

A Proposed Solution:

Safety Interlocks to pause a PCA infusion and activate the nurse-call system when respiratory impairment is detected

Introduction

An interoperable system for PCA pumps using an integrated decision support capability and closed-loop control is being proposed to detect and respond to respiratory depression caused by over-medication. The goal is to close the monitoring and medication administration loop by interrupting the administration of respiratory depressant analgesics during PCA treatment when warranted by detection of adverse respiratory changes. By triggering a safety interlock to interrupt medication infusion and to activate the nurse-call, it is envisioned that the proposed system design will enhance patient safety and the efficiency of therapeutic procedures hospital-wide. Such a system will be built by medical device vendors, not by clinicians, and it will be enabled by emerging medical device interoperability standards. In addition, data collected by the system could be used to improve the sensitivity and specificity of respiratory monitoring systems to minimize nuisance alarms and false alarms.

A Hospital-Wide Vision

* At the Patient Room Level

An Integrated Clinical Environment (ICE) for networked medical devices is proposed to improve patient safety with PCA pumps. In this solution, the patient is continuously monitored in order to be able to:

- (1) Detect the evidence of deteriorating respiratory status;
- (2) Activate a safety interlock to suspend PCA drug delivery;
- (3) Activate the nurse-call system to promptly initiate clinical assessment.

An intelligent Clinical Decision Support System detects the occurrence of respiratory depression based on the analysis and correlation of the patient's SpO₂, PR, ETCO₂, RR and/or other values, provided by the relevant monitors.

The use of multiple monitoring modalities and the integration of orthogonal indicators of respiratory status will improve respiratory compromise detection (high "sensitivity") and decrease false - or nuisance - alarms (high "specificity").

* At the Medical Unit Level

According to the APSF, "it is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner." The status of the patient on PCA is assessed by clinicians based on the information at the bedside, at the central station, and on the Alarm Display Unit. Additionally, the eMAR system confirms the PCA programming and patient-drug match.

* At the Hospital Level

The Medical Device Plug-and-Play Integrated Clinical Environment (ICE) in each patient room and each medical unit can share information with the hospital's Electronic Medical Record (EMR). A clinical application including a clinical decision support system can improve patient safety by detecting adverse events and triggering the necessary response. The new approach includes the hospital-wide data entry to the Document Quality and Safety Program, leading to a higher quality of patient care.

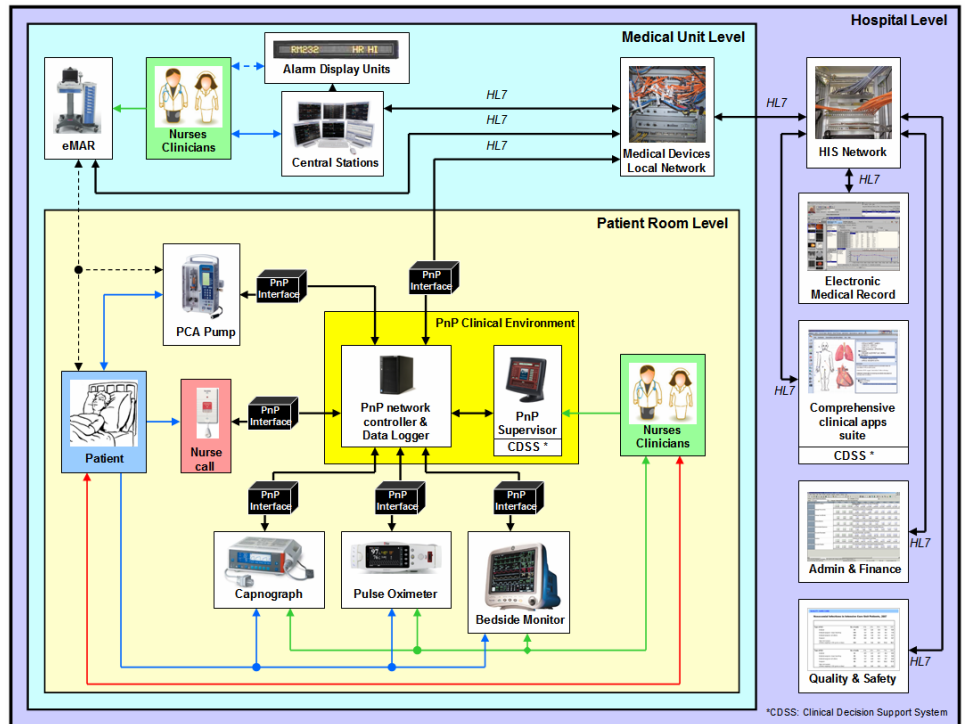


Figure 1. Medical Device Integration for Patient-Controlled Analgesia Infusion

SOLUTION FEATURES:

(as described in the proposed draft ICE standard)

- Provide medical device safety interlocks to reduce use errors
- Provide context-aware clinical decision support
- Provide integrated alarm conditions to relevant operators/clinicians
- Improve and automate workflow
- Provide Plug-and-Play connectivity
- Provide relevant data to EHR and other clinical information systems
- Reduce healthcare costs

Part I of a multi-part standard for the Integrated Clinical Environment (ICE) is under consideration as a new international standard by ISO/IEC. Components of ICE include system functions such as data logging, data security, device authorization, and connectivity to the hospital information system. These functions would contribute to a complete systems solution that could meet clinical, technical, regulatory, and legal requirements.

Figure 2. Functional elements of the Integrated Clinical Environment (ICE) applied to the PCA Use Case

