

Systems Engineering (SE) for Healthcare

- Leading development of public-domain FDA Pre-IDE (Investigational Device Exemption) submission on integrated medical device systems (Regulatory Science)
- NIST analysis of F2761-09, "Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)"
- Identifying and disseminating clinical needs and interactions for safe system development

Standards to support innovative clinical care

Ongoing participation in standards development to steer and inform. Provide use cases, gap analyses, and domain expertise to:

- ASTM F2761
- ISO TC121
- AAMI/UL 2800
- AAMI PCA Safety
- IHE profiles
- IEEE 11073

VA Medical Device Interoperability Program (MDIP)

Provided technical and domain expertise to support the formation of the VA MDIP

FCC

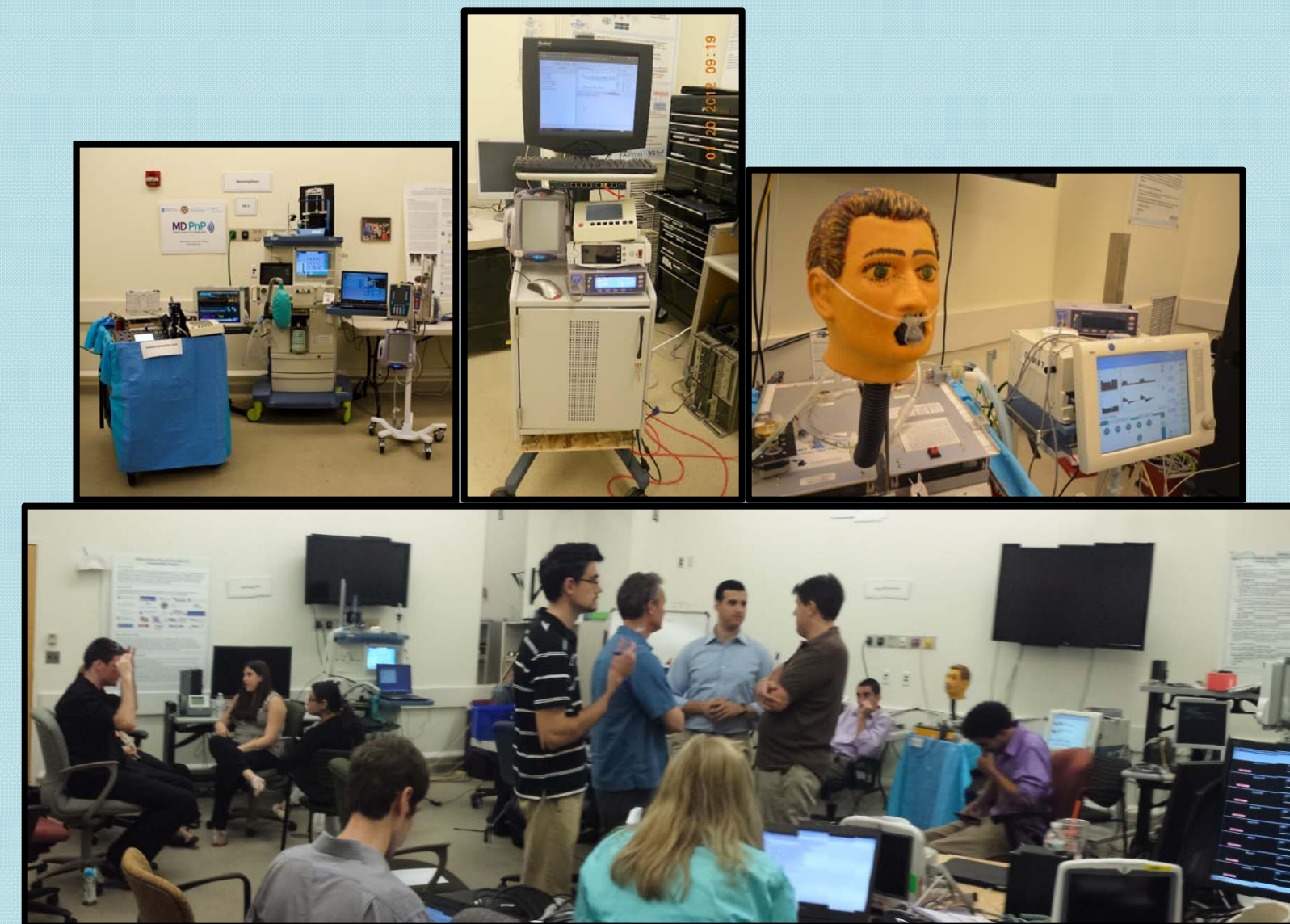
- mHealth Task Force Recommendations
- Consumer Advisory Committee Recommendations
- wireless testbed

GAO

- Expert testimony to GAO
- White paper on medical device security issues

Medical Device – Health IT Safety

- FDASIA** Working Group on Health IT Policy Committee Recommendations
- Use cases and device-HIT system risk management for FDASIA Working Group under Health IT Policy Committee



Interoperable Device Procurement

- MD FIRE, web-available interoperability contracting language document for hospitals, has been signed by Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the VHA
- Advising DoD on procurement

Next step: Creating National Center for Medical Device Interoperability and Patient Safety

- Medical device-HIT adverse event analysis
- Non-Clinical and Clinical test bed for bench-to-bedside development
- Research for safe interoperability and connected health

ONC Meaningful Use

- Research to support clinical data time-stamp requirements
- NIH SHARP grant affiliate

MD PnP and NSF Cyber Physical Systems (CPS)

Collaborating with grantees to provide clinical use cases and hazards, and clinical engineering domain expertise.

- Penn, KSU, UIUC, UMass

Clinical black box recorder (ICE Data Logger)

NIST collaboration on standards-based integrated clinical environment (ICE) data logger

Community Building

- Open source repository of software for the ICE platform on www.sourceforge.net
- Program output shared on mdnp.org
- General membership in the MD PnP Community, with access to DDS Infrastructure Community
- Visiting scholar-in-residence program
- NwHIN CONNECT implementation demonstrated and shared on SourceForge

Industry Adoption of ICE (ASTM F2761) framework

- DoD support of commercial ICE implementations
 - DocBox Inc
 - Moberg Research
- Manufacturers IRAD support
 - Draeger