

Global City Teams Challenge
June 1, 2015
Washington DC

REMOTELY CARING FOR VULNERABLE POPULATIONS DURING A PANDEMIC A CHALLENGE IN 3 PHASES

Team Leads: Julian Goldman and Betty Levine

REMOTELY CARING FOR VULNERABLE POPULATIONS DURING A PANDEMIC



Our GCTC project demonstrates the transformational power of open, integrated, medical device and HIT platforms to automate detection, triage, and treatment of individuals affected by a pandemic, as applied to an Ebola Virus Disease (EVD) use case.



















































Phase I of III

Global City Teams Challenge Kickoff September 29-30, 2014

Remotely Caring for Our Most Vulnerable Citizens In-Place During A Pandemic

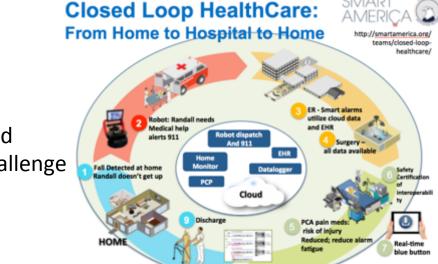






Proposed Project

- Automate aspects of detection, triage, and treatment in the face of pandemic
- Provide early detection of onset of disease; remote support of local treatment by less-skilled caregivers



Based on lessons learned In the SmartAmerica challenge

Phase II / III

Ebola Care Medical-Technology Response

Oct - Nov 2014

OPEN MEDICAL DEVICE AND DATA INTEGRATION
PLATFORMS TO SUPPORT
THE MANAGEMENT OF EBOLA VIRUS DISEASE

PRE-hospital Quarantine





Need for rapid implementation of innovative solutions:

- Detect clinical signs of disease onset with new sensors and data fusion
- Information on evolution of symptoms (phenotype)
- Point-of-care lab tests
- Data dashboards
- Build on open platforms

In Hospital/ICU

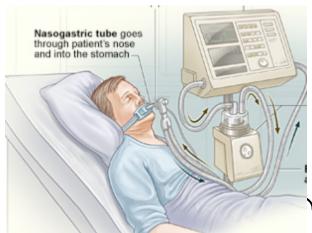


- Personnel must be protected from infection
- Data dashboards essential
- 20 minutes to don/doff PPE -> unsafe delays

Challenges to Manage Patients in Isolation Environments: Data access, Intravenous Fluid management, Ventilation

INSIDE ROOM





- Ventilator adjustments are performed by Respiratory Therapists or other trained staff
- <u>20-minutes</u> don/doff time would occupy all staff time

Patient's ROOM

INFUSION

PUMPS

CARRIFR

FLUID

DRUG

Intravenous Fluid Example:

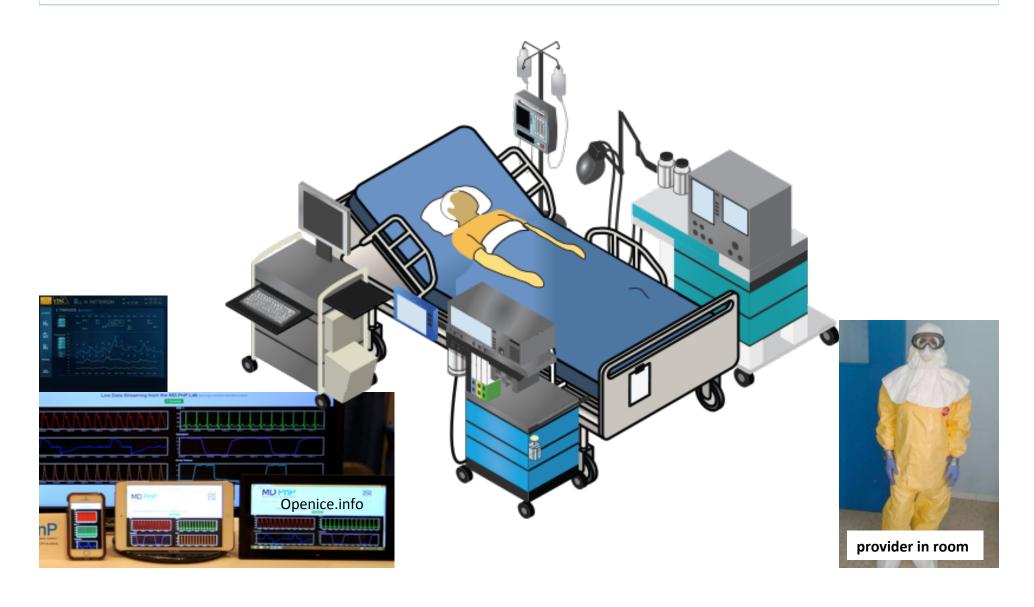
IV fluid flow = 100 ml/min

Begin new medication outside of room:

