nursing is essential, it is not sufficient. There must be a dedicated surgical leader. Often this is the chief of surgery or at minimum a senior associate who has the imprimatur of the chief. In short, success must emanate from the top of the surgical staff. A surgical leader of the suite is critical to ensure functionality. The surgeon needs equivalent leaders in anesthiology and nursing to advance the agenda across all three disciplines. The leader in turn needs to obtain broad consensus of all surgical chiefs / disciplines plus anesthesia, and nursing leaders. The concept is that if the surgical leader clearly spells out a vision the nurse manager can then organize to accomplish it. The surgical leader and his/her anesthiologist and nursing colleagues can then drive the process.

The surgical leader needs leadership skills, visioning ability and "standing" to be effective. The surgical leader must be a champion of specific activities such as:

- JCAHO Universal Protocol ("time out")
- No patient in OR without site marked by surgeon in advance
- Appropriate / equitable allocation of block time
- Appropriate behaviors (Asleep patients foster opportunity for less than ideal behaviors)

The surgical leader with the help of anesthiologist and nurse leaders must assemble a team of engaged, incentivized (not necessarily with money) staff and physicians. Engaged and energized people must be the initial part of the solution.

The leader must interact with all levels of the team; this is no place to be focused on hierarchy. (There is a story about the cardiac surgeon, Dr Michael DeBakey, which illustrates the leader's concept of teams and teamwork – A reporter wanted to interview the famous surgeon. DeBakey would only make himself available at 6am but gave a 30 minute pleasant, engaged interview. At 6:30 he left his office with the reporter and, saying goodbye, turned and walked down the hall to the OR suite, stopping along the way to talk to a housekeeper who was mopping the hall. They talked animatedly for about three minutes. The reporter, watching from a distance, was fascinated that the "great man" would talk to a janitor. After DeBakey went into the OR Suite, the reporter went up to the housekeeper and asked what their conversation had been about. "Me and Dr DeBakey, we take care of the patients," he answered. Obviously, Dr DeBakey understood the importance of small gestures to keep the entire team focused on the true agenda of patient care.)

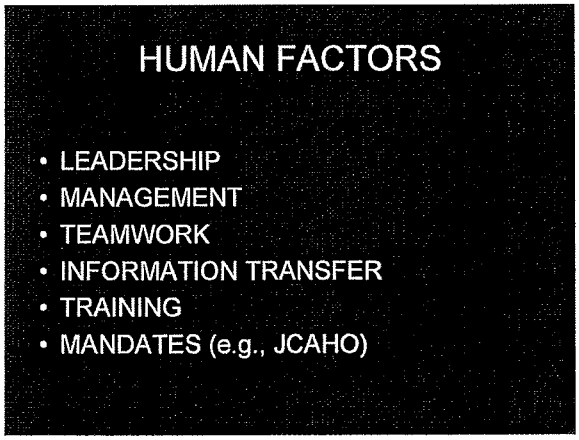
The leader must set the tone that all of the needed data on each patient must be present in order to start the case. There needs to be no surprises (except those discovered during the operation that no amount of currently available data could have foretold.)

Clear leadership will set the tone for the "big picture" and will get passionate people involved in resolving problems. The leader must establish a culture of "caring." Staff will quickly recognize when this is the most basic mission, and will respond accordingly.

The effective leader will, indeed must, disrupt the hierarchical culture of the OR. This requires a strong champion with "standing" in the OR "community." The cockpit example may help him/her sway colleagues. (For years, the cockpit was the height of hierarchy. The captain was the boss and the copilot and navigator accepted the captain's experience and position; challenging the captain's decisions was rare, at best. But studies showed that many airline accidents were the result of errors that someone else in the cockpit realized but did not communicate. Over time this culture has changed so that challenge is not only tolerated but expected with resultant much improved airline safety.) To change the culture, the leader must temper those with "strong" personalities that can become abusive and or prevent other team members such as nurses, technicians or residents from speaking up with safety concerns.

