Computer Automated Total Perioperative Situational Awareness and Safety Systems

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Abstract.

From the time a patient enters the surgical arena until the time they leave, a tremendous data stream is produced. These data pass through various unrelated systems mostly going unnoticed and unrecorded. We have developed a system to integrate these various systems and display the real-time integrated data in an easy to visualize system. The system captures, records and displays data from anesthesia & surgical devices and OR / hospital information systems, consolidating information on a single operating room display. The system will provide improved contextual real-time monitoring of physiological data, real-time access to readiness information and improved patient identity management.

Keywords: Patient safety, Data integration, Perioperative situational awareness, OR of the Future

1. Introduction

Most patient information from the operating room (OR) passes through various unrelated systems that created it, mostly going unnoticed and unrecorded (1). Medical therapy and monitoring systems do not communicate with each other, so fragmentation with paradoxical redundancy is unavoidable. Integration of OR systems and their data streams has been a goal and challenge in the operating room. Enough progress has been made in the integration of surgical devices to appreciate that full integration between devices would yield tremendous advantages (2). Other systems are farther from integration. For example, the anesthesiologist interacts with many separate displays, each attached to its own computer, for needs such as physiologic monitoring, automated anesthesia record keeping, hospital information systems access, order entry and drug/supply chain management (3). This is inefficient, and diverts caregivers from patient care, potentially degrading safety. It is now possible to harness all of the information flux in an OR to enhance intraoperative safety through complete data recording feeding automated, computerized decision support tools (4,5). Integration to streamline data and

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make it more accessible to the clinician will decrease redundancy, improve access to information and improve patient safety.

There is an opportunity for a new layer of software to communicate with various systems and provide the information needed by the physician (or any other healthcare worker) at any time, from any location and in any format necessary to support the safety mandate in the OR. The Massachusetts General Hospital and LiveData, Inc. (Cambridge, MA) have undertaken a collaborative project to record all data passing through an OR, provide unified displays of that data in real time, and to develop real-time tools providing augmented vigilance (i.e., broader and more continuous attention to data than people can achieve) and decision support. The purpose of this publication is to frame the scope of this system, to provide a high level specification of the system and to present example scenarios in which augmented vigilance would be beneficial.

2. Methods

The proposed system is to have three major capabilities: (1) complete data capture and recording, (2) integrated data display and (3) augmented vigilance with decision support. The methods used to develop the system specification are described below, mapped onto these capabilities in order of their description.

We began with a search for input data sources in a technologically advanced OR- the OR of the Future (ORF) project at Massachusetts General Hospital. The ORF is typical of a new OR that would be constructed to support minimally invasive surgery. All equipment in the ORF was cataloged, and each device's communication capabilities were determined and recorded. OR administrative and patient care information systems were cataloged, and their interface capabilities determined.

Because standards for medical device communication and integration do not yet exist, each device's communication protocol and data definition were analyzed. Software was developed to enable communication with each device. Device data definitions were mapped to object models for each class of device. An analysis was performed to determine that the computerized data integration system (LiveData OR RTI Server and Dashboard) could capture all device data, including detailed physiological waveform data, without data loss, in real-time. This included the real-time display of critical data elements. A similar analysis was performed for data coming from the patient care information systems.

Specification of integrated displays was a collaborative effort between human factors designers (Aptima, Inc., Woburn, MA) and the clinicians who would be their end users, seeking to take a 'human factors engineering' approach to medical equipment (6). Initial characteristics of the displays themselves, the information to be presented, and the form the information should take were driven by synthesis of expert opinion from end-users (OR clinicians). Each element was then iteratively refined by the combined human factors/clinician team.

We developed augmented vigilance and decision support specifications as follows: We began with the catalogue of input sources (devices & information system interfaces). We then systematically sought out opportunities for data integration and synthesis, based on the information available from each device. The goal was to find and catalogue all instances in which OR clinicians perform this integration themselves during patient care, as well as to identify new opportunities for data integration and synthesis. Next, common near-miss events in the OR were enumerated. Near misses are situations that might have

negatively impacted patient outcome if not detected and corrected. The near miss catalogue was based on expert experience (anesthesiologists, surgeons, nurses). Finally, the data-source & integration catalogue was cross-referenced against the near miss catalogue to identify instances in which computer recording and integration of device data might contribute to earlier or more reliable near-miss detection and correction.