20 Minute delay for the new medication dose to reach the patient

IV flow analysis Courtesy of R. Peterfreund, MD PhD, MGH

Remote data access, remote device control, resource tracking, to enable more timely care, reduced exposure, and improve monitoring



Project Timeline: Oct 17-Nov 6, 2014

- Over 20 days, 20 organizations collaborated to demonstrate these concepts
- Culminated in a 3-day hackathon and public demonstrations





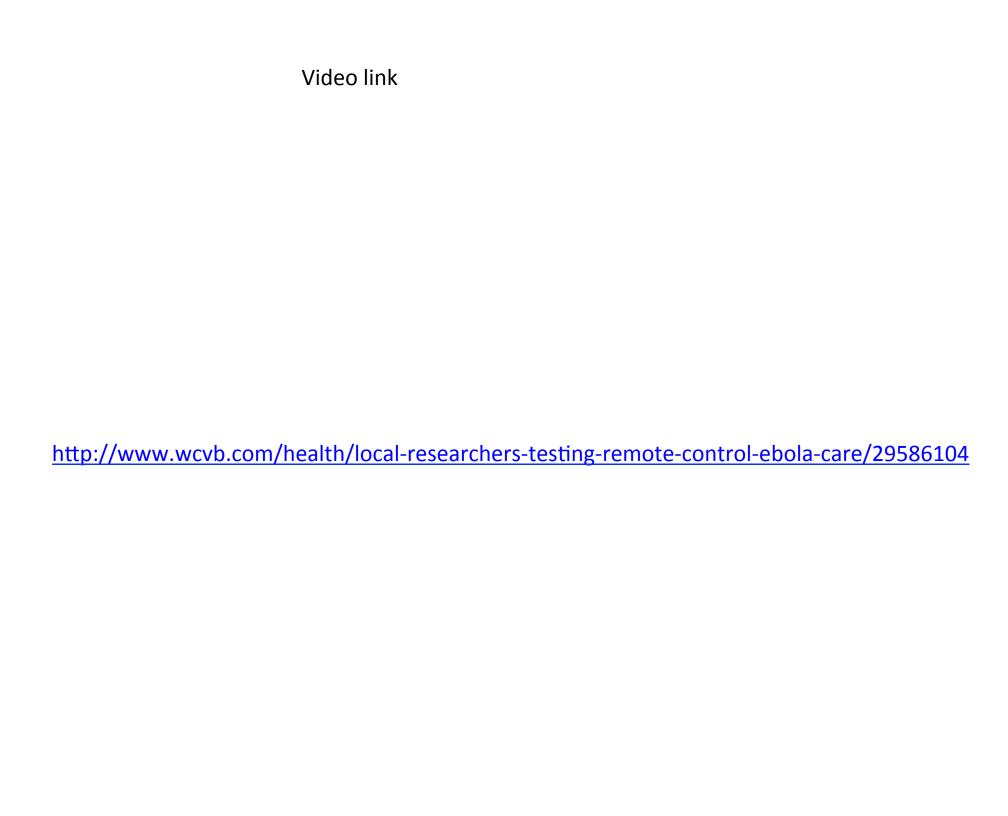


Medical Device Interoperability Lab at Mass General Hospital / Partners HealthCare





www.mdpnp.org



Participation of the US FDA CDRH was a powerful incentive for medical device manufacturers to explore innovative medical technology solutions, especially those benefiting from interoperability between manufacturers



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration 10903 New Hampshire Avenue Room 5447, Building 66 Silver Spring, MD 20993-0002

November 3, 2014

Julian M. Goldman, MD
Director, Medical Device Interoperability Program
65 Landsdowne Street
Cambridge, MA 02139

Dear Dr. Goldman,

Thank you for reaching out to the Center for Devices and Radiological Health (CDRH) via our Emergency Preparedness/Operations and Medical Countermeasures (EMCM) Program.

We understand that The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, under your coordination, has been asked by the White House Office of Science and Technology Program to mobilize resources among medical device manufacturers and the clinical community, so as to design and demonstrate proof of concept for an interoperable platform that would enable critical care of Ebola-infected patients in an isolation environment with reduced exposure to health care workers.

FDA recognizes the importance of implementing strategies that minimize direct exposure of clinical personnel to patients infected with Ebola virus. We understand that MDPNP, along with its collaborators, are developing potential approaches that would include comprehensive data access and potential remote control of medical devices in the isolation environment, thereby reducing the risk of healthcare worker exposure to the virus.

CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency. We are eager to observe the demonstration taking place Friday November 7th for OSTP, and we look forward to participating in the development of next steps with MDPNP and your medical device partners so as to do our part in enabling advancement of technology that can protect our healthcare workers who put themselves on the front line to promote the public health mission.

