Surgical Innovation

http://sri.sagepub.com

Auto Identification Technology and Its Impact on Patient Safety in the Operating Room of the Future

DOI: 10.1177/1553350606298971 Surg Innov 2007; 14; 41 Marie T. Egan and Warren S. Sandberg

http://sri.sagepub.com/cgi/content/abstract/14/1/41 The online version of this article can be found at:

> Published by: SSAGE Publications

http://www.sagepublications.com

Additional services and information for Surgical Innovation can be found at:

Email Alerts: <http://sri.sagepub.com/cgi/alerts>

Subscriptions: <http://sri.sagepub.com/subscriptions>

Reprints: <http://www.sagepub.com/journalsReprints.nav>

Permissions: <http://www.sagepub.com/journalsPermissions.nav>

<http://sri.sagepub.com/cgi/content/refs/14/1/41> SAGE Journals Online and HighWire Press platforms): **Citations** (this article cites 7 articles hosted on the

Auto Identification Technology and Its Impact on Patient Safety in the Operating Room of the Future

Surgical Innovation Volume 14 Number 1 March 2007 41-50 © 2007 Sage Publications 10.1177/1553350606298971 http://sri.sagepub.com hosted at http://online.sagepub.com

Marie T. Egan, RN, MS, and Warren S. Sandberg, MD, PhD

Automatic identification technologies, such as bar coding and radio frequency identification, are ubiquitous in everyday life but virtually nonexistent in the operating room. User expectations, based on everyday experience with automatic identification technologies, have generated much anticipation that these systems will improve readiness, workflow, and safety in the operating room, with minimal training requirements. We report, in narrative form, a multi-year experience with various automatic identification technologies in the Operating Room of the Future Project at Massachusetts General Hospital. In each case, the additional human labor required to make these 'labor-saving' technologies function in the medical

Current State of Perioperative Patient Safety

A coording to the 1999 Institute of Medicine
report, "To Err Is Human"; surgical errors
are second only to medication errors as the
most frequent cause of error-related death.¹ Of the report, "To Err Is Human"; surgical errors Lare second only to medication errors as the most frequent cause of error-related death.¹ Of the various staging posts on the continuum of surgical care, the operating room poses a unique set of hazards. The modern operating room and its environs environment has proved to be their undoing. We conclude that while automatic identification technologies show promise, significant barriers to realizing their potential still exist. Nevertheless, overcoming these obstacles is necessary if the vision of an operating room of the future in which all processes are monitored, controlled, and optimized is to be achieved.

Keywords: Auto-ID; Operating Room of the Future; operating room efficiency; radio frequency identification; patient safety; data integration; operating room supply management; perioperative systems design

constitute a technologically dense, production-driven, high-throughput environment of care. Here a patient is stripped of all identifiers (except for a plastic wristband); is rendered unconscious; has the very integrity of his or her corpus breeched, the anatomy reengineered or portions removed; then the deliberate damage is repaired, hopefully without incurring infection or retention of foreign objects in the wound.

The environment of care in which these activities are performed has never been as busy nor as complex. Care is delivered in facilities designed and built in the past century, before many of today's technologies were invented. Most hospitals lack sufficient storage space for equipment and are challenged to deliver materiel effectively and efficiently to the point of use. Current systems of perioperative care delivery evolved haphazardly, in response to changes such as the advent of minimally invasive surgical techniques.² These techniques are indeed minimally invasive for the patient but add a significant level of technologic crowding and complexity to the operating room environment. In addition, the patient population has grown more complex, as advances in care allow sicker patients to come to the operating room and as

From the Department of Nursing, Massachusetts General Hospital, Boston, Massachusetts (MTE); Harvard Medical School and Department of Anesthesia and Critical Care, Massachusetts General Hospital, Boston, Massachusetts (WSS).

This project was sponsored by departmental funds from the Departments of Nursing and Anesthesia and Critical Care, Massachusetts General Hospital, and by a subcontract to Massachusetts General Hospital from SBIR 1 R43 RR018076-01, awarded to Radianse, Inc by the National Institutes of Health.

Address correspondence to: Marie T. Egan, Department of Nursing, Massachusetts General Hospital, 55 Fruit Street, Clinics 3, Boston, MA 02114; e-mail: mtegan@partners.org.

changes in reimbursement have forced hospitals to do away with preoperative admissions. Even the most complex procedures, such as coronary bypass, are now performed on patients who come to the hospital the day of surgery. All of these factors conspire to create an environment of care that taxes the cognitive capacity of even the most proficient personnel.

