
Clinical Scenario #1 Patient Controlled Analgesia

Part 1: Narrative Description Working Draft Version 5.1

Quantum Medical Device Interoperability (QMDI) Project

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BACKGROUND

Creation of an open, standards-based healthcare intranet will empower the global healthcare community to build smart "integrated" clinical environments by contributing innovative interoperable technologies and clinical knowledge to improve healthcare. The Quantum Medical Device Interoperability (QMDI) project (NIH U01EB012470-03) is building on existing interdisciplinary and multi-institutional collaborations, and eight years of experience in the MD PnP program, to develop a prototype plug-and-play open platform for medical device connectivity, including software tools to ensure the safe and effective connectivity of medical equipment, EHR, and decision support engines to support clinical care. The breadth of this patient-centric clinical connectivity is termed a "healthcare intranet".

The QMDI project is identifying and validating the clinical, technical, and regulatory requirements for the creation of a safe and effective integrated clinical environment for high-acuity care, whether in or out of hospital. In the first year of QMDI, we explored a wide range of clinical scenarios, four of which, if implemented under this NIH award, would create the technical capabilities for a broad range of safe interoperability for clinical care and medical device management. As such, the four QMDI clinical scenarios represent archetypes that, when taken together, will enable numerous other clinical solutions. This report covers one of the four scenarios being implemented in the QMDI project.

METHODOLOGY

Since 2004, we have collected Clinical Scenarios from literature reviews, interviews, and professional experience in order to better understand the broad range of medical, safety, regulatory, and business problems caused by a lack of medical device interoperability and the resultant barriers to effective clinical system integration. We selected four specific clinical scenarios for implementation because:

- They represent real-world problems.
- Each of these clinical scenarios represents a family of closely related clinical problems and thus can serve as an archetype of other scenarios in our database.
- By building sets of requirements for four carefully-chosen clinical scenarios, we can identify common Timing, Data, Communication, Functional, and Safety requirements. Implementing these four scenarios lets us explore the whole space of medical device interoperability from home use to high-acuity environments and from simple documentation to complex physiological closed-loop control. We will apply formal systems engineering methods to assess the completeness and consistency of these requirements, and to test the various implementations of the scenarios.

Our approach follows methodology developed by the MD PnP research program in 2005-2006 to ensure that technology solutions are based on practical clinical needs (Figure 1) and involve the appropriate domain experts. This requirements-based methodology begins with clinical scenario descriptions and

uses workflow analysis to clarify clinical requirements to provide engineering requirements for building solutions.

The steps include depicting the details of each clinical scenario in clinical workflow diagrams. The workflow diagram is then analyzed utilizing unified modeling language (UML) to create workflow steps, timing diagrams and documentation of the data required at each step. Workflows are created for both the current process and the proposed (improved) state. For the *proposed state* workflows, areas where medical errors can or have been known to occur are flagged and these are included in the risk analysis. After the initial draft of a workflow is completed, it is reviewed with clinicians to ensure accuracy. This step is typically completed by a Clinical Engineer.

Clinical Scenario

A Clinical Scenario is a high-level description of a clinical situation or event. Clinical Scenarios provide background and illustrate the need for the development of technical solutions. The **current state** typically describes an adverse event that has occurred to a patient or a current clinical situation that needs improvement. The Clinical Scenario also includes a **proposed state**, which is a brief illustration of the improvement in safety and effectiveness to be obtained by applying an integrated solution. The Scenario description also includes a **clinical concept of operations**, which is a more detailed description of the events that occurred.

Note: These concepts and definitions were developed by the MD PnP research program and codified in an international standard, ASTM F2761-09. (Several clinical scenarios are published in Annex B of F2761.)

Clinical Workflow Diagrams

The Clinical Workflows selected for implementation under QMDI began as general, high level clinical descriptions of both the clinical problems and proposed solutions. In order to ensure that the scenarios were representative of diverse clinical practice and that solutions would be broadly applicable, we collected clinical process and policy documentation from multiple medical institutions, and interviewed clinical staff. These Workflows were then documented using Business Process Modeling Notation (BPMN). These workflow diagrams depict a single pathway through the clinical process, and are not intended to be the only way these clinical events can occur, but rather a representative description of how they occur.

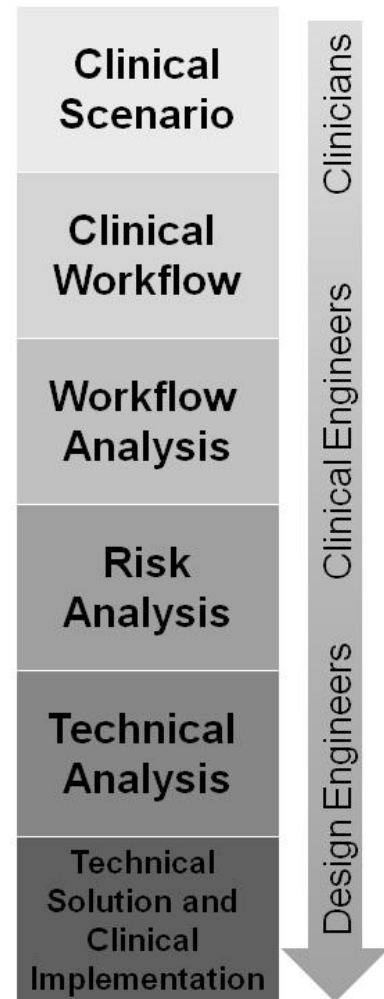


Figure 1: Workflow Methodology. This process is iterative through each block. (Developed by MD PnP Program, 2005-2006.)

Clinical Workflow Analysis

Analysis of the workflows provides understanding of how existing technology fits into clinical processes, as well as insight into how system level requirements for new technologies will be determined.

