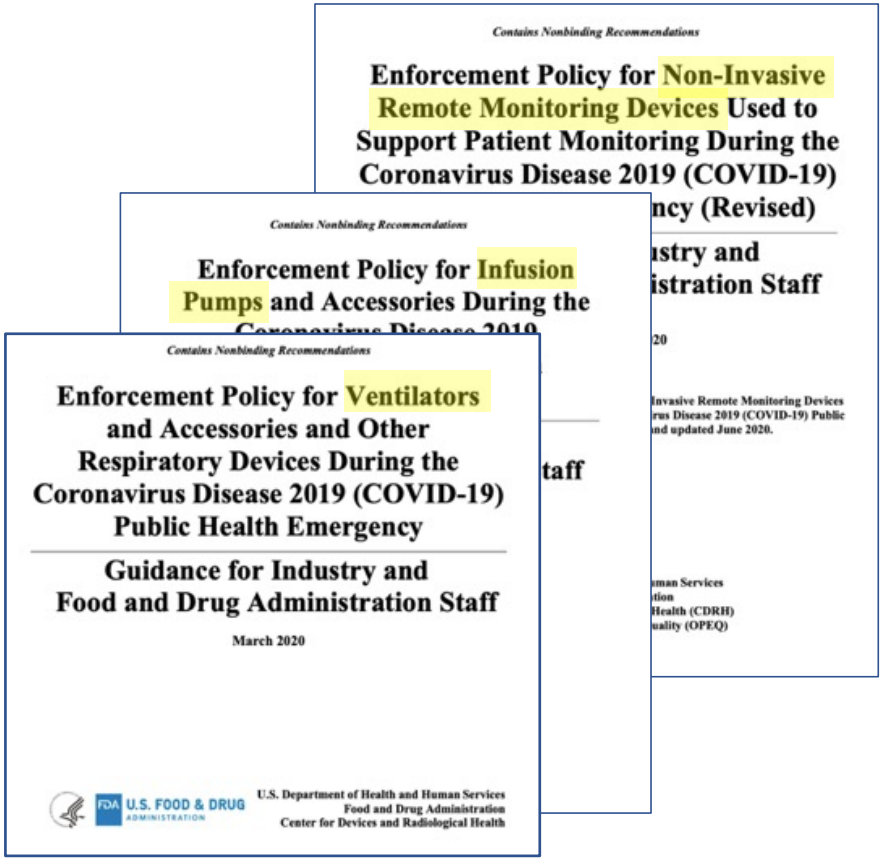


FDA Immediate in Effect Guidance 2020



"… Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters" may be added without the need for 510k submission

https://www.fda.gov/media/136318/download
Page 8



UNCLASSIFIED

Major Capabilities and Maturity Level in Demonstration

Major Capabilities	TRL /KRL @ start	TRL /KRL @ Dec '21	TRL /KRL @ end
Far remote active monitoring and control of ventilator (NKV-550) ==> TRL	2	2	6
Informing local user of remote monitoring/control ==> TRL	2	2	5
Alarm management in the device remote control context (e.g., remote expert can change alarm threshold settings but cannot silence alarms in the device) ==> TRL	2	2	3
Common remote control User Interface (UI) for different ventilators and different devices ==> TRL	2	2	6
Contention for remote control ==> TRL	2	2	4
Remote monitoring and control of ventilator and infusion pump during evacuation/ enroute care ==> TRL	2	4	6
Transfer data Cybersecurity requirements have been identified through MITRE threat modeling analysis --> KRL	2	3	6
Standardization and harmonization of ventilator data terminologies ==> KRL	2	3	8
Safety assurance framework for medical device remote control towards regulatory pathway ===> KRL	2	4	5
Risk management for competing remote control ==> KRL	2	3	5
AAMI remote control standard (before the work an AAMI technical report was released, after this work a draft version of the standard is pending for committee voting) ==> KRL	3	4	6
Lab-based testing capabilities for assessing system safety and resilience under network disruptions ==> TRL	2	4	6
Passive data acquisition and automated clinical documentation across care continuum vs human care provider entered data ==> TRL	6	7	7
Longitudinal care continuity and data transfer (data moves with the patient) ==> TRL	3	5	7
Secured (encrypted) data transfer for enhanced security	2	2	6
Docbox transform from software- and hardware-based to solely software-based ==> TRL	2	6	9
Core DocBox capabilities (including both bedside platform and underlying network/IT infrastructure) that provide a technical foundation to this work have been validated in real-world clinical practices ==> TRL	6	7	9
Medical device interface datasheets for infusion pumps ===> KRL	2	5	7
Medical device interface datasheets for ventilators ===> KRL	2	5	8

This November 18, 2022 demonstration video is available online on Vimeo and YouTube:
https://vimeo.com/784432343 (Vimeo permits downloading the video file)
https://www.youtube.com/watch?v=bgaS9nSLwAg. This section starts at 25:35

Todays Demonstrations - November 18, 2022*

1. Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Seattle, WA

   https://youtu.be/bgaS9nSLwAg?t=1919

2. Far remote management of casualties during enroute care/med-evacuation by UAV from Seattle, WA

   https://youtu.be/bgaS9nSLwAg?t=2301

3. Data continuity and automated documentation from multiple vendor devices across continuum of care (Role II -> Medevac -> Hospital)

   https://youtu.be/bgaS9nSLwAg?t=2635

4. Integrated single UI data integration and control of multiple vendor IV pumps, ventilator, and patient monitor, simulated ICU, Boston

   https://youtu.be/bgaS9nSLwAg?t=2817

5. Remote control safety and performance pre-deployment assessment

   A. Competition for device control: Risk Management presentation: https://youtu.be/bgaS9nSLwAg?t=3450, and live IV pump control demonstration https://youtu.be/bgaS9nSLwAg?t=4004

   B. Network performance https://youtu.be/bgaS9nSLwAg?t=4298

   C. Cybersecurity https://youtu.be/bgaS9nSLwAg?t=4650

** Each description is followed by a YouTube video link directly to that section of the video*

Demonstration Participants 1/2

TATRC
Telemedicine and Advanced Technology Research Center

Matthew Quinn

Nicole Sieling

Ethan Quist

Zack Buono

SPC Perry Matthieu

PFC Daniel Turner

Christine Phillips

SSG Andrew Smith

Evan Feuer

MASSACHUSETTS GENERAL HOSPITAL
MD PnP

Julian Goldman, MD

Colin Gorman

Mosa al Zowelei

Dave Arney, PhD

David Guffrey

Yi Zhang, PhD

Braga Aroulmozhi

THE GENEVA FOUNDATION
Chris Colombo, MD

DOCBOX
THE CLINICIAN ASSISTANT IN CRITICAL CARE

Tracy Rausch

Steven Dain, MD

The DocBox Team

NIHON KOHDEN
Nihon Kohden OrangeMed, Inc.

Hong-Lin Du, MD

Mehran Shafiei

Demonstration Participants 2/2

THORNHILL MEDICAL
Inspiring Innovation

Derek Watt

NeuroWave

Stephane Bibian, PhD

Deloitte.

Shaun Rangappa, MD

Laura Baker

Danial Adams

Andrew LaBarge

iTeleHealth Inc.