Management is different from leadership and equally critical if a patient safety agenda is to be effective. While leadership is about creating a vision, getting others to buy into the vision and ultimately engaging everyone to participate in achieving the vision, management is about putting the vision into action. Management focuses on planning, staffing, organizing, actions and accountability.

All too often, there is no clear management in the OR. Who is explicitly in charge? Generally, the chief of surgery is not interested in fulfilling a management role nor is he or she trained in management principles. It usually falls upon the Director of Perioperative Services, who may or may not have true experience and training in management. Clarity about management roles is critical to OR functionality and to a program of patient safety.



Hospital managers need to overcome the tendency to not visit the OR suite because of the need to "gown up." The OR is too important and too vital to ignore or manage from afar. Hospital management must also recognize the value of the OR and hence the value of physicians and physician's time. If materials (e.g., sterile drapes for IV insertion) are readily available, physicians will use them. If not available, the physician will be frustrated and will "move on" with a less safe approach. In short, if safety is to occur, it must be "easy" to accomplish.

It is advantageous to have a surgeon use the same OR regularly and work with the same team members. This may be less efficient for the hospital but it is far better for safety.

To summarize OR management, with clearly defined surgical leadership and a clearly committed hospital senior management, it becomes possible for the senior nurse to effectively manage the day to day operations of the operating suite.

Teamwork is likewise critical to patient safety yet a true team does not exist in most ORs. Rather there are three disciplines working together for a common good but not really working like a team. They need to become a team; this requires specific training and culture development. One approach may be to utilize the specifics that have been developed in team-creating (e.g., HPTI) such as using the baseline "safety aptitude" test and then working on the demonstrated deficiencies.

There is a need to establish the concept that anyone (not just the surgeon) can call a "stop" (ala the Japanese auto industry when anyone on the line can pull the stop cord if he has a concern) if one believes something is amiss (or, ala the aircraft carrier where a flight deck junior person can call off a landing if he feels it is unsafe.) Miller writes (The Making of A Surgeon in the 21st Century,2004) that he learned when the scrub nurse handed him an instrument that he had not asked for, the proper response was not to yell but to figure out why she did so – because most of the time she was correct and he had missed something.

It is imperative that those who work outside the OR but are critical to OR functionality (supply chain, biomedical, environmental systems, information technology) have a true understanding of their essential role and how the OR is fundamentally different form the rest of the hospital's activities. Recognizing that these staff members rarely enter the OR suite, one first approach in this regard is to be sure they gown up and tour the OR on a regular basis.

The personality mix of the many OR participants may appear difficult to deal with but this should not be ignored or "fought," as is often the case. It is important to recognize the "surgical personality" and to embrace its positive qualities. The surgeon needs to be decisive – and perhaps is more than a little egotistical – but then the surgeon accepts an awesome responsibility in putting a patient on the table and operating upon them. Hence safety approaches should not attempt to change the surgical personality but to find ways to maximize his or her knowledge and expertise.

Perhaps an analogy to an orchestra is appropriate. All play different instruments but follow the same sheet of music – and play in harmony. For the orchestra to be effective there is the need for a team, teamwork and communication. And there is the need for equivalent (high) skill level for each participant.

Leadership, management and teams all need an environment of safety to be effective, and vice versa. The hospital may have already make progress on the culture of safety through other activities such as a medication error program. But recall that the OR is fundamentally different than the rest of the hospital. On a regular unit, a physician writes an order which the nurse can followup at a later time. In the OR, the team must work

together concurrently. This requires a different level of teamwork throughout. In part, this emphasizes why it is better to have consistency of team membership so assure better communication and greater safety.

Creating an environment of safety requires a champion, generally the surgeon leader. But all disciplines must buy in. All too often, various disciplines have a long standing culture that professionals do not make mistakes; and when they do, they should be "punished." Punishment may mean being sent to a training program, notation in a personnel record, or even reporting up to a licensing board. As long as this attitude prevails, any attempt to collect data on errors, no matter how many promises of anonymity are given, is fraught with failure.