Radio frequency identification (ID), or RFID, is one of a group of automatic identification (Auto-ID) technologies that form the basis for work by such groups as the Massachusetts Institute of Technology (MIT) Auto-ID Center. The Auto-ID Center was central to the successful development of the Electronic Product Code and has now formed a worldwide group to create the "Internet of Things." Central to the work is the Auto-ID's vision of synchronizing materiel and information flows. Automatic ID (no manual notation or keyboard data entry necessary) of physical objects is key to coupling objects (people, equipment, supplies) to data, or information (allergies, scheduled surgery, operating room location). Those who are working at the forefront of perioperative systems design are, in effect, conceptualizing an "intranet of things" in which the flow of materiel and information pertinent to the care of surgical patients is synchronized. $2-4$ In fact, the synchronization of information, supplies, and equipment is one of the greatest challenges in fully realizing the "operating room of the future." This work is mentioned here as an example of how innovation in the larger world can inform the development of solutions in the health care environment. It is also indicative of the need for health care leadership to look beyond the traditional boundaries of the health care industry to find novel and innovative solutions to the problems facing us.

As we discuss the potential for new technologies, such as RFID, to affect patient safety, we must consider how they will interact with and affect the environment as a whole. This approach is consistent with the authors' belief that perioperative systems as they exist today need to be studied, measured, analyzed, evaluated, and redesigned from an evidencebased perspective.^{2,5-8} No significant gains in patient safety will be realized until the very systems of care delivery are examined and evaluated with regard to their net contribution to patient safety and efficiency, 2 key metrics of system performance in the operating room of the future. Indeed, the operating room itself cannot be considered without regard to the larger hospital environment and so on.

In today's operating room, safety and efficiency are often held to be at odds with one another. Safety is often the nominal reason for [avoiding the](http://sri.sagepub.com) implementation of change, or perversely, safety is often the reason for additional paperwork, checks, and forced functions. Efficiency is often confused with speed, and speed is believed to be dangerous, as it compresses the time available for the performance of all the checks considered essential to the delivery of safe patient care. It is our contention that true efficiency—as defined by the timely provision of all required data, equipment, and materiel (and the concomitant minimization of busywork) to those in the front lines of care delivery—actually enhances safety. Safety and efficiency are not mutually exclusive, but rather complementary. The pursuit of one without regard for the other will not result in the full realization of the operating room of the future as a technologically integrated, efficient, data-integrated, and safe operating room environment.

Overview of Current Automatic Identification Technologies

The discussion of the potential for RFID and other Auto-ID technologies in the operating room of the future is best served by an overview of the current technologies and their relative advantages and limitations. Radio frequency identification is one of a group of identity and location technologies that includes bar codes, both 1 dimensional (1-D) and 2 dimensional (2-D). Radio frequency identification itself is further divided into passive RFID, semipassive RFID, and active RFID. While bar codes are ubiquitous and widely recognized, passive RFID has a higher public profile than active RFID, as demonstrated by the widespread and unfavorable response to the recent attempt by the clothing retailer Benetton to utilize passive RFID tags for inventory control. RFID technology has been recently reviewed in this journal.⁹ We will look at both passive and active RFID applications for patient safety and efficiency as it relates to safety. Each technology has unique attributes (Table 1) and will likely play a role in the operating room of the future.

Bar Codes

Bar codes provide a simple and inexpensive method of encoding text information that is easily read by inexpensive electronic readers. Bar coding allows data to be collected rapidly and with extreme accuracy. Bar codes are typically used with a database application, where the information encoded in the bar codes is used as an index to a record in the database that contains more

Technology	Characteristics	Pros	Cons	General Use	Health Care Use
1-D bar code	Alpha and alpha- numeric data, 20-25 characters	Inexpensive, ubiquitous	Limited data capacity; reader requires line of sight	Ubiquitous; virtually all commodity items in everyday life have a 1-D bar code on the package	Patient identification bands (limited penetration); drugs (limited) penetration)
$2-D$ bar code	100-2000 characters	Can hold large amount of data	Requires special reader and line of sight		Patient identification bands (limited penetration)
WiFi	Uses WiFi for location; can locate personal computers, handhelds, and tags	Multitasking; global trend to ubiquitous deployment of networks	Tags need batteries; radio frequency can impact performance; security issues	Data transfer from portable computing devices	Hospital information system data to PDAs, laptops, and computers on wheels (limited penetration)
Passive RFID	Label is energized by a reader and transmits data to reader	Relatively small and inexpensive	Short read range; very limited data capacity; does not provide unique identification; location and time data only as good as last read	Electronic article security, clothing tags in stores	Staff identification; medium and large sized items, such as implantable prostheses, blood products, patients (all experimental)
Semiactive RFID	Battery-powered tag; passive reader activates tag	Longer range $(\sim 40 \text{ ft})$	Same cost and battery issues as active tags, but no location data- portal application	E-Z Pass on highways	
	Active RFID Battery-powered tags that transmit radio signals	Provide identification and location; long range (30 ft); real- time data	Battery life; blocking of RF; tag cost and size; some require infrastructure		Location in time and space of assets moving through the covered area