Loretta Schlachta-Fairchild, PhD

MITRE

Amy Cotter

Alice Isenberg, PhD

Matt Weir, PhD

Margie Zuk

Penny Chase

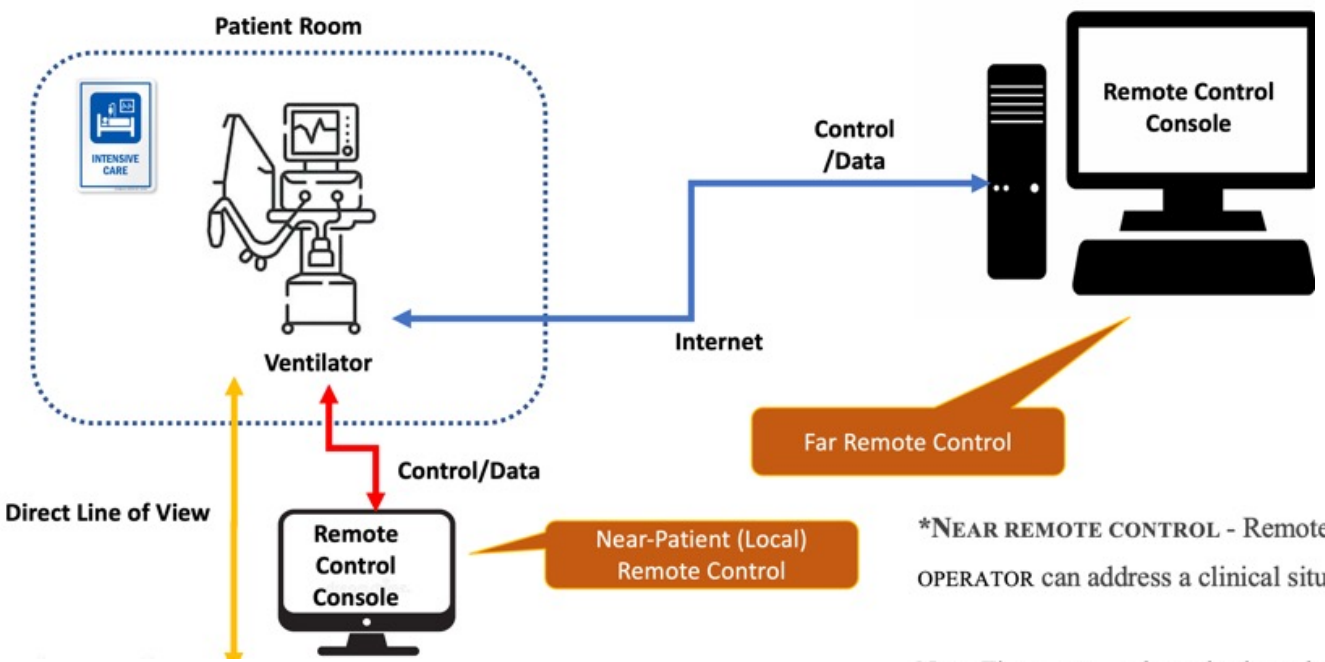
Chris Riha

FDA U.S. FOOD & DRUG ADMINISTRATION

Sandy Weininger, PhD

Heather Agler, PhD

Near-Patient (Local) Remote Control vs. Far Remote Control



*NEAR REMOTE CONTROL - Remote control of ME EQUIPMENT from a location where the OPERATOR can address a clinical situation in a timely manner.

Note: Time to respond may be dependent on environment attributes such as physical proximity to the patient environment (ability to make adjustments to the patient/ ME EQUIPMENT UNDER CONTROL), time to take mitigation actions (e.g., time to don/doff), and the line of sight to patient environment.

*FAR REMOTE CONTROL -. Remote control of ME EQUIPMENT from a location where the OPERATOR cannot address a clinical situation in a timely manner.

Draft remote-control definitions from standard under active development in AAMI Interoperability Working Group

Contact AAMI or the committee co-chairs (J. Goldman and S. Weininger for more information)

#1 Remote-control to manage, support, and evacuate mass casualties @ Ft. Detrick

A. Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick, from Tacoma, WA

B. Far remote management of casualties during enroute care/med-evacuation by UAV from Seattle, WA

C. Data continuity and automated documentation from multiple vendor devices across continuum of care (Role II -> Medevac -> Hospital)

Point of Injury

Medics Arrive and Perform TCCC

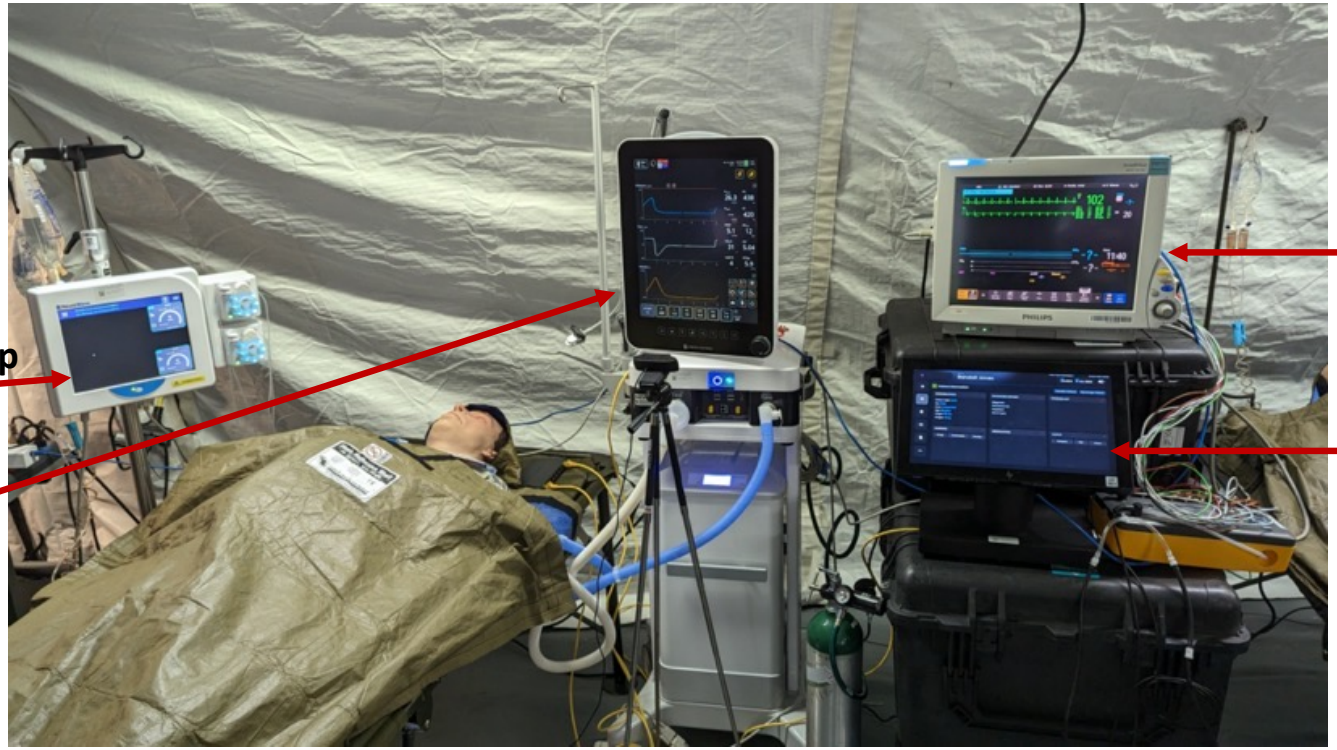
Move Casualty from Point of Injury to Field Hospital (Role II Medical Treatment Facility)

TATRC Simulated Role II Field Hospital, Ft. Detrick, MD

After stabilization in Role II, casualty will be evacuated by M4 Medical Evacuation Pod

1: Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Tacoma, WA

Casualty #1 in Medical Field Hospital Role



#1: Far remote-control of multiple medical devices for mass casualty event, Medical Field Hospital Role II @ Ft. Detrick from Seattle, WA

Far Remote Control and Monitoring of NKV-550 Ventilator and Philips vital signs monitor using DocBox platform

https://youtu.be/bgaS9nSLwAg?t=1919

Casualty @ TATRC (Ft Detrick, MD)