Read Back is a simple but effective means of reducing error. In the cockpit one crew member announces a setting to be made or an instrument reading; another crew member "reads it back" to validate agreement before proceeding to the next steps of preparation. In the Navy, the Line Officer on the bridge may command "left 5 degrees." The Helmsman responds with "left 5 degrees" to indicate that he heard properly and the Line Officer then approves with "Aye, aye." Once the new setting has been actually made the Helmsman cries out "we are left 5 degrees." This constant read back is considered normal yet essential routine in the cockpit or the bridge; it needs to become so in the OR where it is definitely not the culture today.

Near Miss and Error Reports are done anonymously by pilots to the Federal Aviation Administration. The FAA collates the information looking for patterns. If a type of error shows up consistently, a new system is considered to help detect the error or eliminate the opportunity for its occurrence. Key to the effectiveness of this program is confidentially. In another country a similar system was introduced only to have confidentiality breeched. Pilots immediately stopped submitting data on near misses and no amount of persuasion could get them to reconsider. But in the USA it has been an excellent program with a long history of positive results. A similar system is needed in all ORs and should be considered" institutional learning," not just "counting errors."

Variation Reduction is the touchstone of the Deming concept for quality management. The Operating Room however has immense variations and a staff, particularly surgeons, that actively avoid standardization. Agreeing to a common set of instruments or implants by all surgeons doing the same procedure is an act of reducing variation; this needs to be emphasized – not as a cost reduction measure (which it is) but for improving quality and enhancing the safety of the surgeon's individual patient.

Information transfer is critical to safety. The airline cockpit changes that have occurred over the past fifteen years can serve as a good model of the changes that are needed in medicine in general and the OR in particular. Completing a thorough checklist to ensure that the aircraft is ready for flight became the norm in the 1930's and "read back" has long been the standard operating approach yet errors continued to occur, some with fatal

consequences. For years, no one felt empowered to challenge the decisions of the captain; he after all was more senior and more experienced. (The junior copilot or navigator also did not want to risk humiliation nor an adverse report by the captain regarding promotion.) But close evaluation demonstrated that many accidents could have been averted if the copilot or navigator had spoken up when an error was perceived. Changing this attitude in the cockpit so that the copilot feels empowered to question the captain has lead to a much safer airline industry.

As with the cockpit, everyone in the OR needs to feel empowered to speak up. Often activities out of line of sight of the surgeon are unknown to the surgeon and so must be voiced by other team members. Similarly, in laparoscopic surgery, all team members can see the same monitor; but the nurse and anesthiologist may "see" different elements on the monitor and need to report them to the surgeon.

The absence of critical/key information can be improved with technology or modifications to current technology (see below.)

Training of staff, all staff, is essential to patient safety programs. The case can be made that more registered nurses are needed in the OR. However, many if not most nursing schools have long since stopped teaching OR nursing; a sort of negative recognition of nursing's role in the OR. The result is that the average age of OR nurses is now about 48 years and rising. The response has been to develop surgical scrub tech positions. These are well trained and invaluable individuals but they are not invested with the fuller background and education of the registered nurse.

Surgical and anesthiology residents need to be trained in order to take their place as the next generation of health care providers. But it is time for a change in the system. Not just assurance that the resident has had some sleep but also that he or she is prepared to be in the OR. The OR leadership team needs to prescribe that the attending surgeon and anesthiologist must be in the room at all times, not just for the "critical" elements of the case. It should no longer be acceptable to honor the adage that "a resident makes the case take longer." The resident needs to be trained and be ready to assume his or her proper role in the case from the start. A good way to begin is to emphasize the use of simulators (below.)

Surveys have proven useful to understand the staff concerns about a specific environment such as the operating room. Asking "Would you feel it safe for your loved one to have surgery here?" gets to the root perception by staff of an institution. The question, "What is the likely next thing we will do the hurt a patient?" opens a window on staff perceptions about specific patient safety concerns in a unit such as the OR.

Mandates are arguably the "stick" that has propelled patient safety agendas in America's hospitals. The JCAHO and other regulatory bodies will need to be increasingly clear and directive about the specifics of OR and Perioperative safety. The JCAHO mandate, effective July 1, 2004, to have the surgical team discuss the patient (identification),

procedure and site immediately before initiating surgery has forced at least some dialogue when often none occurred before.