Table 1. Examples of Automatic Identification Technologies in Health Care

Note: PDA = personal digital assistant; RFID = radio frequency identification; WiFi = wireless fidelity.

detailed information about the item that is being scanned. Bar codes also provide a quick and error-free means for inputting data into an application running on a computer. By using bar codes, the potential for errors from manual data input is eliminated. Another typical application for bar codes is for inputting data without having to type. A bar code is scanned with a light source, the reflected light is then measured for intensity, and the results interpreted. New 2-D bar codes have the capacity to encode a lot more data than is possible with the more familiar 1-D bar codes, although they require more sophisticated readers.

WiFi (Wireless Fidelity)

WiFi refers to a local area network that uses highfrequency radio signals to transmit and receive data over distances of a few hundred feet, typically about 30 to 50 feet indoors. With WiFi networks quickly becoming ubiquitous, the opportunity to use the infrastructure for location determination presents itself. Every wireless access point (WAP) broadcasts a unique signal that can be used to differentiate it from other WAPs. Either WiFi-based active RFID tags or WiFi devices themselves can send out a wireless signal at regular intervals. The signal is picked up by a WAP and sent to a location engine that uses algorithms to determine the asset transmitter's location.

Location resolution is accurate to the nearest WAP. Thus, a very dense WAP network could probably provide room-level resolution. This may be adequate for most purposes, and with the added advantages of using a multipurpose infrastructure.

Radio Frequency Identification

Radio frequency identification is a system that consists of a transponder, or tag, that transmits a signal and an antenna and transceiver that read the signal and transmit it to a server. Radio frequency identification uses the radio frequency portion of the electromagnetic spectrum to transmit signals. The tag contains radio frequency circuitry and memory containing the data to be transmitted. Whether or not the tag has a power source determines the category of RFID in use—passive, semi-passive, or active. Two significant differences between bar codes and RFID are that RFID can provide an ID unique to a particular object and that the reader does not require a line of sight. However, RFID is orientation dependent, particularly the passive RFID systems. These require magnetic induction between the reader and the tag to supply power and receive signals from the tag. Thus, orientation between the tag antenna and the reader cannot be orthogonal.

What Is the Opportunity for Automatic Identification Technology in the Operating Room of the Future?

Patients often exhibit a high degree of trust in the health care system and the professionals who inhabit it. The typical patient is not likely to think of himself as 1 of 150 cases taking place that day or even as 1 of 5 or so cases in a particular room, although that is in fact the case. For the patient, the surgical experience is unique or at least rare. For the staff, though, the patient is far from unique and is 1 case among many. The larger environment is always part of their awareness, and accountability for delays or for failing to have the correct equipment in place vies for attention with the patient himself. We expect staff to block out superfluous stimuli, prepare for surgery, gather and evaluate essential data while creating a personal interaction with each patient, all without falling behind schedule. It is only surprising that errors are not more prevalent in these circumstances.

What is the key element that ensures patient safety? The authors would argue that providing staff with timely, ubiquitous, effortless access to accurate, relevant, and up-to-date data is a key prerequisite to a safe environment for the provision of care. One could further argue that the necessary data would include not just patient-specific data but also data concerning system readiness (equipment and supply availability/function), 2 team membership, upstream

and/or downstream system performance or dysfunction, and any other information that could negatively impact the environment of care in any given operating room.

For the purposes of this discussion, which is focused on the potential contribution of Auto-ID technology to the creation of a safer environment of care, data will be defined as all and any information that is necessary or desirable for the individual care provider to have in order to deliver safe, efficacious, and efficient patient care.

In addition to an expanded definition of data, it is crucial to frame any discussion of patient safety in the operating room with the concept of the perioperative period as extending from the first point of contact with the surgeon to discharge from the hospital following surgery. From the first point of contact with a surgeon, at the office, the surgical patient travels along a care trajectory with many points of contact with the health care system.¹⁰ From that first appointment, pieces of data relevant to that particular patient and the planned procedure start to accrue. These pieces of data range from key details of medical history and planned preoperative testing to insurancecoverage information and the identity of next of kin. All the data collected have relevance at some point in the care process, but may be superfluous or distracting at others. Data continue to accrue as the patient progresses toward the actual act of surgery and then beyond, into the postoperative period. Along the care path the patient may encounter the outpatient laboratory for blood testing, radiology for imaging, or a number of other points of care.

