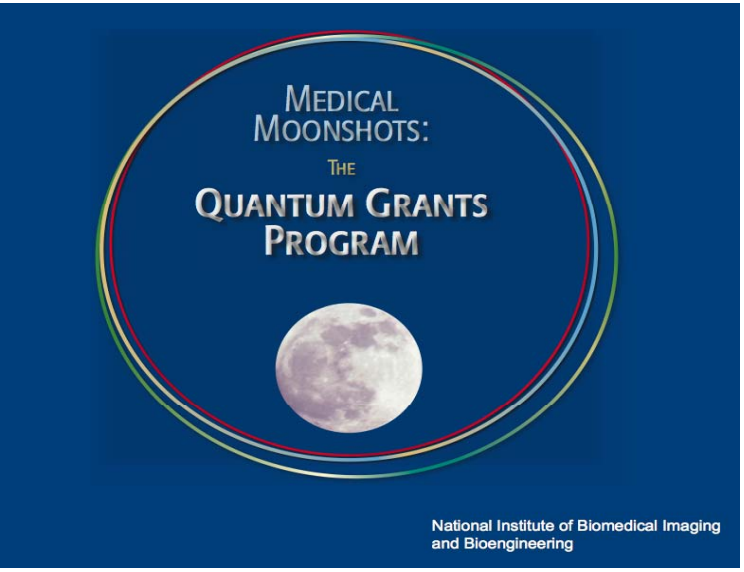


NIH/NIBIB U01 Cooperative Agreement
Oct 2010 – Sept 2015

"Quantum Medical Device Interoperability" Project (QMDI)

PI: Julian M. Goldman, MD

Massachusetts General Hospital

Medical Device Interoperability Program
Since 2004

MD PnP™
Getting Connected for Patient Safety™

NIBIB Quantum Grant Program

"The [NIH's] National Institute of Biomedical Imaging and Bioengineering (NIBIB) established the Quantum Grants Program to make a profound (quantum) improvement in health care."

"This program challenged the research community to propose projects that have a highly focused, collaborative, and interdisciplinary approach targeted to solve a major medical problem or to resolve a highly prevalent technology-based medical challenge."

"Major advances in medicine that lead to quantifiable improvements in public health require focused intellectual and financial commitment."

http://www.nibib.nih.gov/Research/QuantumGrants

Development of a Prototype Healthcare Intranet for Improved Health Outcomes

- The creation of an eco-system for interoperability of medical device and clinical information systems to support innovation in patient safety and healthcare quality

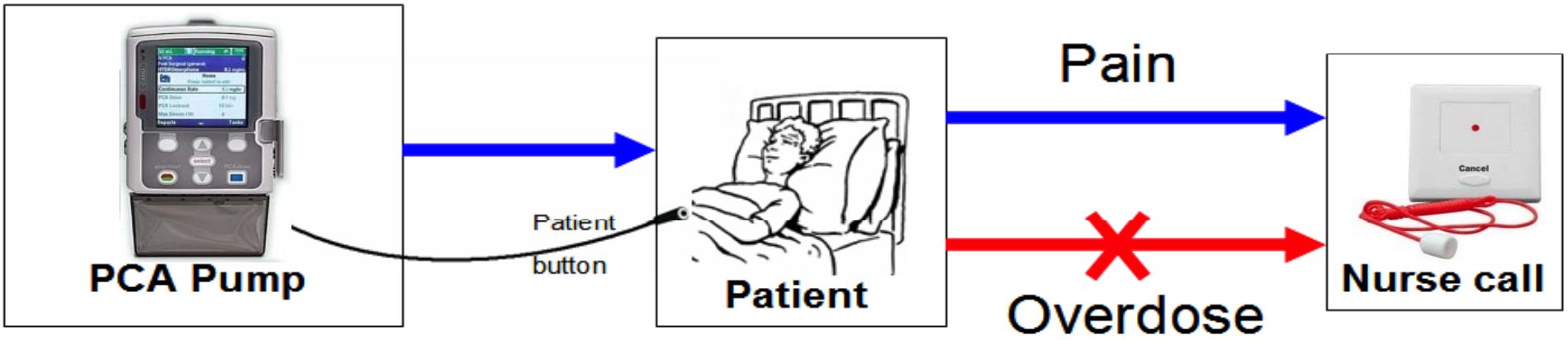
- **Funded Collaborators:**
  - Massachusetts General Hospital (Julian Goldman P.I.)
  - Anakena Solutions, California (Michael Robkin)
  - DocBox Inc, Waltham, MA (Tracy Rausch)
  - Penn (Insup Lee)
  - Kansas State University (J. Hatcliff)
  - Moberg Research, Ambler, PA (Dick Moberg)
  - University of Illinois at Urbana-Champaign (Lui Sha)

An HHS ONC Health IT SHARP affiliated program (by MOU NIH-ONC)

Quantum Clinical Scenarios

1. **PCA Safety Interlock:** example of component-level medical device interoperability to improve safety of medication infusions
2. **ICU preparedness:** example of ability to support safer in-hospital patient transfer & dynamic checklists to reduce errors
3. **Tele-health** devices in hospital: example of transferring care from home to hospital and use of devices for high-acuity care
4. **FDA regulatory/Safety:** sedation for G.I. procedure as a framework for levels of interoperability and associated levels of hazards and their mitigation

Patient-Controlled Analgesia (PCA)
system safety challenges



- *Patients can call to request more analgesia, but, cannot call for help when over-medicated.*
- *Over-medication can cause respiratory and cardiac arrest*
- *Comprehensive monitoring is not typically used due to high false/nuisance alarm rate*
- *How can we improve safety of this system?*
- Solution: Smarter alarms with sensor fusion + capability to stop medication infusion and summon help, prior to injury