Technology Factors and Patient Safety

Technology factors can and will have a major impact in reducing errors in the OR. However, technologies can become a burden and even lead to more errors if the basics (environment of safety and human factors) are not addressed first. The OR needs an active culture of safety and must have leadership and basic management operational systems in place to which technology can then be a very valuable overlay.

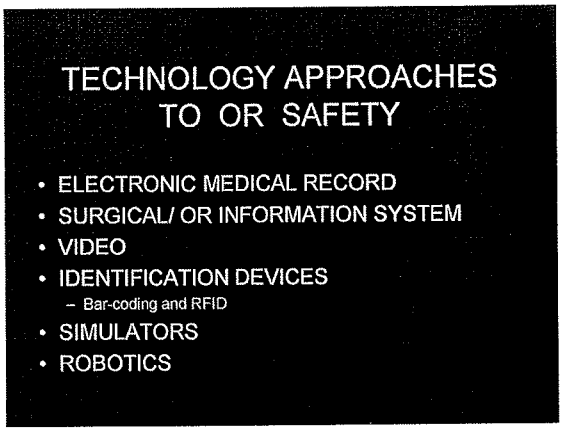
There is a revolution in medicine occurring as a result of digital technology. The conversion of information into digitized form has the opportunity for major advances in patient safety. Consider the digitized total body scan that today can present the physician with remarkably clear anatomic data, including in three dimensions. Soon that scan will include physiologic and possibly even genomic data as well. Efforts at patient safety must recognize and embrace these advances.

As an introduction to the power of technology consider that a new device will allow infra red light to detect veins followed by exact insertion of needle or catheter without puncturing the far wall of the vein. This technique will assist the anesthiologist and benefit the patient. Similarly, control of pain with automatically released anesthetics using carbon nanomaterials can give prolonged duration of relief yet reduced cardiovascular and central nervous system toxicity.

Even videogames have proven too be valuable to the surgeon! "Warming up" before surgery with some of the common video games leads to increased skill levels during surgery (sort of like warming up on the golf driving range before a match.) The residents that regularly play video games have been found to make about one third less errors and complete tasks about 25% faster on a standardized surgical skills test with a simulator.

Specific Technologies

A good place to start with technology assists is in patient identification and all that the term entails and encompasses. This term is used to cover all of the information about the patient that is necessary to complete the surgery in a safe, efficient manner. Thus includes the patient's identify, planned procedure, site of procedure, patient's medical history with allergies and other important medical information such as cardiac, pulmonary or renal disease and medication history. It also includes the results of the preoperative evaluation by surgeon and anesthiologist,



including laboratory studies and consent forms. Further it includes the surgeon's preference list for the specific procedure, including instruments and equipment needed. This list becomes more or less complex depending on the patient and the type of surgery. The otherwise healthy patient having a minor lipoma removal needs less evaluation than an elderly ill individual undergoing a Whipple procedure. The data collection process must recognize these differences and "push" the data into the system rather than waiting for a person to "pull" it in.

Patient identification must begin at the surgeon's office and be followed up at admission. It must include the patient's medical record number and hospital number (if different.) Bar coding or RFID technologies can positively identify not only the patient but everything that comes in contact with the patient including the surgeon, anesthiologist, scrub tech, instruments, equipment, and supplies and medications. ID technologies can be used to help assure the proper site and side is chosen for surgery; that the procedure is as planned , that the drugs are for this patient, that the consent has been signed and recorded, that allergies are accounted for, and that medical problems (e.g., cardiac and pulmonary) that are known are actually known in the OR. RFID technology coupled to wireless technology could establish where a patient is located, which patient is in the OR, and collate the patient ID to the patient's procedure, site, required instruments and equipment. The electronic medical record should be accessed with RFID/wireless such that all medical data are available, including that collected at the surgeon's office visit, the anesthiologist's preoperative evaluation, PREP center data collection plus all images, lab data, etc. It should also be able to access important historical information such as difficulty with prior intubation or prior anesthesia.