A major challenge for operating room staff on the day of surgery is to ensure that all relevant data have coalesced into a coherent and complete record that furnishes all the information necessary to provide this one patient with safe, efficacious care. Given the scope and diversity of input sources and methods, it is indeed no surprise that many surgical patients' charts are incomplete or that missing information is still being collected at the threshold of the operating room. In addition, data are often necessarily collected right up until the time of surgery. Vital signs, blood sugar levels, medications taken or omitted, and fasting status are all routinely collected and added to the chart just before surgery.

This challenge is compounded by the myriad data collection systems in place in most hospitals, some electronic and some paper. In fact, electronically stored data are often printed on paper for the purpose of inclusion in the medical record. If such data exist

Technology	Vendor	Function	Purpose	Deployment
Active RFID with infrared	Radianse	Asset tracking	Commercial	Medical equipment tagging
Active RFID with infrared	Radianse	Patient tracking	Research	Tracking surgical patients across horizons of care
Passive RFID	Mobile Aspects	Inventory control	Commercial	"Smart" inventory cabinets deployed in working OR
Passive RFID	Mobile Aspects	Medication safety	Research	"Smart" anesthesia cart with RFID-tagged medications
Passive RFID	Surgichip	Patient safety	Commercial	RFID label containing procedure, site data placed at surgical site
Passive RFID	Precision Dynamics	Blood-product safety	Research	Blood type data encoded on label on blood bag; checked against RFID patient wristband

Table 2. Examples of Radio Frequency Identification Applications (Commercial and Research) in Health Care

Note: OR = operating room; RFID = radio frequency identification.

but are not present in the chart, the staff must recognize that the data are absent and then locate and include the data in the record, frequently by reducing a digital file to paper.

The potential for flawed data to enter the record is ever present. The safeguards against this are the diligence and attentiveness of the staff and the input of the patient himself (at least until he is rendered unconscious). The best hope for a complete, integrated, and universally accessible medical record, spanning the complete course of care, is the electronic medical record.

If one accepts that communication and information transfer are at the root of most human errors and near misses in the operating room, then the assurance of a complete, accessible and accurate patient record is a key component of any safety initiative. The question is: can Auto-ID technology contribute meaningfully to the association of necessary data with the unique entity that is the particular patient?

Apart from patient-related data, the other key input for the surgical process is the flow of materiel (supplies, instrumentation, and equipment). The increased complexity of surgical procedures has already been alluded to. In today's operating room, it is quite possible to have 17 or 18 trays of instrumentation for a total joint replacement, an everyday procedure. Not only must all those trays be present, but their contents must be complete and each item must be in good working order. The assurance of these goals is the responsibility and task of many staff members—from those who clean the instruments between each use and sterilize them, to those who open the trays and prepare the surgical field just before surgery. Also required in the operating room are

various devices such as electrocautery. These machines need to be present and to be in good working order. They also have associated disposables that will be required during the case. There are many ordinary supplies that are needed in sufficient amounts (sutures, sponges, drapes, and so on). When a joint is being replaced, implants need to be selected according to the patient's anatomy (several may be brought into the room if there is doubt). Antibiotics will be administered, and blood products (including the patient's own, collected in advance, or allogeneic blood) might be required. Without going into excessive detail, it is already clear that the logistics of preparing the operating room for surgery are significant. Of equal importance is the timely presence of the patient and the appropriate staff. Again, the question is: can Auto-ID technology make a positive contribution to assuring operating room readiness? Nagy et al⁹ exhorted researchers to engage the clinical environment in the deployment, evaluation, and analysis of RFID technology to better understand potential benefits and challenges. At the time, the Massachusetts General Hospital (MGH) had developed the Operating Room of the Future (ORF) project as a test bed for these and other technologies.

The title, Operating Room of the Future, is a Rorschach test of sorts, conjuring up different images in the minds of different observers. Operating room of the future projects are many and varied, but the one implemented at MGH comprises a working operating room suite, equipped with off-the-shelf, best-of-breed surgical and anesthesia technology. The room has a unique architecture that facilitates the practice of parallel workflows. There are adjacent spaces for the induction of, and initial recovery from,

anesthesia. This allows the work of anesthesia to progress while the operating room itself is undergoing turnover and set up. Since the inception of ORF, a rigorous outcomes analysis study was planned and implemented to measure the system's performance.^{5,8} Real production expectations have been set for ORF's performance, and they are higher even than normal expectations because the room requires additional human resources to optimize its performance as a unit of production. The RFID technology played a role in the collection of data; staff and patients were tagged with active RFID tags from Radianse for the purpose of monitoring workflow.^{9,10}

In addition to the use of active RFID for the purpose of personnel and patient tracking, we have used the ORF to evaluate the use of passive RFID in inventory management. These 2 applications reflect our interest in developing an environment in which automatic patient identity (and by extension access to associated electronic patient data) and automatic inventory replenishment bring together data and materiel at the point of care, where the providers of patient care are most in need of them.