Monitoring Data

MD Communication with Medic,
MD Controls ventilator

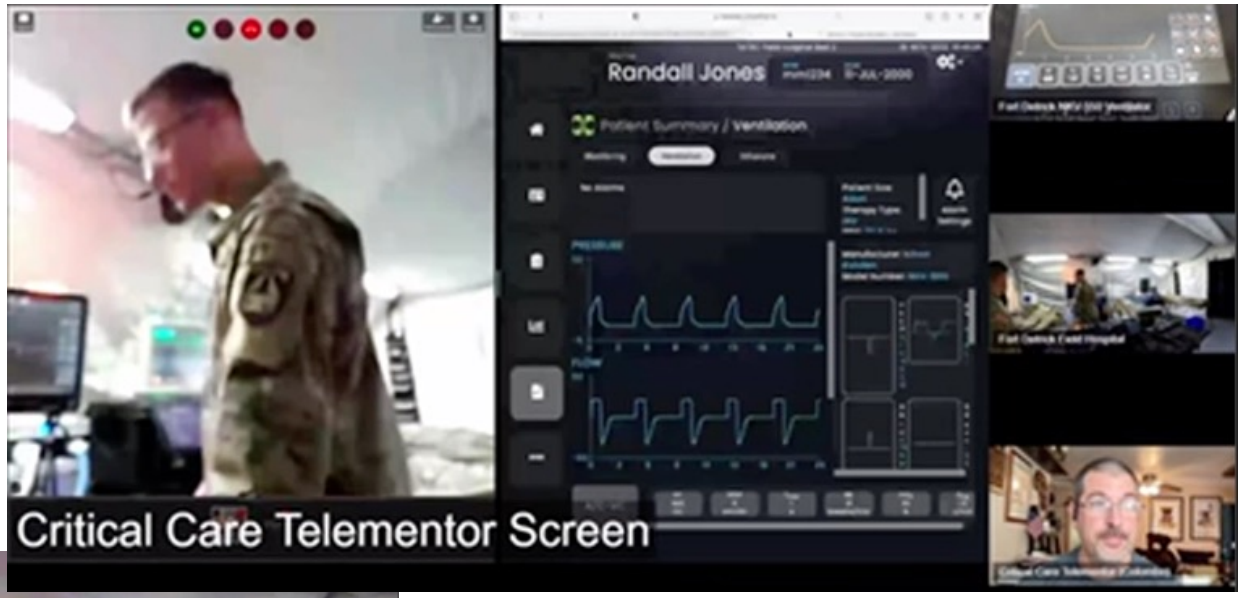
REMOTE MD in Tacoma, WA

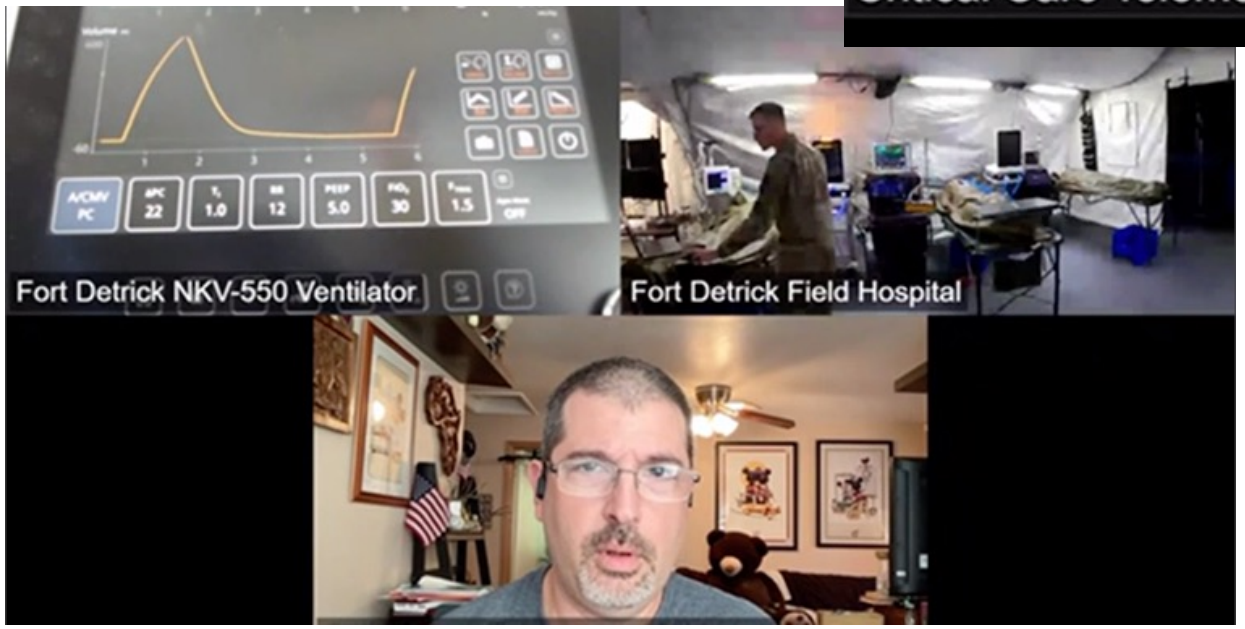
Monitoring through DocBox Apiary System and Communication with NETCCN Platform

Scenario:

- 4 Patients brought into field hospital with 1 Medic. Two casualties (C1 and C2) are critical. Casualty 1 needs evac.
- Casualties placed on NKV-550 ventilators and AccuPump IV pump.
- Medic: Calls for help with casualties.
- Remote MD monitors patients, assists with adjusting ventilator to resolve clinical issue.
- Medic prepares Casualty 1 for transport by UAV

Simulation #1:
Screen capture from 11/18/22
demonstration video





2: Far remote management of casualties by MD in Tacoma, WA during enroute care/med-evacuation by UAV

M4 UAV Medical Evacuation Pod, Ft. Detrick, MD

Remote Monitoring and Control of Thornhill MOVES SLC ventilator/monitor and NeuroWave AccuPump Dual-channel IV pump

Ventilation and IV pump Infusions connected via DocBox Apiary System (ICE platform)

Monitoring Data

Control of Devices

REMOTE MD @ Tacoma, WA

DocBox Web-interface for Remote Data and Control

Scenario:

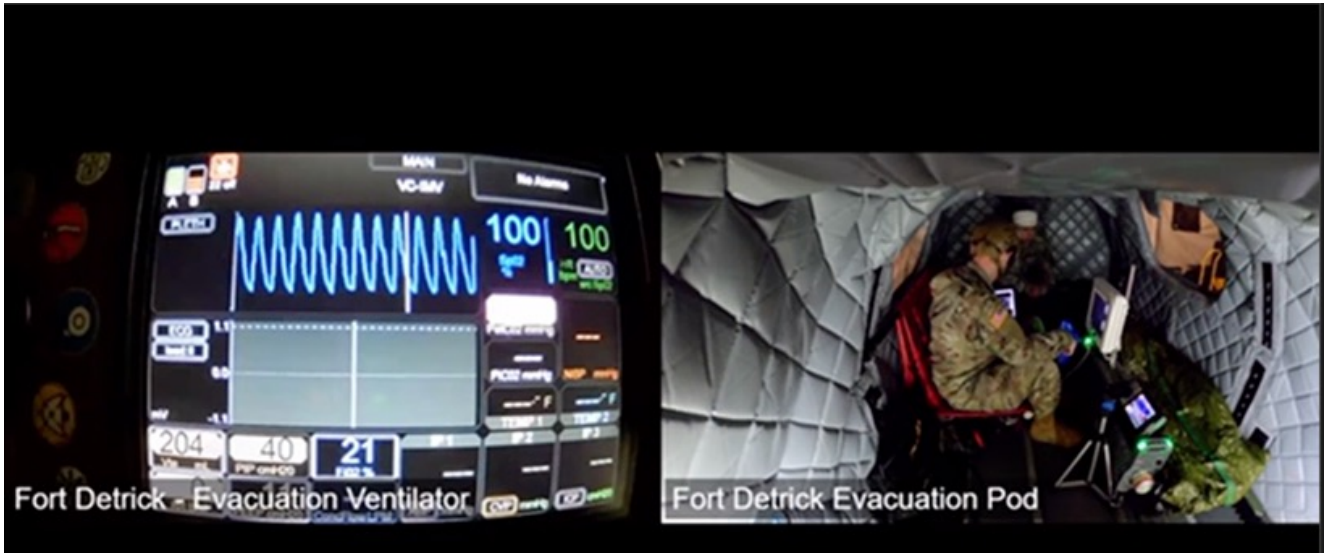
1. Casualty on MOVES SLC Ventilator and NeuroWave AccuPump being evacuated.
2. Medic required remote medical assistance
3. Medic reports: Patient is hypotensive, oxygenation is good.
4. Remote MD sees live data from from the MOVES monitor and ventilator, and IV pump
5. Remote MD decreases sedative rate and reduced ventilator PEEP setting