The electronic medical record (EMR) will become standard over the years to come. Medicine has lagged other industries in adapting digital record keeping albeit that the medical record is more complex then, say, banking. Much data is directly generated digitally today, e.g., imaging with CAT or MRI scans, results of many laboratory tests, and some transcribed dictations. Other data such as that from monitors must often be hand entered into the medical records, either in written or digital format. Most notably, health care professional notes are usually still maintained in a handwritten format. But this is changing and within a few years most if not all medical data will be digital. Younger physicians may become users more readily than more senior attending surgeons and anesthiologists but routine use by the nursing staff is often the best role model for physicians. Physicians need one-on-one training in use of the EMR, over time with lots of repeats. Time will make or force a change but critical to success is intensive, one-on-one training and continued support until the professional is comfortable with the new system.

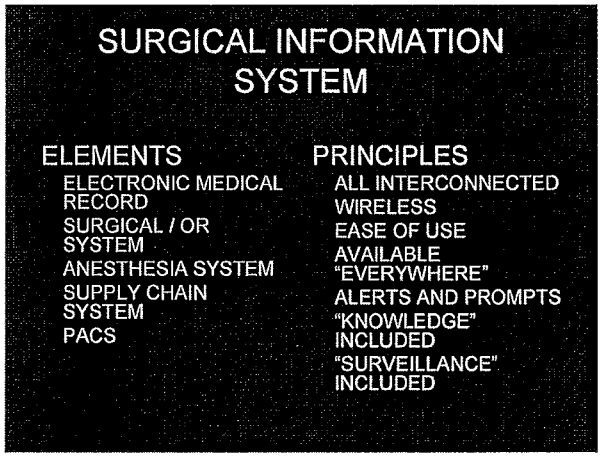
We are approaching a new age in the availability of the EMR. But it is also the opportunity to convert from the passive (i.e., recording what has happened) medical record of the past to an active record. In other words, the opportunity exists to use the digitized data for processes such as surgical simulation, modeling or instructions to robotic assistants.

Further, the EMR can hold baseline data of a much greater utility than the long established "History and Physical Examination." A total body scan, especially as they are continuously improving, for example, serves as a unique baseline prior to the development of cancer or heart disease or prior to trauma.

Finally, the EMR must be readily accessible at all times and in all places. Ideally, each person's EMR should be in their procession (ala the Army's Personal Information Carrier or PIC) or available with a proper password from all sources via the Internet.

For practical purposes in the Perioperative setting, one needs to be able to access all of the patient's data, in a digitized form, from any source (surgeon's office note, preop evaluation record, radiology department, etc.) on demand in the OR, PACU or elsewhere. Such ability will have an immediate salutary impact on patient safety.

Key to effectiveness in the OR or perioperative environment overall is information; information about the patient, the instruments, the equipment and the staff. All of this information needs to be present, coordinated and prioritized. Surgical information systems should be a significant help in aiding patient safety. Some of the key elements that will be needed in today's systems are integration, "intelligence," update ability and prompts. The medical record must be integrated, meaning that the entire patient–relevant material must be available, by anyone, at any time. Preferably the record will be electronic, but this is a second step after addressing the issue of integration. The system will be particularly useful if it is "intelligent" with a system that allows manipulation of data to assist with the surgical task at hand. The DOD "smart" card (personal information carrier) may be the prototype of this function. The surgical information system must have the capability of storing the specific plan of care for this specific patient with the surgeon's preferences for equipment, instruments, even choice of music in the OR. The system needs to be able to be updated by any (authorized) person, at any time, from any location. It should store and manipulate patient protocols for the care plan based on the patient's specific procedure. As any deviations occur (and they will!) there must be a mechanism to alert staff and allow for an update to the plan. Built in prompts to alert the staff to do something (give a prophylactic antibiotic) or to watch for something (blood sugar) will improve staff performance. Finally, the system should be able to prompt the leadership as to whether the surgeon is credentialed to use a device (e.g., laser) or the scrub tech is familiar and has experience with the device to be used today in this specific case.