3. Results

3.1 Input data sources

Most devices in the ORF with digital user interfaces have a digital output. Key devices with data-out ports include the laparoscopic surgical insufflator, physiologic monitors, breathing circuit gas analyzers, level-of-consciousness monitors, the anesthesia machine itself and medication infusion pumps. Communications protocols for the syringe infusion pumps, physiologic & level of consciousness monitors and anesthesia machines have been obtained.

Hospital information systems in the ORF provide a rich source of patient data awaiting integration. A computerized provider order entry system forces recording of allergy information before patient orders can be written, ensuring that allergy data are available. An Anesthesia Information Management System (Saturn, Drager North America, Telford PA) provides recording of anesthesia interventions, but without integration with any other OR system. Our institution uses an internally developed computerized system called the Nursing Perioperative Record (NPR) for perioperative documentation. This includes time stamps for key milestone events. Unique to the ORF and several other ORs at MGH is a patient tracking system (Radianse, Lawrence MA) that uses a dual radiofrequency / infrared technology to locate patients and devices with room-level spatial and 10-second time resolution.

Using a standard PC, the computerized data integration system successfully captured, recorded and displayed real-time data simultaneously from the laparoscopic surgical insufflator, physiologic monitor, breathing circuit gas analyzers, level-of-consciousness monitors, the anesthesia machine itself, medication infusion pumps and the patient care information systems. The system was able to display critical data elements, including complex physiological waveforms, on the plasma display with no perceptible delay.

3.2 Display of real-time integrated data

The characteristics of an ideal display were based on the experiences of ORF personnel. The display must be visible and legible from any point in the OR, up to 9 meters away. This limits the minimum acceptable font size and dictates a very large display. The requirement for legibility, combined with the demand for information content (described below) dictated the specification of two 50-inch plasma screen displays. The system is shown in a conceptual drawing in Figure 1.

Figure 1. Representation of the OR of the Future at Massachusetts General Hospital with computerized data integration system visible and legible from any point in the OR. Displays are shown on the left side of the ORF. Primary display shows surgical image. Secondary display integrates physiologic, surgical equipment patient & team identity and case progress data. 42 and 50-inch plasma displays are represented.

Key data elements for continuous display were identified. Chief among these is live display of the surgical procedure. Continuous display of images from laparoscopes or OR-light mounted cameras occurs whenever surgery is being performed in the ORF. This allows ORF team members not directly in the surgical field to 'self-update' to surgical events. It also minimizes interruptions of the surgical team's work by reducing other team members' need to ask for progress updates. Finally a continuous visual display of the operation allows the rest of the team to see most of what the surgeons see when a visually-manifesting surgical complication develops. The surgical scene data fills the first display. Patient identification, medications (with dosing and administration schedule information for critical drugs) and allergies are placed on the second display in the left upper quadrant (see Figure 2 for conceptual drawing). Pertinent elements of the presenting medical problem, as well as salient additional medical problems are listed on the second display. Top level physiologic data (with trends) are visible at all times in the center of the second display. A time line of surgical & process events (i.e., incision, insufflation, electrocautery, desufflation) is provided as well. Together, these data provide a 'self-update' to anesthetic, physiologic and workflow events.