M4 UAV Medical Evacuation Pod, Ft. Detrick, MD

Screen from 11/18/22 demonstration video: https://youtu.be/bgaS9nSLwAg?t=2474

M4 UAV Medical Evacuation Pod, Ft. Detrick, MD

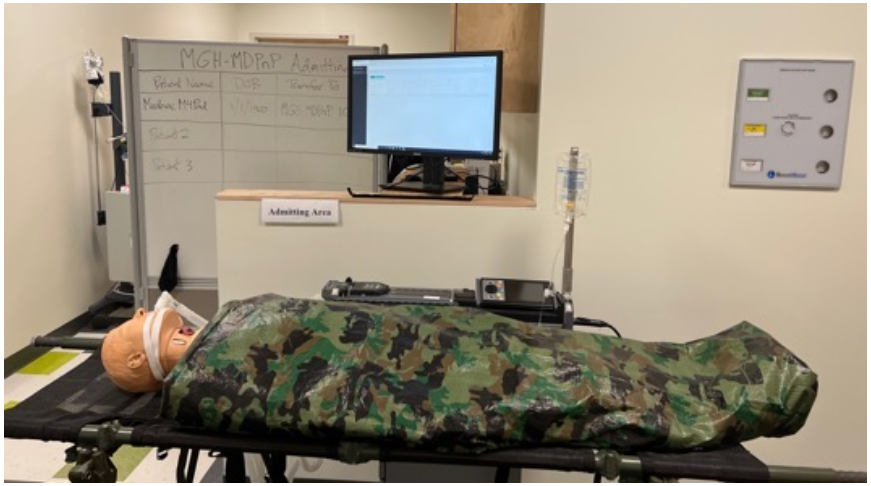
Local view



Remote views of medical equipment, medic, and simulation mannikin during medevac

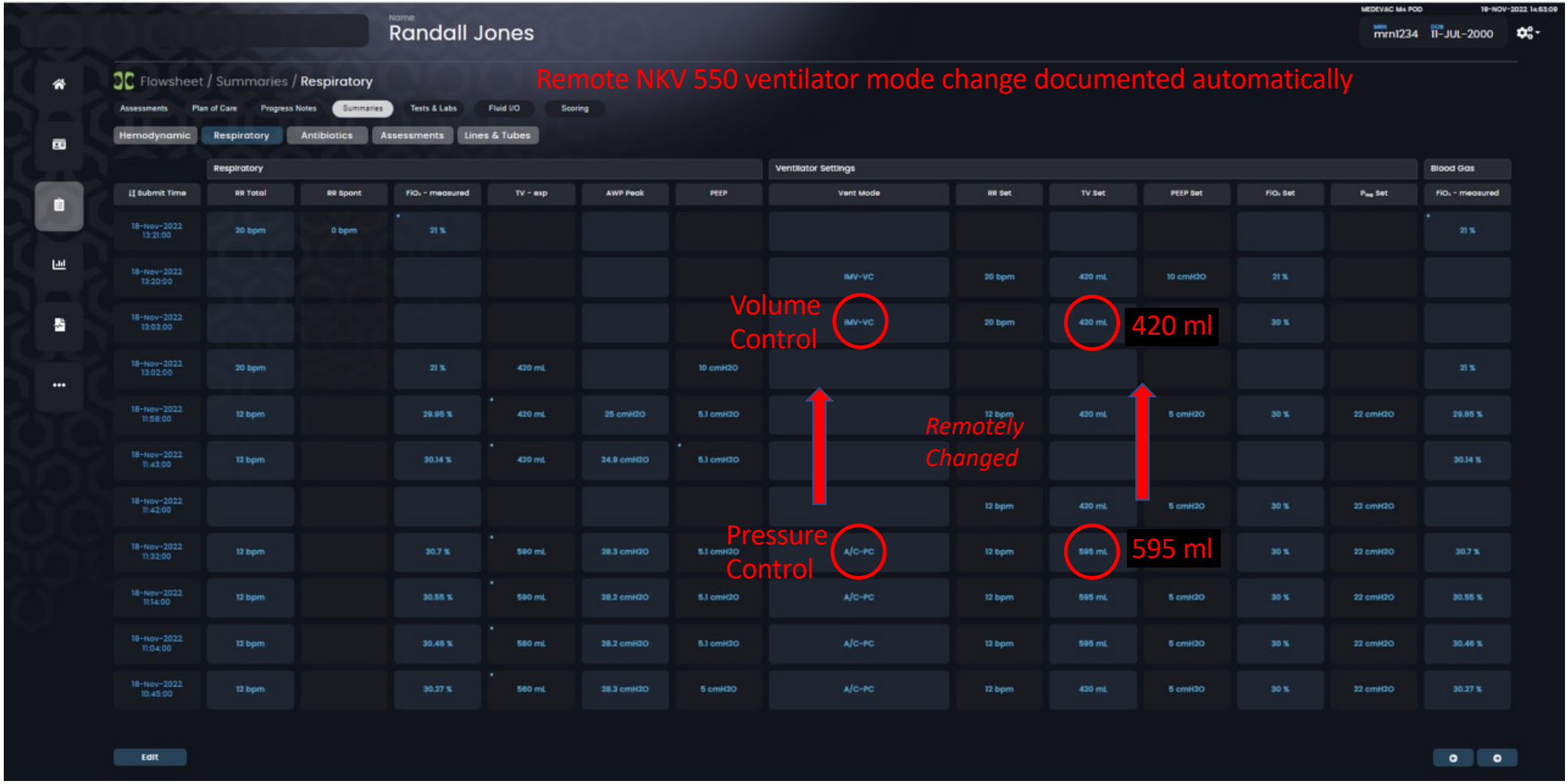
#3 Data continuity and automated documentation from multiple vendor devices across continuum of care (Role II -> Medevac -> Hospital)

Admitting: MGH MD PnP Sim Hospital



- Casualty is transported via M4 UAV Medical Evac Pod to hospital
- Data from Role II and Evac periods are available in flow sheet (next slide)

Manual and automatica documentation from Field Hospital and En-route data is available for SA and clinical care

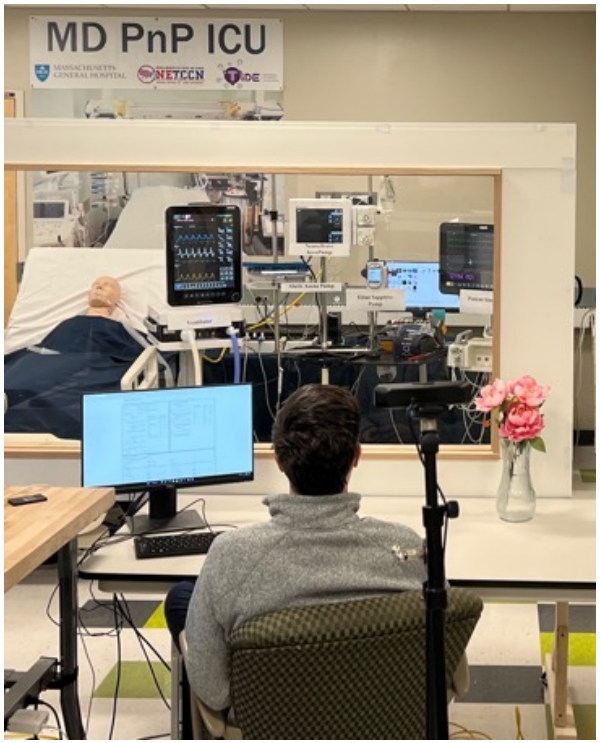


This chapter can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=2832

#4 Single UI with data integration and control of multiple vendor IV pumps, ventilator, and patient monitor, in simulated ICU, Boston

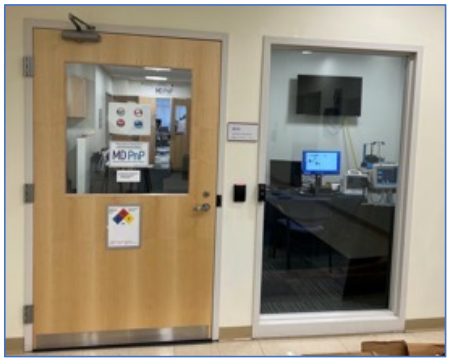
Remote-control from outside of patient's room:

- Single integrated UI to control multiple brands of IV pumps and ventilators, and to view vital signs and device data in real-time. Messages in demonstration:
  - IV pump capabilities vary -> UI must accomodate
  - Near-remote control (directly outside patient room)
  - Far-remote control (via web interface)
- Using OpenICE research platform (Integrated Clinical Environment) deployed in MD PnP Lab @ MGH for:
  - Prototyping, research, and emulation environment
  - Specialized networking and related infrastructure
  - Specialized testbeds (IV infusion, networking, closed-loop control, cyber-range)

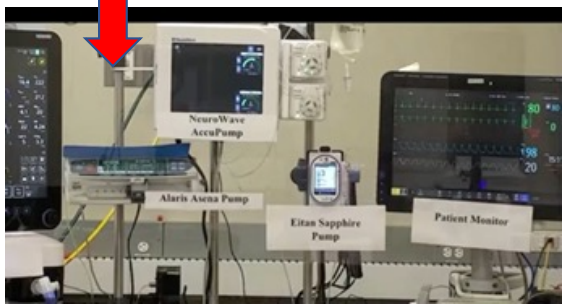


MGH MD PnP Lab

MGH MD PnP Lab
65 Landsdowne St, Cambridge



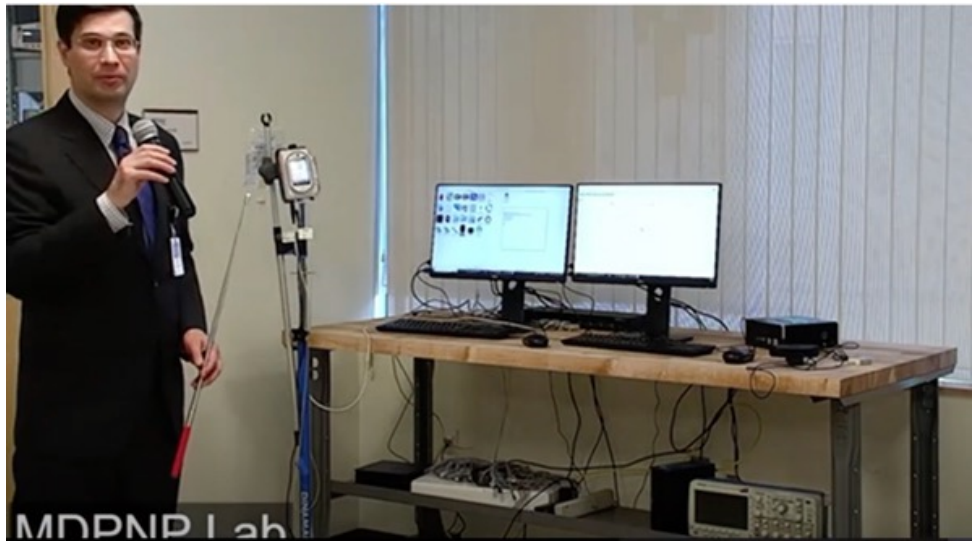
Preparing for
Live Demonstrations



#5 Remote control safety and performance pre-deployment assessment

- A. Competition for device control (local remote vs. far remote)
  - *This chapter can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=4001*