The Surgical Information System needs to integrate with the EMR. Surgical information systems, in general, tend to have been created to assist the needs of hospital management with the surgeon, anesthiologist and nurse needs being secondary. As a result, professional staff often "reject" or "rebel" that the installed system does not serve their immediate clinical needs such as documentation and information presentation. Commercial vendors will need to address these deficiencies. Further, the professional staff need help to avoid data overload. The system needs to prioritize so that all the data needed to make a decision is available but other extraneous data is segregated away.

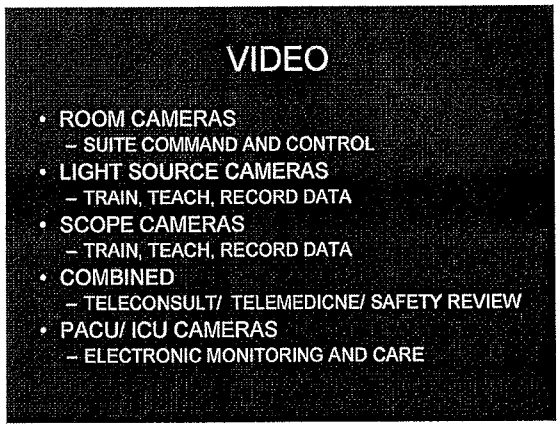
A related technology is for operative note/ documentation of the case. The current approach is to dictate a note following the case but a better approach is to have voice activation or pedal activation of the dictation system so that the surgeon can do the note as the case progresses.

Just as computer physician order entry is entering the general hospital, so must it enter the OR for medication ordering, monitoring and recording. The situation in the OR is somewhat different, but even more critical, since the anesthiologist serves as the prescriber, preparer (usually a pharmacist elsewhere in the hospital) and administrator (usually a nurse elsewhere) of drugs. So the anesthiologist needs added assistance since he or she does not have the other professionals involved as a form of check and balance

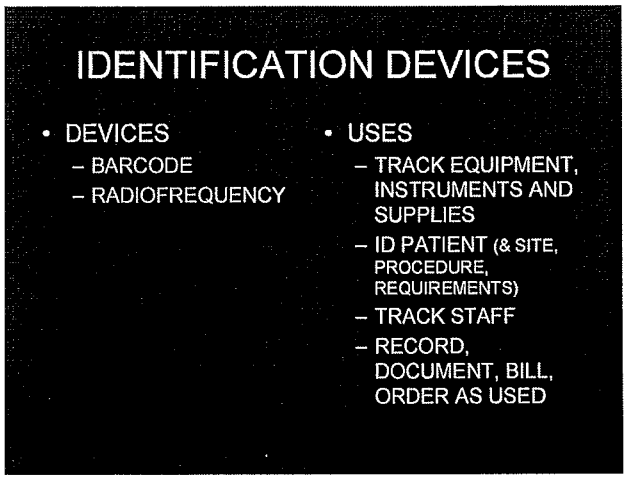
There are other technologies associated with the surgical information system that can improve patient safety. Among these are: Measurement of the pH of the air emanating from the endotracheal tube (yellow or purple) to give an indication of carbon dioxide levels. Intraoperative gas analysis of oxygen, nitrous oxide or volatile gases. Automated blood pressure cuffs that relieves the anesthiologist of a task and frees up time for attention to the patient. Monitors with alarms, provided they can be integrated and ergonomically positioned, should be created for detecting pressure on the patient's limbs or nerves or for detecting electrical current leaks that could harm the patient.

Alerts can come to the OR professional in many ways. One is an alert built into the surgical information system indicating that a particular patient is a risk, for example, of deep-vein thrombosis. The alert is based on a predetermined review of all risk factors and the system then offers advice on dealing with the potential issue. Such systems need to require that the physician respond to the alert (he or she can decline to act but must indicate awareness of the alert.)