Sincerely

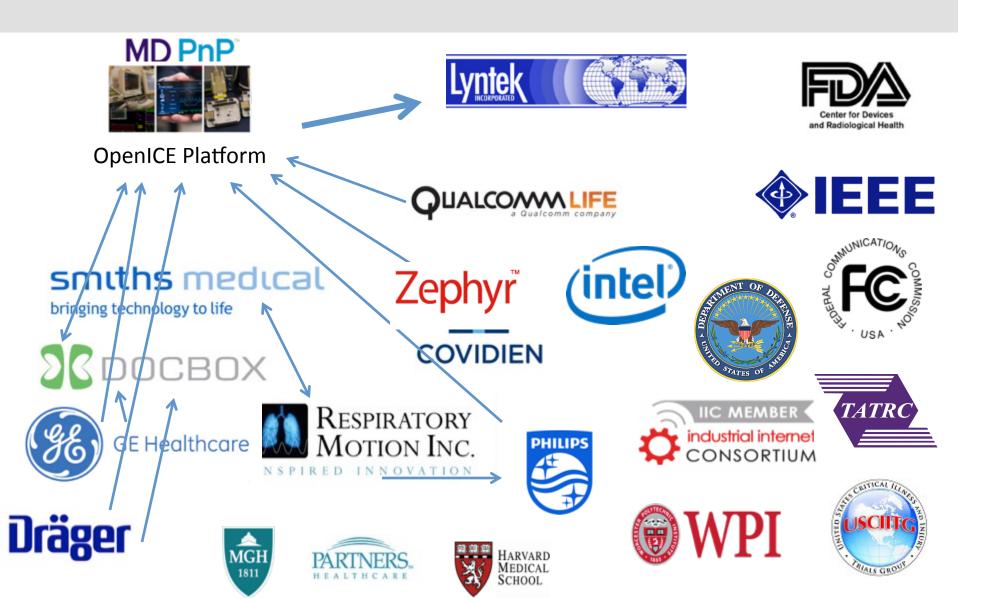
Jeffrey Shuren, M.D., J.D.

Director

Center for Devices and Radiological Health



Ebola Project COLLABORATORS



Formation of the ICE Alliance to enable collaboration and innovation

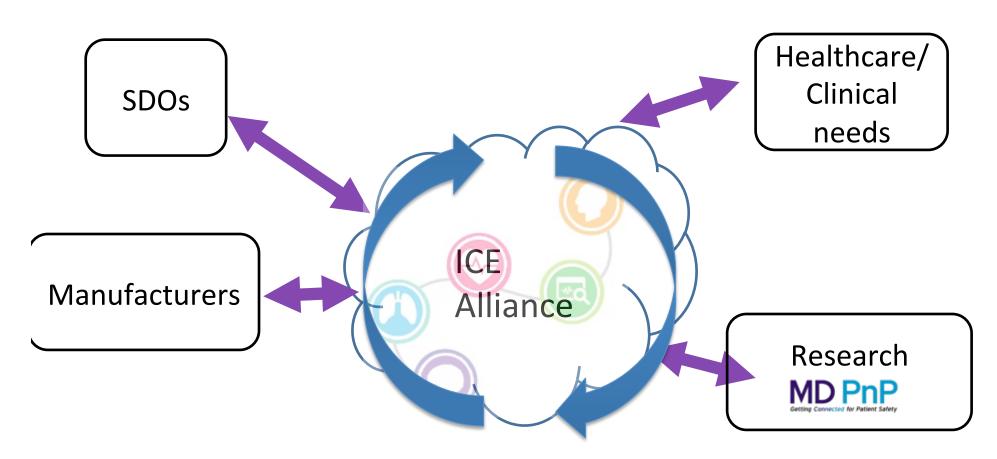


The ICE Alliance is a non-profit program committed to establishing healthcare environments that are <u>safe</u>, <u>secure</u>, and <u>interoperable</u>

Note: The ICE Alliance is hosted by the IEEE-ISTO

www.icealliance.org

Virtuous Cycle of Stakeholders

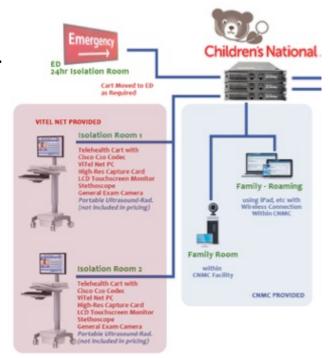


Phase III

Incorporate new technologies as they become available

Creative approach to telemedicine ...





Point-of-care Chem/Bio Screening Testing



- Rapidly reads and interprets FDA approved medical tests
- Rapidly reads and interprets
 DoD environmental tests
- Information and results can be transmitted and incorporated into the Military Electronic Health Record





Request, Perform, Interpret and Send Assay Results