Active Radio Frequency Identification—Proof of Concept

A proof-of-concept study performed at MGH's ORF project demonstrates a possible patient safety application for active RFID tags.¹⁰ An active RFID tag, from the Radianse indoor positioning system (IPS), was assigned to a mock surgical patient whose tag was then transported to the wrong surgical suite. Because the patient's identity was known and crossreferenced with the surgical schedule, the IPS "knew" the patient had been delivered to the wrong location. Through an interface to the hospital paging system, the IPS sent an alert or page to the anesthesia provider in the true scheduled location.

This is an example of comparing actual care trajectory to a process map (planned care) to detect a process exception—the patient arrived at the wrong location or failed to show up at the planned location. Because the context (patient identity, location, and time) of the planned care was known, the exception was noted and an alert sent. Here we have several key concepts at work. The concept of process exception refers back to the value of mapping care processes. One use of the process map is to overlay context on the map and then use the combined data of the process map and context to create a "smart" environment.

Although the ideal of patient safety is to prevent harm, if error cannot always be prevented, then the next safest option is to identify the error quickly and notify someone who can intervene. This proof of concept effectively demonstrated that active RFID tags can help realize this gain for patient safety. However, in the course of using these tags, the project team made a number of discoveries. The logistics of managing the process of tagging patients were more complex and time consuming than anticipated. The tags are reusable (a disposable tag is in development) and need to be retrieved, cleaned, and assigned to new patients at the end of every day. Tag assignment requires that the tags first be dissociated from the previous patient in the system database. Assignment to a new patient requires manual data entry at a personal computer and provides an opportunity for data-entry error, as the hospital record number is typed in along with the tag identification number. This work is boring and not presently part of any staff member's usual workflow. Research personnel continue to perform the role of tag assignment because the tracking system has not been widely implemented by the hospital.

Keeping the current version of the tag on the patient is also an obstacle. When patients change out of their clothes into a hospital gown, the tag needs to be attached to their gown. The location of the tag on the gown is important; if covered in layers of blankets, the tags do not effectively transmit the infrared signal to the readers.

To collect meaningful data (and to serve as a faithful and reliable patient tracking system) the tags need to be deployed properly. Unfortunately, getting staff to consistently meet these parameters is challenging for a variety of reasons, one of which is that tag management adds work to the patient care process. It is our belief that solutions that add work or complexity for staff are less likely to be successful, even if they have clear benefits from other perspectives. A system-level remedy to this obstacle is needed. Fortunately, a version of the tag that can be coattached with the patient ID band is under development.

A Case Study of Automated Inventory Management

The logistics of supplying all necessary materiel at the point of care in operating rooms is daunting in its complexity. Just as the technology supporting the performance of surgery has increased in range and complexity, so have the associated disposables, implantables, and other aids. Basic supplies have not changed much over time, but are just as important to safe and efficient patient care.

In an effort to improve the resupply of operating rooms, MGH first installed Omnicell inventorymanagement cabinets in the ORF. These cabinets utilize supply-chain software and a touch-screen user interface. They are capable of real-time inventory reports, automated replenishment orders, and even internet-based connectivity with medical supply distributors. For the purposes of the installation in the MGH ORF, the development of "back-end" capability was limited to automated replenishment and inventory reports. As mentioned, it is a fundamental belief of the ORF project team that solutions to operating room problems must require no additional effort from users if they are to succeed. Our experience with automated inventory-management cabinets heavily influenced this perception.

In this instance, Omnicell cabinet users sign-on to the cabinet and select a patient. After selecting the item to be removed from the cabinet, the door opens, and the user pushes a button on the shelf next to the item. This button is associated with a specific item and must be pressed once for each unit of the item removed. The process is reversed for the purpose of returning unused items to the shelf or for adding inventory. Our experience was that the staff was never fully compliant with the button pushes, with the result that there were variances between automatic replenishment requests generated by the cabinet and the real inventory in the cabinet. This resulted in many man-hours of reconciliation every night and sometimes resulted in insufficient or missing inventory. This was not considered a sufficiently advanced solution for the ORF.