Remote IV control Testbed in MGH MD PnP Lab, using OpenICE software



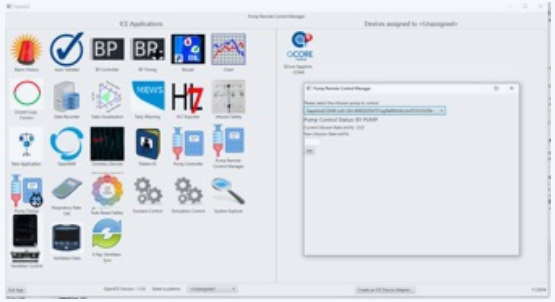
Dave Arney, PhD presenting live demonstration (from video)

Management of Competition for Control

Patient Room

Serial Communication for Data & Control

Eitan Sapphire Pump



Local (Bedside) OpenICE-Based Remote Control

HTTP for Data, Control, and Authorization

Web-based Far Remote Control

MD PnP
Getting connected for patient safety

Risk Management for Medical Device Remote Control

Premise: Remote control is being added to devices that have been FDA-cleared.

Coordinated risk management across the ecosystem

- Device Manufacturer: assure adding remote control does not compromise device safety & performance
- This collaborative team addressed new risks arising from using remote control in clinical workflows that are different than was assumed with standalone devices.
  - Assure the availability and sufficiency of device data to enable safe remote control.

    Example: Communicating data/waveforms/alarms. May not be safe to adjust ventilator when waveforms are not available.
  - Select device features that can be safely controlled remotely
  - Assess the impact of network quality to data quality and remote-control reliability
  - Evaluate emerging new care models and align remote-control capabilities with these new models.
  - Analyze cybersecurity threats and implement/plan enhancement.

MD PnP
Getting connected for patient safety

Critical Safety Implications for Remote Control Technologies

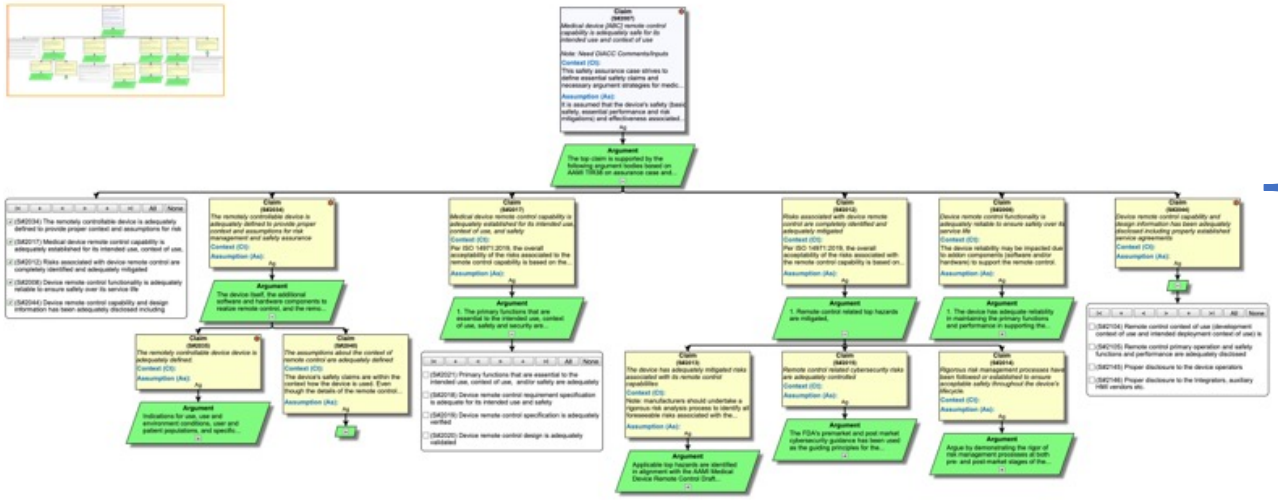
- Altered locus of control => impacts usability and clinical workflow
- Contention (or competing) control for the same devices
- Insufficient device input/output => unsafe remote control or lack of situational awareness (both local and remote)

The team has identified practical safety implications, investigated and implemented risk control measures, and documented the acquired knowledge in a safety assurance framework.

Applying Assurance Case to Communicate Risks & Safety Requirements

A safety assurance case – a means for documenting structured argument commonly used for mission-critical systems - for medical devices for remote control is developed:

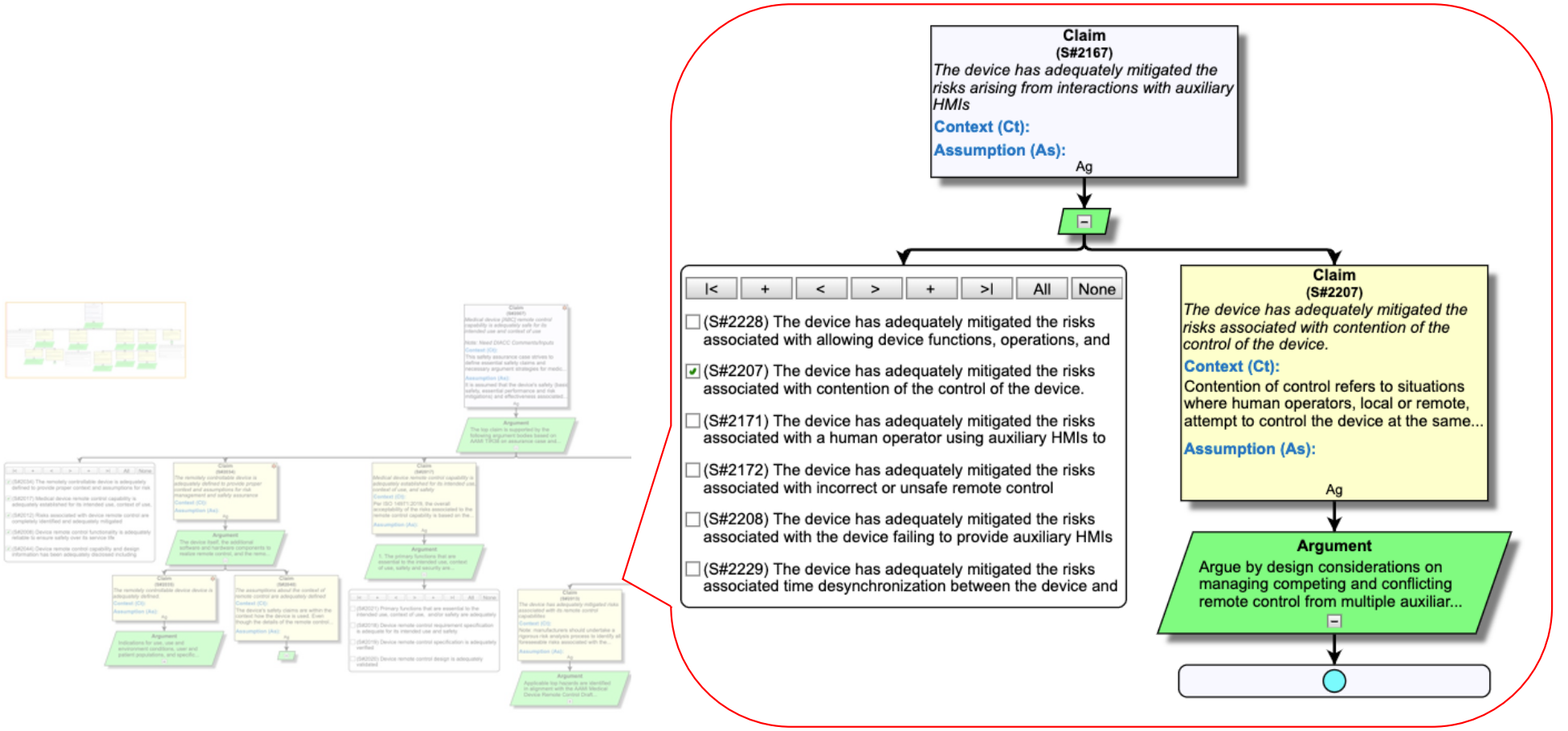
- Considers standards and regulatory guidance to the extent possible
- Provides a basis for the stakeholders to communicate and discuss the essential safety requirements towards market approval and adoption.