"A picture is worth a thousand words." Video technologies can be useful in a variety of ways. A camera in the light source allows the anesthiologist and scrub tech/nurse a much improved view of what is going on in the operative site; as a result they can be of more assistance. A surgeon can call a colleague to look in on a difficult case without the need of traveling to the OR and scrubbing in. Video of the OR itself can assist the medical and nursing management team to best utilize the ORs in a suite, i.e., command and control. Similarly, a video white board allows all those in the area to get a quick "take" on what is happening in any OR. Video information on the condition of a patient in the PACU or ICU can be sent in reverse to a surgeon or anesthiologist in the OR who recently operated upon that patient and who now has a problem. Video is much better than just a phone call with a verbal report. Finally, video will augment the training of residents and medical students as it will allow them to be in a distant conference room with an instructor rather than in the "third row" in the OR where they cannot see what is happening well. Finally, video records of the entire case incorporated with the electronic medical record and the voice activated dictation will allow for in depth evaluation of a case after the procedure is completed. This will allow for teaching specific issues or techniques and for root cause analysis of errors or near misses. By analogy, every Monday, each NFL team critically studies the videos of yesterday's game to detect errors and plan improvements.



There is a good precedent for distant monitoring by video of patients in the ICU setting. The founders of VISICU, Johns Hopkins faculty, demonstrated that distant video monitoring by an attending intensivist of a medical/surgical intensive care unit at an academic medical center with in house resident coverage led to significantly improved care, fewer errors and reduced length of stay. This technology allows the senior physician to monitor multiple ICUs at one time. In short, it multiplies the physician capability. For the future, robotics will further extend these capabilities.



Bar code and RFID technologies will have a major impact on the "supply chain." This will be a revolution in the OR just as it is in Wal Mart. Now there will be the ability to locate equipment, instruments, and devices no matter where they may have gotten within the hospital. Further RFID on patients and staff will mean that the patient's whereabouts with be known as will that of doctor and staff.

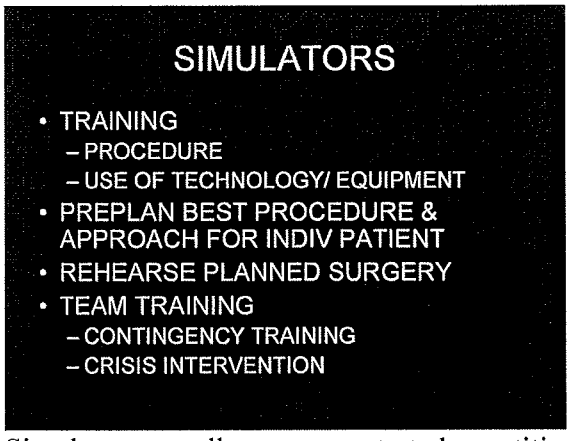
Education and training can make good use of technology. Simulation devices can help not only with specific task training but also with team training. The time is fast approaching when a surgeon will review the planned case on a simulator before surgery on a particular patient. The surgeon or trainee can practice the key portions of the operation with patient specific data built into the simulator so that it becomes practice for "Mrs. Jones cholecystecomy" rather than general cholecystectomy practice. Certainly, the resident should be trained on the simulator until he or she has demonstrated competence sufficient to take the step into the OR. The OR should no longer be the place to learn the basics; these should be mastered on a simulator.

Surgeons, like everyone, develop a "perception" of issues and also of errors. Simulator training can overcome these psychological perceptions and help the trainee to recognize the needed change in approach.

Simulators are still in their infancy relative to, say, the airline industry but various models are available and can be put to immediate use. Use will beget more use and more use will drive insistence on routine use. Hospital management will need to recognize the critical importance of simulation and fund the simulation laboratory appropriately.

Simulators can greatly assist with team building. It can enable a group to learn how to respond as a team to various situations that might occur in the OR or following surgery. Dr David Gaba has pioneered the use of simulation to teach team crisis response during surgical situations. This mirrors the use of aircraft simulators that test the cockpit crew's reaction to various virtual emergencies.