Of interest, the anesthesia team in ORF was working with a drug and supply cart using the same technology, with controlled access medication and supply drawers. In that instance the clinicians were dissatisfied with having to sign-on and use selection menus to access medications. The administration of medication by anesthetists in the operating room differs from the practice elsewhere in a hospital. Safety systems, such as physician order entry, are generally not use, and drugs are kept immediately available, often in the drawers of a Blue Bell-type cart. Anesthesia practitioners speak in terms of "drawer-to-vein time" for drugs; response times need to be as short as possible. It was this principle that led to the rejection of the technology by the anesthesia care team.

A passive-RFID-enabled cabinet system, from Mobile Aspects, promised to come closer to fulfilling our goals for effective, efficient supply management in the ORF. Because the system manages inventory through passive RFID labels, the cabinets theoretically remove all requirements for manual compliance with button pushes. The units read the RFID tags on items stored on the shelves and, when an item is removed, the reader notes the absence of the tag. Similarly, the return of items is managed by the monitoring of the RFID tag by the interior of the unit. The ORF project team partnered with Mobile Aspects to deploy the cabinets in ORF as a mutually beneficial experiment. Although the company knew their cabinets were capable of managing a homogenous, high-value inventory, such as cardiac valves or catheters, they had not attempted an installation in a general operating room. In the process, we discovered some valuable lessons in the deployment of RFID inventory management technology.

Before even stocking the cabinets, we began to recognize some challenges. The interior capacity of passive RFID cabinets is significantly smaller than their exterior dimensions would suggest. This is because of the space required for the RFID-reader antennae in the walls and shelves. The limited read range of passive RFID labels means that items cannot be far from the reader, ie, shelves must be close together. This means that a larger footprint is required to store an equivalent amount of inventory; a real problem in the already technology-crowded operating room environment. We quickly realized that not only did the individual cabinets have a bigger footprint than their predecessors, but that we needed more of them.

Tagging the inventory presented another set of issues. Individual items were to receive passive RFID tags, applied in the operating room's materials management area by a staff member. It was quickly realized that typical operating room inventory comprises many small items that may be necessary, but are of less value than the RFID label being applied to them. Furthermore, many items are so small that a typical RFID tag would completely cover the item's descriptive label. An ingenious way to work around this issue was developed by the team; items were placed in small bins and RFID-enabled cards assigned to the bins. The intent was that, when inventory in the bin ran low, the user at the time would pull the card from the bin, triggering the cabinet to reorder the product from materials management. When the product was restocked, the card was to be returned to the bin. This might have worked if it were limited to a small number of items; but by the time a full evaluation of the inventory took place, it was determined that 100 bins of small items would have to be

managed in this way. This approach resulted in the same user-compliance issues that had beset the Omnicell cabinets, but made worse by the fact that users had to attend to the proper movement of RFID-tagged cards representing myriad items. In addition, we had a subset of items that, although valuable, could not be effectively tagged because of their foil wrapping. Foil packaging can interfere with the performance of RFID.

User access to the cabinets was mediated by scanning staff ID badges. After an initial sign-on to make the tag/user association, the cabinet could scan and read the passive RFID chip in a staff person's ID. Possession of ID tags is mandatory for staff, and compliance is enforced by controlled access to the operating room suite; ID badges are the only way to get into the operating room suite, and so all staff have them at work. Thus, the badge-swipe sign-on was a natural extension of their regular habits. This was a significant improvement over a typed password system.

Overall, however, it was decided that passive RFID cabinets were promising, but the current state of technology did not provide a comprehensive solution to managing inventory in the ORF.

From this experience the project team again took several lessons: If a solution increases the workload of staff members, it will probably fail. Automation alone does not guarantee enhanced system performance. There are no failures; only lessons learned.

Having concluded that there is no "killer application" for inventory management in operating rooms, the ORF team at MGH is planning to implement barcode mediated management of supplies in standard stainless-steel cabinets. The nursing staff will not be asked to scan bar codes at the point of use, which adds work and depends on compliance for accuracy. Instead, a nonnurse with no patient care responsibilities will take stock of room inventory with a bar-code reader and manage to preset par levels. Orders will go directly to the materials management and the hospital distributor. The cabinets will be restocked prior to the start of work every day. An old-fashioned solution, but in the opinion of the ORF team, technology does not yet offer a better alternative.