Top Three Layers of the Generic Safety Assurance Case for Remote Control

1. Clear Definition of Intended Use & Context of Use of Remote Control
2. Rigorous Implementation & V&V
3. Adequate Risk Management
4. System Reliability with Remote Control
5. Adequate Disclosure

Assurance Case Snippet related to Contention/Competing for Control



Top Three Layers of the Generic Assurance Case for Remote Control

Research Leverages and Improves Standards

- AAMI Remote Control for Medical Devices - preliminary draft Standard
- Medical Device Interface Data Sheets (MDIDS) (for Infusion Pumps and Ventilators)
- IEEE 11073 clinical standard family
- AAMI 2700-1 Integrated Clinical Environment Standard
- AAMI 2700-21 ICE Data Logger (“Black Box Recorder”)

Remote Control Verification & Validation at the System Level

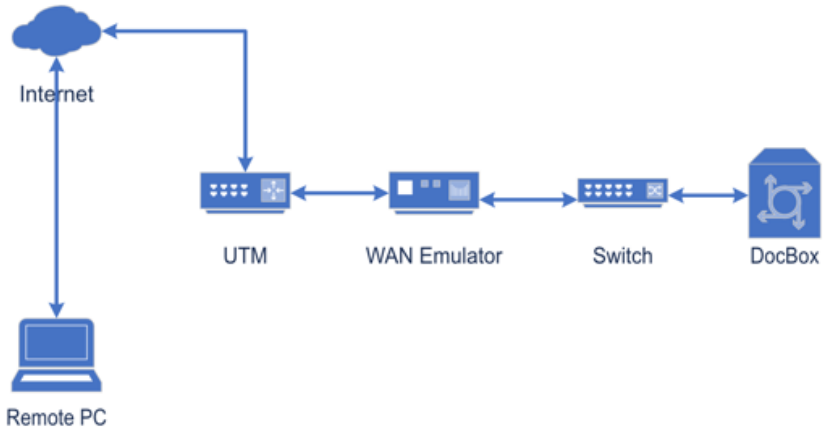
Leveraged the MD PnP lab emulation environment to:

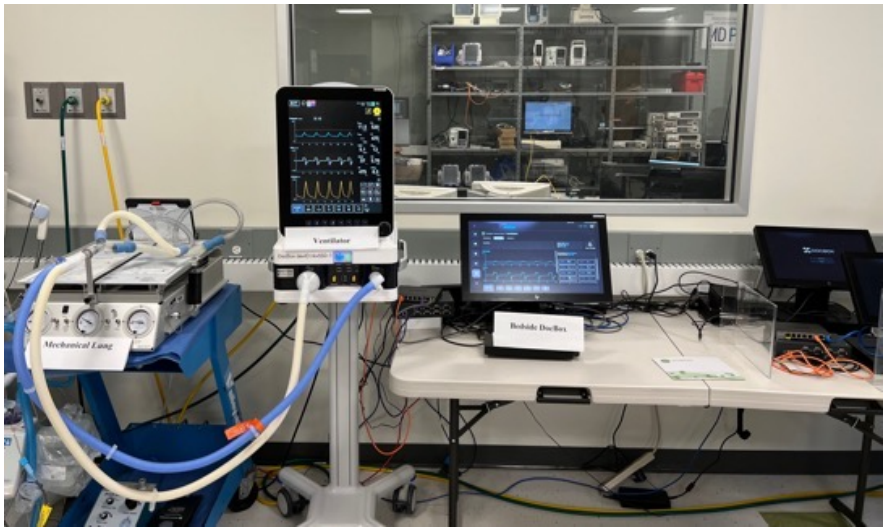
- Conduct end-to-end system V&V in simulated clinical environments
- Evaluate effectiveness of risk controls using simulated clinical scenarios
- Assess networking requirements for safe remote control using advanced network manipulation technologies

Medical Device Network Manipulation Testbed in MGH MD PnP Lab

#5 B Remote control safety and performance pre-deployment assessment: Network performance implications

- B. Live remote control of Nihon Kohden NKV-550 Ventilator via DocBox platform with insertion of controlled network traffic delay:
  - Bedside control
  - Far-remote control





This demonstration can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=4323

This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=4648

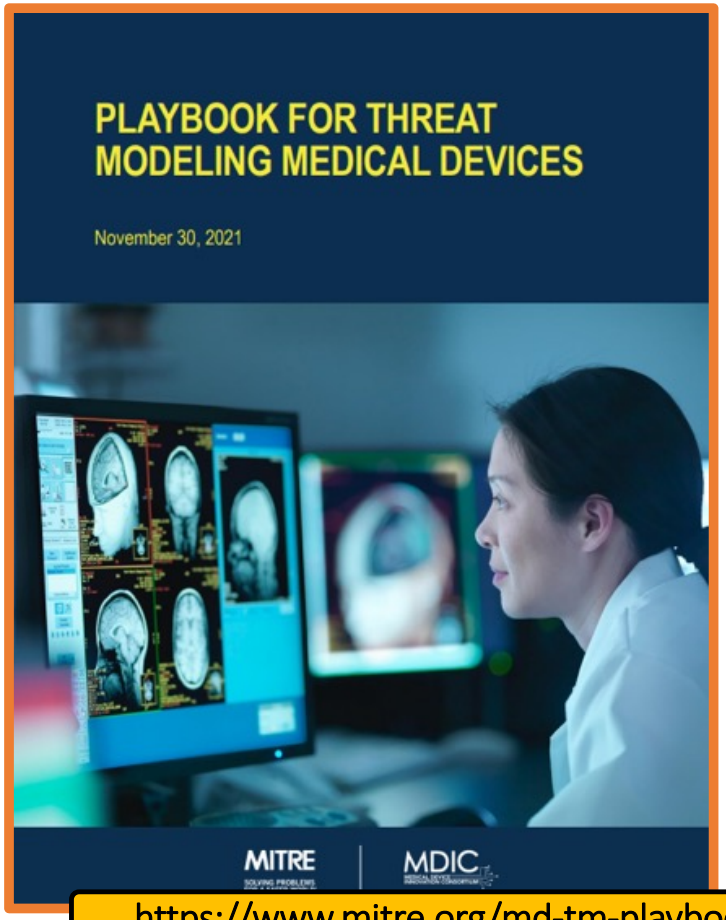
#5 C - Remote control safety and performance pre-deployment assessment

Cybersecurity Threat Analysis & Enhancements

Matthew Weir, PhD – MITRE

Tracy Rausch - DocBox

MITRE Threat Modeling Framework For Medical Devices



https://www.mitre.org/md-tm-playbook

Four Question Framework For Threat Modeling

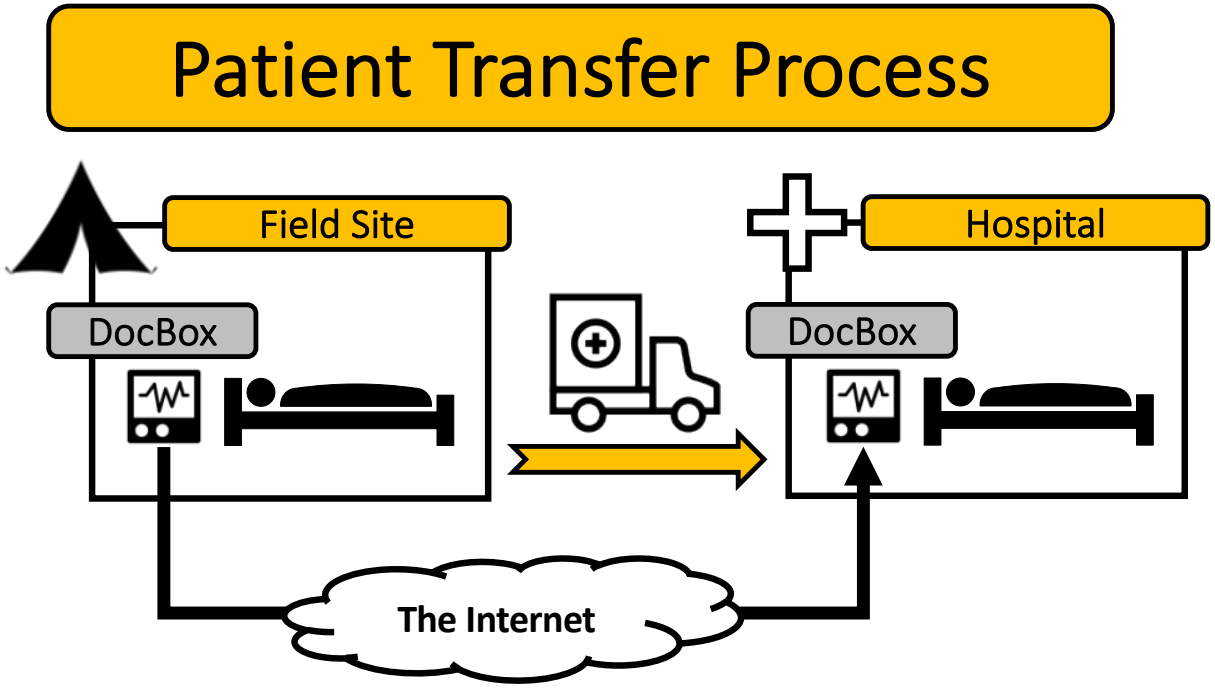
Question 1: What are we working on?

