

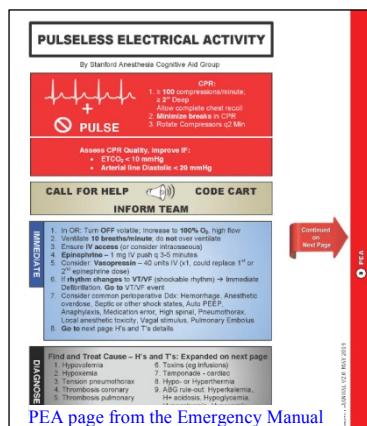
Integrated Clinical Environments (ICE) to Improve Safety and Enable Rapid Innovation

Julian M. Goldman, M.D.¹, Dave Arney, Ph.D.², Jeff Peterson, M.S.², Diego Alonso, M.S.²,
Mike Feinberg², Sandy Weininger, Ph.D.³, Steve Dain, M.D.⁴, Thomas Engel, M.D.⁵, Tracy Rausch, M.S.⁶

¹Anesthesia, Mass General Hospital, Boston, MA, USA, ²Mass. General Hospital, Boston, MA, USA, ³OSEL, FDA / Center for Devices in Radiological Health, Silver Spring, MD, USA, ⁴University of Waterloo, Waterloo, ON, Canada, ⁵Loma Linda University Medical Center, Loma Linda, CA, USA, ⁶DocBox Inc, Newton, MA, USA.

Demonstration: Safety System to Automatically Detect PEA and Display a Cognitive Aid

Our exhibit demonstrates the ability of an OR Integrated Clinical Environment (ICE) in which a smart “app” can read data from physiologic monitors, detect the onset of a serious event such as Pulseless Electrical Activity (PEA), and automatically display the PEA treatment page of the Stanford Emergency Manual cognitive aid. Applying automation to clinical vigilance in this manner may reduce the time to detect and respond effectively to critical events.



Prototype App: Pulseless Electrical Activity: PEA is a clinical condition characterized by unresponsiveness and lack of palpable pulse in the presence of organized cardiac electrical activity. PEA was chosen as an example to demonstrate the safety capabilities enabled by medical device interoperability and OR medical device integration.

Detecting PEA: The “PEA detection app” monitors the ECG heart rate, invasive blood pressure, pulse oximetry, heart and pulse rates, and E_TCO₂:

ICE PEA app detection criteria:

ECG, and Heart rate from ECG- not significantly changed

CO₂ - waveform unchanged, but greatly decreased amplitude (ETCO₂ around 5-10)

SpO₂ pleth - flatline, SpO₂ “heart rate” = 0 or dashes (not able to read)

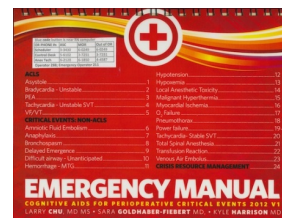
Invasive Arterial pressure - flat line, Pressure approx 20 mmHG

Note – criteria were based on expert opinion, not analysis of clinical data. The system has not yet been evaluated with clinical data.

Other ICE apps could enhance safety by continuously looking for the presence of various conditions, provide an early warning, propose diagnostic or treatment options, and call for help. As with smartphone apps, new ideas could be rapidly implemented without necessarily updating medical equipment. Additional research is required to ensure suitable clinical performance of this emerging technology.

Cognitive Aids: Cognitive aids, such as the Stanford Emergency Manual, provide clinical suggestions for handling a number of preoperative critical events. Used for years in aviation, they are becoming increasingly popular in medical practice.

Unfortunately, the nature of the critical event may interfere with remembering to use the aid and may require an expert assistant to find the manual and locate the correct section – assuming that a manual is available. Our exhibit demonstrates a means to address these issues.



<http://emergencymanual.stanford.edu>



The MD PnP Program and OpenICE: The capability of running smart apps that can use medical device data and display contextual information to improve patient safety is not generally available today. Researching and developing these

capabilities has been the foundation of our Medical Device Interoperability research program (MD PnP) at the Massachusetts General Hospital Department of Anesthesia, Critical Care, and Pain Medicine since 2004. This ASA demonstration is implemented on open-source software called “OpenICE”, developed by our Lab and collaborators, supported in part by the NIH, NSF, and DOD [5U01EB012470-03, IIS-1239242, W81XWH-09-1-0705, W81XWH-12-C-0154, & W81XWH-13C-0107] OpenICE is based on the ICE standard, ASTM F2761.

See video of Scientific Exhibit demonstration: http://bit.ly/ASA_ICE_video

Learn more about our program at www.mdnp.org and OpenICE at www.OpenICE.info