Obstacles to Automated Identification Technology

Apart from issues related to individual products, there are some significant obstacles to deployment of Auto-ID technology. At present there are numerous niche players in the Auto-ID technology marketplace, but no integration. Because different Auto-ID technologies best serve different purposes, an organization seeking to deploy Auto-ID technology might well find itself using a number of vendors, each with a stand-alone system. The real benefit accrues when inputs from different Auto-ID technologies are brought together, in real time, and the resulting data are available to users in the format that they can best use. For example, one can imagine having a combination of bar codes, passive and active RFID (including some wireless installation) deployed for the purposes of tracking patients, supplies, and surgical equipment. Data from all these systems are most powerful when brought together, along with other data streams (operating room schedule, laboratory systems, and so on). A biomedical engineer will have different search priorities from those of a nurse or anesthesiologist. Data must be presented in the fashion most useful to the user.

The burden that would be placed on enterprise computing is considerable. Handling large amounts of real-time data, integrating data streams, and then delivering those data to users where and when they need it is a formidable challenge.

Summary and Discussion

In the ideal operating room of the future, the process of delivering surgical care occurs in an environment that automatically tracks patient progress along a defined process trajectory, aware of the presence or absence of all tools, equipment, personnel, and materiel. The individual patient care map is part of the process map of the larger system that considers each individual surgical process as part of a larger integrated process, the operating room schedule for the day. This comprehensive map extends beyond the traditional boundaries of the operating room and instead incorporates both upstream and downstream points of care, even out to the hospital inpatient floors.

Automatic event detection, comparison to process models, and automatic annunciation of errors to those who can intervene are seamlessly woven into the desired operating room of the future. Materiel and equipment are easily available and usable at the point of care. Any foreign body or substance that can cause harm to the patient (drugs, blood products) or foreign objects that might be retained in the patient (sponges, instruments) are tagged before arrival in the care environment, identified as being present once there, and excluded (or included) automatically, depending on the patient's unique needs.

Technology	Vendor	Function	Limitation
Active radio frequency identification with infrared (IR)	Radianse	Asset tracking	Effective only within coverage area; affected by lead-lined walls; tag location and orientation on asset affects performance; infrared requires line of sight
Active radio frequency identification with IR	Radianse	Patient tracking	Reusable tags need to be collected after use and cleaned; labor intensive; requires manual data entry to unassign tag and reassign to new patient; surgical drapes may block infrared
Passive radio frequency identification	Mobile Aspects	Inventory control	Tags need to be applied to each item; do not work on foil packs; cost prohibitive for numerous inexpensive items
Passive radio frequency identification	Mobile Aspects	Medication safety	Tags too large for medication bottles; bottles fall over, becoming orthogonal to antennae

Table 3. Limitation of Current Radio Frequency Identification Applications (Commercial and Research) in Health Care

The desired hospital of the future is almost alive in its electronic self-awareness. The systems that provide this level of system readiness are seamless, integrated, and almost invisible to the users, while allowing them to respond quickly to process exceptions. They provide real-time information on the status and the location of all the vital inputs of the patient care processes personnel, equipment, materiel, supplies. The enterprise computing systems are able to manage vast amounts of real-time data and offer users explicit and tailored outputs that allow human oversight and management of complex systems. The data collected by these systems, the integration of databases and data streams, the mapping and measurement of workflows and care processes, all combine to inform rapid communication, provide raw material for data-mining that supports clinical decision making and the development of best practices.

We believe that Auto-ID technologies will ultimately facilitate safety and efficiency in surgical care. In our original publication on perioperative systems design, we described a research schema defining 4 broad concepts pertaining to the fundamental goals of systems research in the operating room.² These goals encompass the "why" of perioperative systems design research, and any proposed effort must be critically evaluated with respect to how it impacts them.

User expectations address the needs of the users of the surgical environment, including patients, the surgical

team, and other aligned clinicians. Expectations may range from the emotional (eg, reducing frustration and increasing satisfaction) to the physical (eg, reducing fatigue and stress). In addition, expectations may emanate from awareness of technologic progress in other industrial and cultural settings, eg, use of wireless bar coding in retail, robotics and machine-assisted tasking in manufacturing, customer service models enhanced through connectivity with the internet and so on. On a cautionary note, user expectations may exceed the ability of the technology to deliver. Naive users may overestimate the functionality of technologies such as Auto-ID technology. In addition, when users are exposed to technology early in its development or in a new application, they may not be prepared for bumps in the development pathway, ie, the iterative nature of early deployments, the repeated upgrades and the learning curve, not just of the users but of the developers too.

Readiness pertains to the ability of the perioperative process to be fault-tolerant as well as self correcting and to gracefully accommodate unanticipated events.

Workflow addresses the optimal design and deployment of resources and processes associated with the preoperative, intraoperative, and postperioperative timeline.