Question 2: What could go wrong?

Question 3: What are we going to do about it?

Question 4: Did we do a good job?

Identifying and Validating Threats



Investigated Threats

Spoofing:
- Creating fake patients to transfer

Tampering:
- Modifying patient data in transit

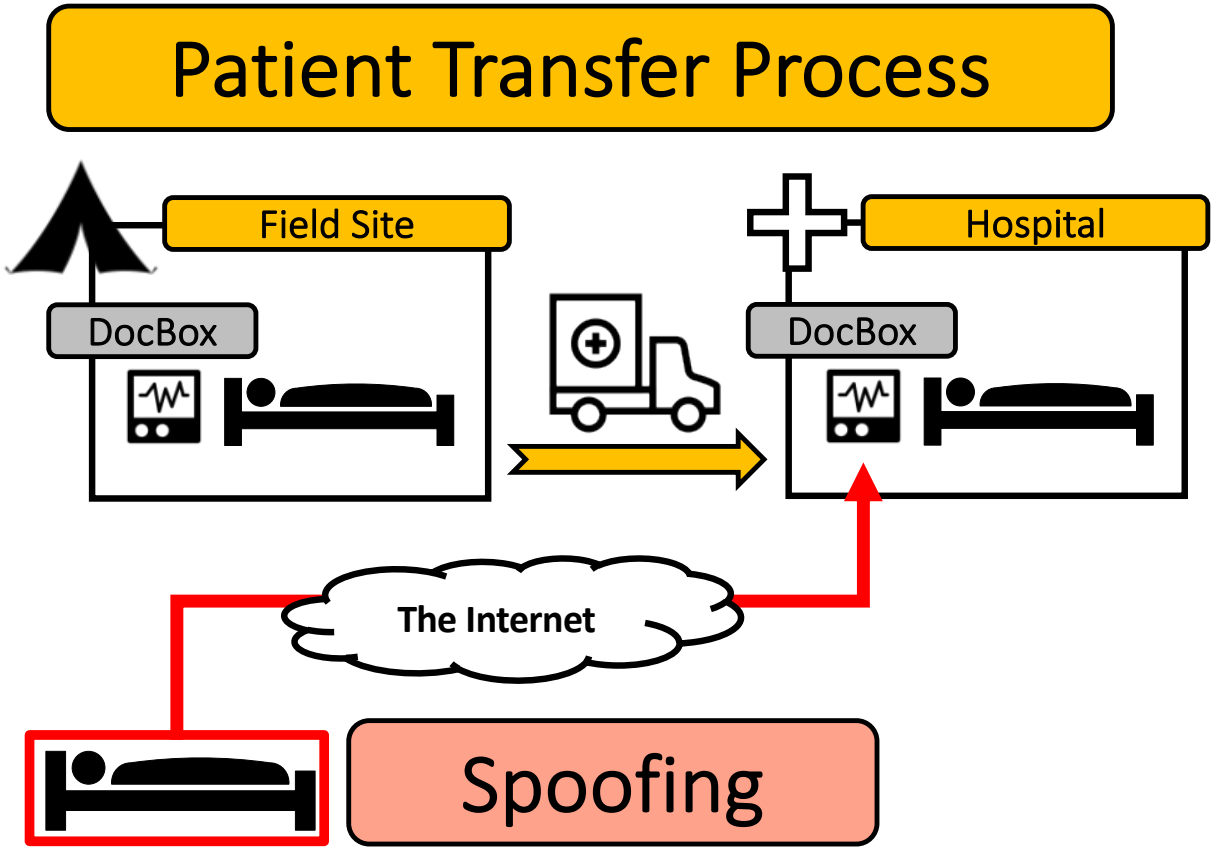
Repudiation:
- Identifying accountability gaps if a patient is incorrectly transferred

Information Disclosure:
- Viewing patient data during transfer
- Requesting transfer of patient data

Denial of Service:
- Blocking patient transfers from happening
- Creating fake patient transfers to create confusion

Escalation of Privilege:
- Injecting malicious data during patient transfer

Identifying and Validating Threats



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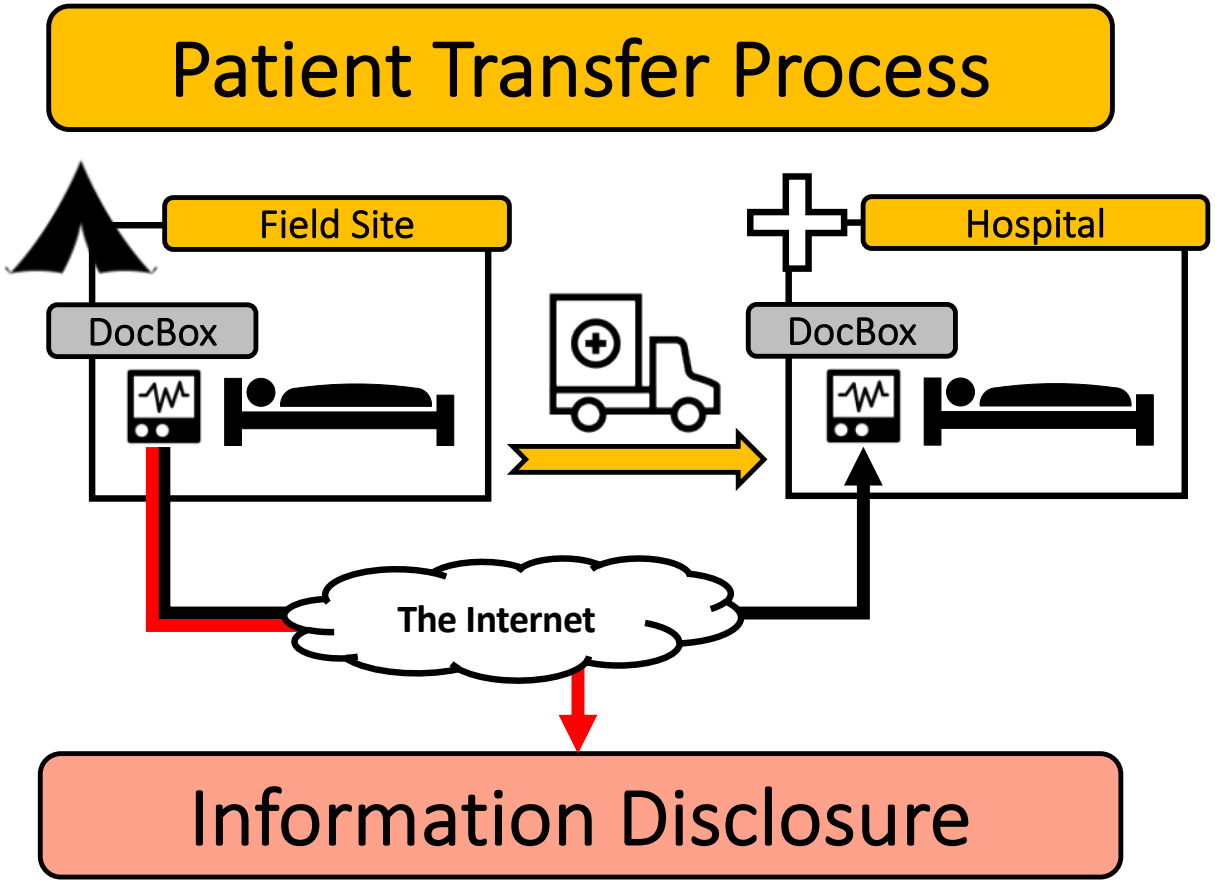

