Medical Device Interoperability

What Is Happening Today?

There are emerging commercial integrated solutions for the PCA risk scenario that involve continuous monitoring and safety interlocks.

Interoperability standards and groups like the MD PnP program will provide the glue to enable use of legacy systems with emerging technologies.

Part I of a multi-part proposed draft standard for the Integrated Clinical Environment (ICE) has been submitted to ISO/IEC and is under international review.

What Are the Challenges to Improving PCA Safety?

- Algorithm development
  - Data to design PCA monitoring algorithms is limited, because hospitals cannot easily connect to devices to collect data during adverse events and near misses.
  - There is inadequate clinical data to select optimum alarm strategies for different patient populations. Use simple threshold limits? Statistical limits?
  - Which devices? Pulse Oximeter? Capnograph? Other monitors?
- Liability
  - Does connecting devices create a new medical device? Who will be responsible for failures?
  - Solutions include: Conformance to the proposed "Integrated Clinical Environment" (ICE) standard. This would include recording all alarms and data to support adverse event analysis and vendor cooperation.
- Device integration
  - Today, we cannot easily integrate monitors, infusion pump, and nurse-call to implement safety interlocks, especially from multiple manufacturers.
  - Single vendor solutions are emerging, but would require replacement of patient monitors.

Adoption of medical device interoperability can help address these challenges.

What Can You Do to Help?

MD PnP™
Getting connected for patient safety™

There are many unknowns, but this problem is solvable.

- Start planning to use interoperable systems to improve patient safety
- Contribute clinical scenarios / use cases so that commercial solutions will be clinically useful
- Collect and contribute data on PCA activity as part of the ongoing research to elaborate the clinical requirements
- Specify adherence to interoperability standards in your organization's medical device vendor contracts, as is being done by Kaiser Permanente:

> **Medical Device Plug and Play.** Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the "Integration Standard"), and … will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue … to provide open interfacing protocols …

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