Training addresses creating enhanced competency of the perioperative team (individually and collectively) before, during, and after the surgical process.

Auto-ID technology-based systems in the operating room are being developed to address specific user expectations arising from knowledge of RFID and similar technologies. However, our experience has shown that this technology requires skilled operators, unique supplies, and meticulous attention to detail. Thus, our Auto-ID technology supply-management trial deployments had a negative effect on overall readiness, as compared to our standard supply management process. Because we could not provide the significant resources required to meet the needs of the technology and because of immaturity of the technologies themselves, workflow was compromised for minimal gain. Finally, although the training burdens of the new technologies seemed slight and the potential benefits of compliance were apparently large, it proved impossible to use the Auto-ID technology equipment effectively.

The use of Auto-ID technology and RFID systems in a real-world operating room environment allows us to hone our own understanding of their readiness for the operating room of the future. The deployment of cutting edge technology does not guarantee success; the technology truly must fit the problem. Even when a technology seems to offer promise, there are often factors that need to be identified before widespread deployment is undertaken. Examples include management of the active RFID tags used in the ORF at MGH added workload that was not well understood prospectively. With respect to inventory management, even simple Auto-ID technologies, requiring only the push of a button to count inventory as it was removed, posed too much of a barrier to achieve the compliance needed for effective inventory management. Finally, passive RFID promised to be completely transparent to the users at the point of care, at the expense of considerable funds and labor at the point of tagging; but the technology was not up to the task. The ORF proved its value as a clinical test site: knowing the labor implications of a full deployment in advance might either deter implementation of an Auto-ID technology or at least properly inform the planning process and cost/benefit analysis.

In addition, solutions must be developed in close proximity to the end-users—they must be tested in the real world. This places an additional responsibility on those of us who promote innovation. Project leaders learned the importance of developing realistic expectations ourselves and of then transmitting those expectations to the actual users. This illustrates the

enormous value of being able to experiment in a real working operating room but of also limiting the disruption to a single operating room. The ORF of today is not truly the operating room of the future, but instead a crucible, grounded in the present and looking forward to the future, used by today's clinicians to develop and test solutions that will work in the operating room of the tomorrow.

References

- 1. Institute of Medicine. *To Err is Human: Building a Safer Healthcare System*. Washington DC: National Academy Press; 1999.
- 2. Sandberg WS, Ganous TJ, Steiner C. Setting a research agenda for perioperative systems design. *Semin Laparosc Surg.* 2003;10:57-70.
- 3. Gage JS. Anesthesia information management systems. *American Society of Anesthesiologists Newsletter*; June 2002;66. Available at: http://www.asahq.org/newsletters/ 2002/6_02/gage.html. Accessed January 18, 2007.
- 4. Satava RM. The operating room of the future: observations and commentary. *Semin Laparosc Surg*. 2003;10:99-105.
- 5. Sandberg WS, Daily B, Egan M, et al. Deliberate perioperative systems design improves operating room throughput. *Anesthesiology.* 2005;103:406-418.
- 6. Stahl JE, Egan MT, Goldman JM, et al. Introducing new technology into the operating room: measuring the impact on job performance and satisfaction. *Surgery*. 2005;137:518-526.
- 7. Stahl JE, Rattner D, Wiklund R, Lester J, Beinfeld M, Gazelle GS. Reorganizing the system of care surrounding laparoscopic surgery: a cost-effectiveness analysis using discrete-event simulation. *Medical Decision Making*. 2004 Sept-Oct;24:461-471.
- 8. Stahl JE, Sandberg WS, Daily B, et al. Reorganizing patient care and workflow in the operating room: a costeffectiveness study. Unpublished data.
- 9. Nagy P, George I, Bernstein W, et al. Radio frequency identification systems technology in the surgical setting. *Surg Innov.* 2006;13:61-67.
- 10. Strauss A, Fagerhaugh S, Suczek B, Wiener C. *Social Organization of Medical Work.* New Brunswick, NJ: Transaction Publishers; 1997:8-39.
- 11. Levine WC, Meyer M, Brzezinski P, Robbins J, Sandberg WS. Computer Automated Total Perioperative Situational Awareness and Safety Systems. In: Heinz Lemke, ed. *Computer Assisted Radiology and Surgery: Proceedings of the 19th International Congress and Exhibition Berlin, Germany, June 22 - 25, 2005*. London, UK: Elsevier; 2005: 856-861.
- 12. Sandberg WS, Hakkinen M, Egan M, et al. Automatic detection and notification of "wrong patient-wrong location'' errors in the operating room. *Surg Innov*. 2005; 12:253-260.