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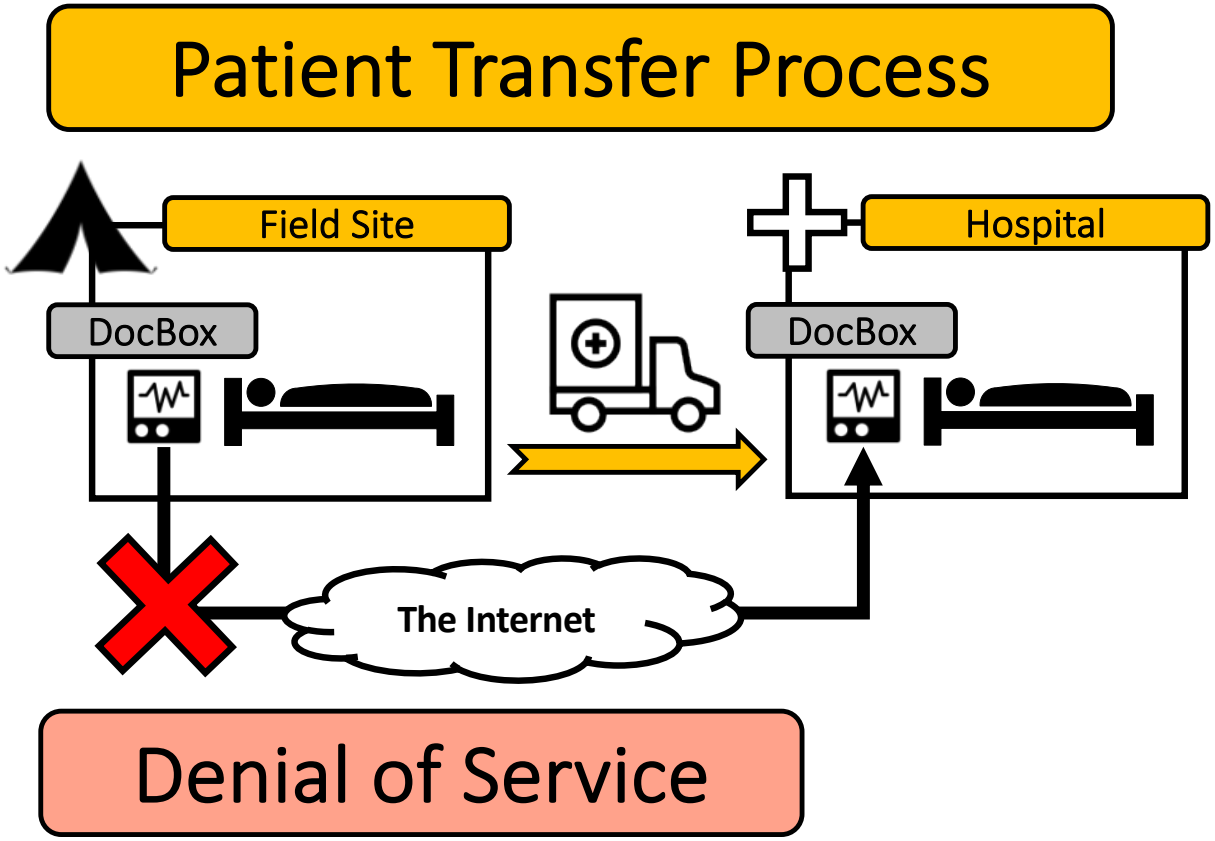

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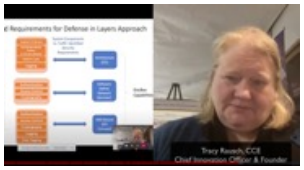
This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=5132

Analysis Generated Requirements for Defense in Layers Approach



Tracy Rausch, CCE
Presenting this section live

Threat Analysis

FedRamp Audit/Review Analysis

Isolation of Devices
Distributed Attack Surface (1 ICE per patient)
Platform Layer
Logging

Authentication
Access Control
Cryptography

Authentication
Access Control
Cryptography
Logging
Data Tagging

System Components to Fulfill Identified Security Requirements

Architecture (ICE)

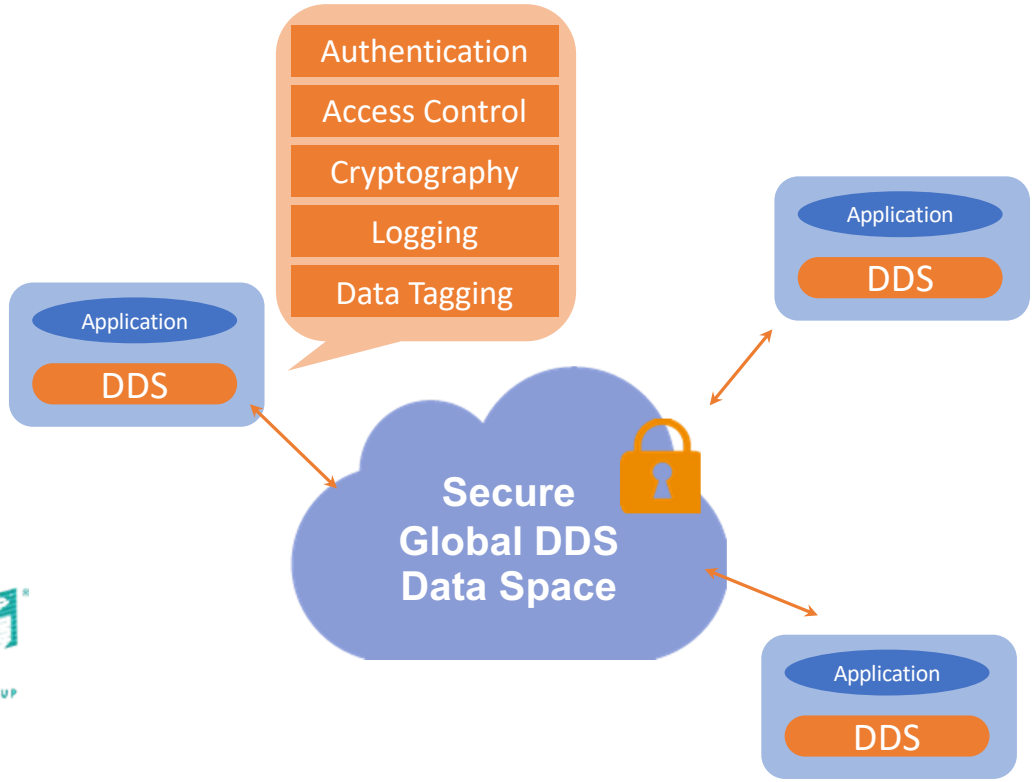
Software Define Network (Zerotier)

DDS Secure (RTI Connext)

DocBox Capabilities

OMG DDS Security standard* in a nutshell

- Entity authentication
- Access control for Domains/Topics/Partitions
- Data integrity and confidentiality
- Data-origin authentication



...while maintaining interoperability & high performance communication

* https://www.omg.org/spec/DDS-SECURITY/

Next Steps

- Implement Plan of Action and Milestones for security items
- Implement DDS Secure upgrade on DocBox system
  - Ongoing via DHA SBIR
- Comprehensive testing

This section can be found in the online video at https://youtu.be/bgaS9nSLwAg?t=5320

Conclusion and Pathway to Adoption

- Many capabilities demonstrated today have been deployed or are close to adoption
- Far remote-control requires more RTD&E for widespread adoption, but urgently-needed solutions can be rapidly deployed based on risk/benefit assessment

Major Capabilities and Maturity Level in Demonstration

Major Capabilities	TRL /KRL @ start	TRL /KRL @ Dec '21	TRL /KRL @ end
Far remote active monitoring and control of ventilator (NKV-550) ==> TRL	2	2	6
Informing local user of remote monitoring/control ==> TRL	2	2	5
Alarm management in the device remote control context (e.g., remote expert can change alarm threshold settings but cannot silence alarms in the device) ==> TRL	2	2	3
Common remote control User Interface (UI) for different ventilators and different devices ==> TRL	2	2	6
Contention for remote control ==> TRL	2	2	4
Remote monitoring and control of ventilator and infusion pump during evacuation/ enroute care ==> TRL	2	4	6
Transfer data Cybersecurity requirements have been identified through MITRE threat modeling analysis --> KRL	2	3	6
Standardization and harmonization of ventilator data terminologies ==> KRL	2	3	8
Safety assurance framework for medical device remote control towards regulatory pathway ===> KRL	2	4	5
Risk management for competing remote control ==> KRL	2	3	5
AAMI remote control standard (before the work an AAMI technical report was released, after this work a draft version of the standard is pending for committee voting) ==> KRL	3	4	6
Lab-based testing capabilities for assessing system safety and resilience under network disruptions ==> TRL	2	4	6
Passive data acquisition and automated clinical documentation across care continuum vs human care provider entered data ==> TRL	6	7	7
Longitudinal care continuity and data transfer (data moves with the patient) ==> TRL	3	5	7
Secured (encrypted) data transfer for enhanced security	2	2	6
Docbox transform from software- and hardware-based to solely software-based ==> TRL	2	6	9
Core DocBox capabilities (including both bedside platform and underlying network/IT infrastructure) that provide a technical foundation to this work have been validated in real-world clinical practices ==> TRL	6	7	9
Medical device interface datasheets for infusion pumps ===> KRL	2	5	7
Medical device interface datasheets for ventilators ===> KRL	2	5	8

Questions, Closing Remarks, & Next Steps

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N. Sieling, T Rausch, M Quinn, J Goldman, J Pamplin

TATRC Prep Meeting

TATRC Medical Device Interoperability & Autonomy
Demonstration @ MGH MD PnP Lab
November 18, 2022
MD PnP ICU
NETCCN
TIDE