Clinical Scenario #2: Operating Room to Intensive Care Unit

Part 1: Clinical Scenario Narrative Description

Working Draft Version 3.1

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.

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

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 <u>not</u> intended to be the <u>only</u> way these clinical events can occur, but rather a representative description of how they occur.

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

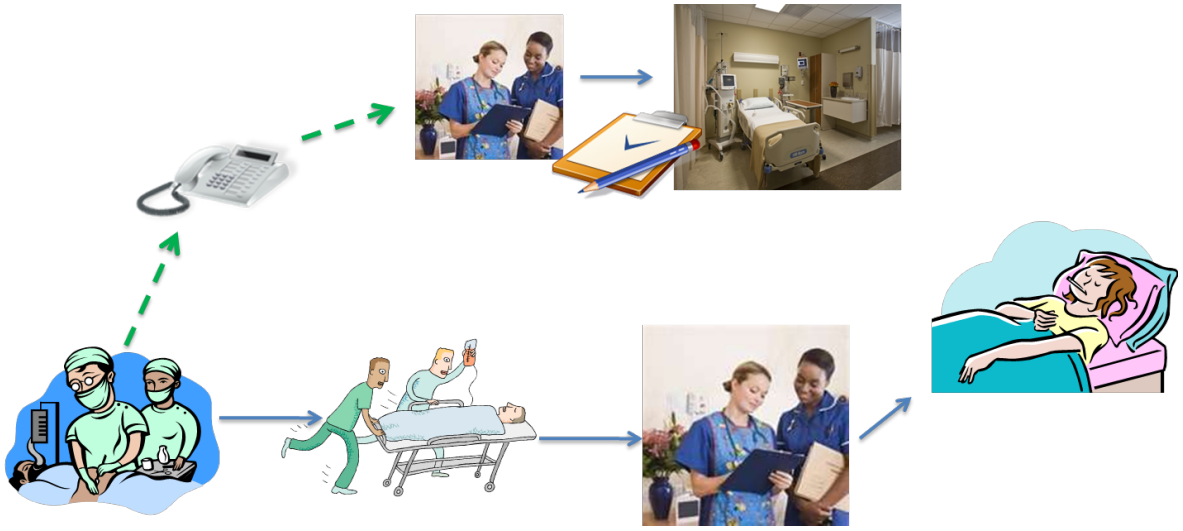
The Zachman Framework is a structured way of gathering information that can help to formally define a system. It gives a framework for answering the "What, Where, When, Why, and Who" questions about the workflow. It is meant to provide additional background information for the workflow and allow a larger 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 that 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.

System Readiness Assessment in SICU for New Patient Admission



Accepting Transfer from OR to SICU of Patient after CABG Surgery

A. Use Case Current State

Transferring patients from the OR to the ICU is a complex and almost completely manual process that is a major source of adverse events. A recent study shows that an average of 5.42 technical errors occur per handoff, 2.09 information omissions are made per handoff and 39% of handoffs involved errors of both types (1) (2). Checklists have been shown to reduce errors but are currently updated manually, requiring caregivers to integrate large amounts of distributed information. Even with checklists, significant additional time may be required, information loss is frequent and medication errors are frequent.

Typically, there are three phases in the OR to ICU **Handoff Process**: Room Readiness, Patient Handoff, and Post Handoff. Most of the interactions between clinicians occur verbally – at most, they will sometimes include a single page worksheet at the time of handoff. If information about the patient's status or previous treatment is not transferred during these verbal communications, it is often lost. Patient data is stored in many places, and it is very difficult to piece together a complete picture. While this data may be retrieved from hospital information systems, it is often scattered across multiple systems that make it virtually impossible to retrieve quickly. Not all teams members may be present when verbal reports are made, causing further complications as different caregivers have different ideas of the patient's status and treatment plan. The patient's status can be very dynamic, with rapid changes as they are moved from the OR to ICU. For this clinical scenario, we are focusing on the Room Readiness phase.

Room Readiness consists of the preparation for handoff within the target room. This includes selection and preparation of medical devices, medical supplies, and medications the patient will need. This preparation is critical for sourcing specific items not generally located in the unit and items that may take time to arrive (i.e. blood, infusion pumps, etc). The patient is often attached to 10 to 20 medical devices in the OR and many of these devices provide monitoring and therapy to the patient which continues post operatively. Managing this equipment transition with the complexity of device settings and use history is critical to providing a complete and accurate record of care. When the ICU is not ready for patient delivery it requires the patient to stay in the OR longer. This means the patient stays in the OR being managed by OR staff who are waiting for the ICU bed to be ready. This time in the Operating Room delays the time until the next case can enter the OR and leads to an increased chance for medical error as the OR staff try to manage the previous and incoming cases simultaneously.

B. Use Case Proposed State

In order to improve the handoff process, it is necessary to automatically push patient data and device settings from the OR to the ICU. This proposed state would enable a system in the OR to communicate with a system in the ICU in order to assist with setting up devices and to enable a system readiness checklist. This is a dynamic and interactive checklist that maintains near real-time updates of the patient status, required devices, physicians' orders and necessary supplies depending on the patient's history, current status and physician orders. It would also provide the OR with a continuous assessment of the state of the ICU.

Clinical Concept of Operations: Electronic Transfer

In the proposed state, the handoff worksheet and verbal reports would be supplemented with a dynamic, interactive application that would be available in both the ICU and the OR simultaneously. The OR would begin an "App" that allows the OR staff to input information about the patient's status, progress of the operation, and anything extra that might be necessary in the ICU such as additional drugs or more units of blood. This "App" would allow for the anesthesiologist, Circulating Nurse and Surgical Team to input orders and information. This information would then be transferred to the ICU where it would be used to assemble a checklist of supplies and medical devices that will be needed in the patients room. This app places all of the necessary information in one spot and assists clinical staff with keeping the information complete and current. This helps to ensure that complete and accurate communication can occur between all members of the team.

Once the appropriate devices and medications are gathered, the App would then interact with clinicians to determine which OR device settings should be carried over and, once proper settings are determined, automatically program the devices. These devices include infusion pumps, the ventilator, and the bedside patient monitor. Thus, when the patient arrives, all

necessary equipment is available, programmed, and ready to be attached to the patient. When the room is ready, an update is transmitted to the OR notifying staff that room is ready for transport. When the patient arrives in the ICU, data from this App will be available as part of the handoff process ensuring the most up to date and reliable information is available for the patient.