Workflow analysis consists of three separate analyses: (1) Zachman Framework; (2) completion of the UML activity diagram, which shows the connections between system components, the relationship between data from different parts of the system, and a list of data required at every step of the workflow; and (3) completion of the timing diagram, which shows the relationships between components of the system with respect to behavior or time.

Zachman Framework

The Zachman Framework is a structured way of gathering information that can help to formally define a system. It gives a framework for answering the “What, Where, When, Why, and Who” questions about the workflow. It is meant to provide additional background information for the workflow and allow a larger picture of the scenario to be understood by non-clinicians. It is also a structured way for non-clinicians to interview clinicians in order to understand the complete clinical picture. This framework does not have to be complete, and we chose to fill in only the first 2 rows at this point in the analysis (the Contextual and Conceptual).

Data and Timing Analysis

The Data Analysis consists of tables at each workflow block which state the data and data type that is transferred; it also demonstrates the source of the data along with cardinality. The Timing Diagram shows the relationships between components of the system with respect to time. This is the first look at the time-sensitive components, which will become important requirements in the Technical Development phase of this project. For example, patient safety concerns arise if certain components are required to occur prior to others or if data at a step expires within a specific timeframe.

Workflow analysis also generates a risk list, which uses available information to systematically identify hazards and estimate the risk within both a specific procedure and the larger process. (Risk is usually based on a function of hazard type, severity, and likelihood of occurrence.) This risk list is not a list of individual components or devices, although it may reference these. It is a list of hazards based on a holistic analysis of the system of systems for the clinical scenario. Each risk is referenced back to a clinical workflow block for traceability and is essential to complete the Risk Analysis.

CLINICAL SCENARIO

QMDI Clinical Scenario #1: Medication Infusion Safety Interlock – PCA Safety Interlock

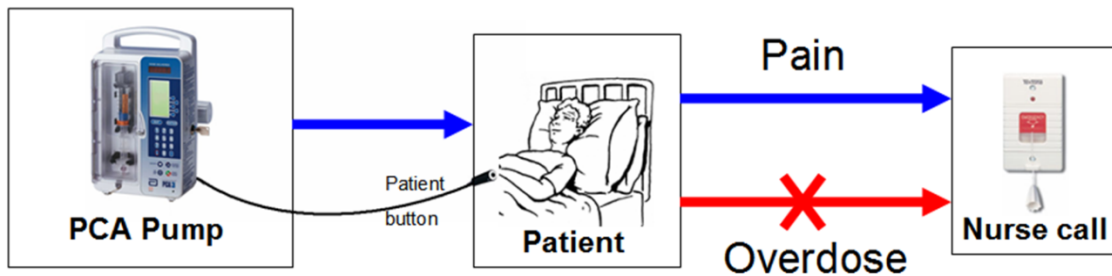


Figure 2: Graphical Image of Current State

Clinical Scenario Narrative Description

Scenario Current State

A 49-year-old woman underwent an uneventful total abdominal hysterectomy and bilateral salpingo-oophorectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She began receiving a continuous infusion of morphine via a patient-controlled analgesia (PCA) infusion pump. A few hours after leaving the post-anesthesia care unit (PACU) and arriving on the floor, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a “code,” and the patient was resuscitated and transferred to the intensive care unit on a respirator. Based on family wishes, life support was withdrawn and the patient died. Review of the case by providers implicated a PCA overdose (1)

Scenario Proposed State

While on the PCA infusion pump, the patient is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre-determined range, the infusion can be stopped and alarms sent to notify the clinical staff and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart monitor to optimize sensitivity to detecting respiratory compromise while reducing false alarms.

Clinical Concept of Operations (“CConOps”): PCA Safety Interlock

The patient is connected to a PCA infusion pump containing morphine sulfate, a second “large volume” infusion pump acting as a carrier line of saline, a pulse oximeter, a respiration rate monitor, and a nurse call system. Clinicians involved are a physician, nurse, and nursing assistant. Heart rate, blood pressure, respiration rate, pain score and sedation score are collected as directed by the clinical process for set-up of a PCA pump. An IV line assessment is also completed. The PCA infusion pump, large volume infusion pump, and pulse oximeter are attached to the integrated system. The system queries the hospital information system for the patient’s weight, age, and medication list (specifically, whether the patient is on medications known to potentiate the effects of PCA medications), and searches for a diagnosis of sleep apnea. The system then accesses the physician’s orders from the computerized physician order

entry system for the PCA and large volume infusion pump's dosage and rate, and verifies the values programmed into the infusion pump. The patient's SpO₂, respiration rate, and (optionally) End Tidal CO₂ are then monitored continuously. The system uses an algorithm based on weight, age, medication list, diagnoses, SpO₂, and respiration rate to determine the state of the patient. Sedation and pain scores also contribute to this algorithm. If the algorithm determines that the patient is experiencing noteworthy respiratory depression based on changes in the patient's SpO₂ and/or respiration rate, a message is sent via the nurse call system with the appropriate level of alarm. If the algorithm activates a high-level alarm, a command is sent to pause the PCA pump.

This Scenario demonstrates the following general functionality:

- devices are actively identified
- appropriate algorithm is selected based on available devices
- supervisory algorithm is started
- infusion is stopped based on advanced clinical criteria
- alarms are activated based on advanced clinical criteria
- event log is created
- rich data log is created for clinical algorithm development

Devices – PCA infusion pump, pulse oximeter, respiratory rate monitor (CO₂)

Notes – Connectivity to multi-parameter monitor (to get SpO₂, CO₂, respiration rate) is an option for system configuration. If a respiratory CO₂ monitor (capnograph) is used to monitor respiratory rate, exhaled CO₂ levels could be incorporated in the respiratory depression algorithm.

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