MD PnP
Getting connected for patient safety

PCA Safety Issues continue …

http://ppahs.wordpress.com/2012/02/01/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/
This is the story of an 11 year old who died from narcotic-induced respiratory depression.
"Ten years after my daughter's death, nothing has changed in the codes of monitoring post-op patients continuously, until they leave the hospital. Alive."

http://www.apsf.org/newsletters/html/2010/spring/12_coalition.htm
This is a statement from a multi-hospital coalition frustrated by ongoing adverse patient events:
"A closed-loop system, which stops or pauses opioid dosing if respiratory depression is detected, is desirable. Systems are most ideally centrally monitored. In any case, alarms should be audible or otherwise available to the primary caregiver, and a mechanism for prompt response should be in place."

http://ppahs.wordpress.com/about/
"Carly Ann Pritchard ... suffered an ankle injury and then underwent surgery to reduce lingering pain from her ankle injury. Unfortunately, although she survived surgery, she suffered brain damage because of an accidental overdose from a morphine-filled pain pump - after surgery. A California appeals court recently upheld a jury's award of about $9.9 million in damages."

Clinical Scenario 1: PCA Safety

- See http://mdpnp.org/MD_PnP_Program___Clinical_S.html

Current State: No monitoring or many false alarms

PCA Safety – Proposed State

See http://mdpnp.org/MD_PnP_Program__Clinical_S.html

(scroll down to “proposed state”)

Proposed State: Monitoring and infusion safety interlock

Clinical Scenario #2
Preparing ICU to Receive OR Patient

See
http://mdpnp.org/MD_PnP_Program__Clinical_S.html#Jump_to_Clinical_Scenario_2

(scroll down to animation of current state)

Current State: Verbal; may include checklist

Preparing ICU to Receive OR Patient
Proposed State

See http://mdpnp.org/MD_PnP_Program___Clinical_S.html#Jump_to_Clinical_Scenario_2

(scroll down to “proposed state”)

Standard for the "Integrated Clinical Environment" ASTM F2761-09

"Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

Provides a standards-based system architecture intended to support safe interoperable medical systems

(Development led by MD PnP program and several QMDI collaborators)

Recognized by FDA 8/2013: http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf

Functional Elements of the Integrated Clinical Environment
ASTM standard F2761-09

Clinician

Integrated Clinical Environment (ICE)

ICE Supervisor (run apps)

External Interface

ICE Network Controller

ICE Data Logger

ICE Interface

Medical Device

ICE Interface Adapter

Medical Device

ICE Interface

Other Equipment

Patient

Standard for the Integrated Clinical Environment (ICE)

ASTM F2761-09: Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)
Part 1: General requirements and conceptual model

The ICE standard specifies general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE), including:

- The characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single patient
- Requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices
- Requirements for design, verification, and validation processes of a model-based integration system for an Integrated Clinical Environment

What You are Seeing Today
(end of year 3 of 5)

QMDI

PCA Safety Interlock
Prevent pain medication overdose and create smart alarms in patient-controlled analgesia infusions

Preparing ICU to Receive Patient from OR
Automatically read OR device settings and pre-set ICU equipment; Smart checklists

Open Source Medical Device Connectivity
Open source repository of software for the ICE* platform
Clinical research test bed using MATLAB

Architecture Safety
The features required for the safe assembly and operation of systems made up of interoperable medical devices

Synergistic Projects

Data Logger
Tracking adverse events with the "flight data recorder" of the healthcare environment

Clinical Scenario Repository
Documenting clinical scenarios in which interoperability could improve patient safety

Integrating Clinical Technology for Military Health
DocBox implementation of ICE manager in clinical environment

Collaborator Research†

ICE* Authentication Framework
Enabling ICE components such as devices, apps, and infrastructure to be integrated at the point-of-care in a trustworthy manner

ICE* Device Model Framework
Addressing gaps in existing interfacing technologies to enable flexible automated interoperability checking between ICE apps and devices

MIDAS Real-Time Middleware
A system ensuring that clinical applications receive the necessary resources to guarantee real-time performance

Medical Device and Network Security
Problems and solutions that support building secure interoperable medical device systems

*ICE: Integrated Clinical Environment

†Anakena Solutions, DocBox, Kansas State University, Moberg Research, University of Illinois, University of Pennsylvania

MD PnP Program Contributions to Federal and National Initiatives

MD PnP™ Getting Connected for Patient Safety™

Program: www.mdpnp.org P.I. Julian M. Goldman, MD jmgoldman@partners.org

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 mdpnp.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

Supported in part by NIH/NIBIB 1U01EB012470 / DoD USAMRMC W81XWH-12-C-0154 and W81XWH-09-1-0705 / DoD USAMRAA W81XWH-09-2-0001 / NSF CNS-10-35715, IIS-1239242, CNS-08-34524, and CNS-08-34709 / NIST 70NANB10H258

August 19, 2013

MD PnP™
Getting Connected for Patient Safety™

CIMIT®
Center for Integration of Medicine & Innovative Technology

MD PnP Team

Julian Goldman, MD
Director, PI

Sue Whitehead
Program Manager

Dave Arney
Lead Engineer

Rick Schrenker
Senior Biomedical Engineer

Jeff Plourde
Applications Developer

Diego Alonso
Applications Developer

Pratyusha Mattegunta
Clinical Engineer

Andrea Lenco
Research & Grants Assistant