3.3 Augmented vigilance and decision support

The cataloguing and cross referencing of data sources against typical near miss events revealed numerous potential targets for near miss reduction. Two salient scenarios were
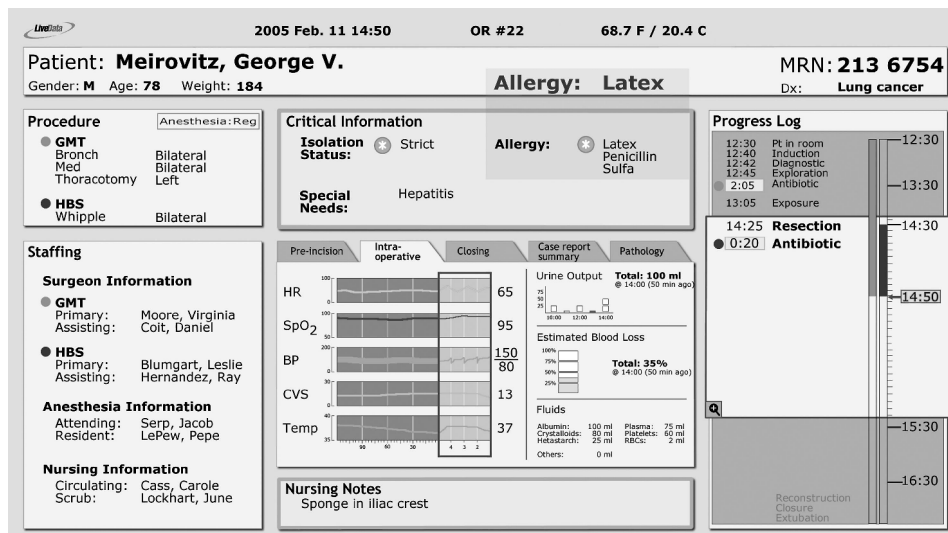
Figure 2. Graphic display of computerized data integration system capturing real-time data from the physiologic monitors, the anesthesia machine, electronic medical record, and the patient care information system for simulated patient. Data from the laparoscopic surgical insufflator, breathing circuit gas analyzers, level-of-consciousness monitors and medication infusion pumps is customizable by the user.

chosen for proof of concept demonstrations: (a) physiologic derangements due to insufflation and (b) heart rate effects due to succinylcholine.

Problems during laparoscopic surgery are often related to the cardiopulmonary effects of pneumoperitoneum. Insufflation is usuallye uneventful, but can cause bradycardia, sometimes to the point of asystole, and rarely results in massive intravascular gas embolism. During routine cases, personnel might initially attribute the sudden loss of heart rate tones or the disappearance of exhaled CO2 as an equipment failure. Machine based decision supports based on integrated data (insufflation pressure, noninvasive arterial pressure monitor, airway pressure monitor, pulse oximeter, end tidal CO2 monitor, electrocardiogram) can suggest these more rare and sinister causes.

Paralysis facilitates laparoscopic surgery. The brief nature of some laparoscopic procedures ensures that succinylcholine, the shortest-lived skeletal muscle paralytic available, will continue to be used. The drug is given as boluses or by continuous infusion using syringe microinfusion pumps with serial data outputs. In repeated doses, succinylcholine can cause slowing of the heart in 10% of all patients. Cardiac arrest can also result. Brief laparoscopic procedures have high task demands competing for OR team member's attention, and heart rate changes induced by succinylcholine can go unnoticed until severe. By combining data from physiologic monitors with equipment-derived data (in this case, 'infusion pump running succinylcholine') the system can produce an alert signal to re-focus attention on the consequences of giving succinylcholine before they become pronounced.

Rules algorithms to detect both of these conditions are under development for the purpose of proof-of-concept demonstrations (in a high fidelity simulator) of the larger principle of cross platform data integration for fault detection.

4. Conclusions

We are developing a computerized system for the complete capture, recording and display of data from surgical devices and information systems in the OR. The qualitative value of some elements of the system has already been demonstrated in the ORF. For example, the provision of live surgical images on the large format plasma video display keeps the anesthesia and surgical members of the team integrated and in proximity, effectively removing the psychological separation that can inadvertently be created by the physical presence of drapes separating these team members.

The core functions described above will enable a number of capabilities for clinicians and other end-users. A subset includes the following:

Improved Contextual Real-Time Monitoring of Physiological Data – Because all the perioperative data will be available in one system, it will be possible to display a concise context-sensitive subset of the critical data on an electronic whiteboard. For example, applying contextual information to physiologic data (such as: apnea is expected during induction of anesthesia, or: hypotension accompanying insufflation of the abdomen has different consequences than isolated hypotension) will result in improved handling of physiological parameter alarms.

Real-Time Access to Readiness Information – Equipment, material and personnel readiness information can be displayed in real-time.

Patient Identity Management – By integrating with the HIS patient record, OR scheduling information and patient location information obtained through indoor positioning systems, basic, critical patient identity functions will be enabled in the perioperative environment

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