Training in surgery is less to develop expertise as it is to develop "adequacy." A few surgeons will become true experts at a few procedures given their interest and repeated efforts. But most important is to assure that every surgeon is "adequate" at every procedure for which he is credentialed. Good training allows the surgeon to know his weaknesses and overcome them; to know when there is a problem and how to overcome it. Simulation has great potential to assist a surgeon become "adequate" at each task by allowing practice on patient-specific parameters built into the simulator from registering the patient's digitized images, etc. This, then, graduates to specific practice for a specific patient from general practice on an "average" patient's data in the simulator.



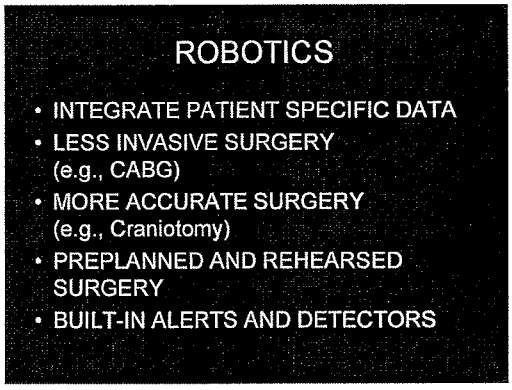
Simulators can allow a concentrated, repetitive experience because the "student" need not do all of the peripheral (yet vital with a real patient) work needed to prepare a real patient. He can get immediately to the portion of the procedure for which he needs

practice/training/evaluation/feedback. In a "team setting" he can be "lulled" by conversation about a sports event, etc. while quietly and unnoticed the blood pressure is falling due to undetected blood loss.

For simulator training to be successful it must be accompanied with a proscribed curriculum that includes milestones of learning and measures of improvement. These become the incentives for a surgeon or trainee to use the simulator – it offers "value."

The opportunities for simulation and simulators to enhance patient safety in the OR are thus legion. The problem is that today, only a few hospitals have any semblance of a simulator laboratory. This will need to change and hospitals will need to allocate the needed resources. A key role of TATRC will be to create the momentum for simulation requirements and outline the infrastructure required to be successful.

Robotics- Surgery began to change dramatically with the introduction of the laparoscope about fifteen years ago. This created a disconnection between the surgeon and the tissue and introduced digitized images which could be fed to computers. More recently has been the introduction of robotics to the OR. Today's' surgical robots use industry robotic technology to create surgical assistants which are under the complete control of the surgeon via computerized visualization and direction. Other robots are under development as replacements or assistants to the scrub nurse or technician and still others to serve as implementers of the supply chain for drugs, instruments or supplies. It is not far fetched to predict that there will soon be a merging of digitized anatomic imaging (CT, MRI, PET, ultrasound, etc) with simulation by the surgeon to establish the most appropriate approach to surgery for a specific patient with a specific problem. This will then be followed by transferring the precise surgical plan for this patient to the surgical robot for the patient's operation. The opportunities for patient safety are obvious – a surgical plan developed with the patient's own anatomy as the driver.; a "practice run" on the simulator to "perfect" the best approach, and then the precision of the robot in the delivery of surgery – all the while under the surgeon's control. Similarly, the robotic "scrub tech" will not miscount instruments at the end of the case and the logistics robots will deliver the precise medications, instruments and supplies needed for this specific case.



Safety Programs of Major Organizations

A survey of many organizations otherwise involved with patient safety indicates that relatively little is being done with regard to OR or Perioperative safety compared to safety issues elsewhere in the hospital. The author believes that this is largely related to the paucity of data available on the perioperative setting, the fact that the OR is insular (no one goes there except those who work there because of the need to gown, etc), and

the fact that no one has written much about the subject to generate interest or alarm as has been done with, say, medication errors. Further, there is limited "integrated" work; each is a separate "project" without being overtly part of a whole. That said, a number of organizations have extensive programs in OR related safety. Unfortunately, since the various organizations are independent, there has been limited interorganizational activity or planning. Just a few of the many organizations with safety programs are mentioned below:

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) – JCAHO has a very active program related to patient safety. Its mandates are to a large degree credited with getting hospitals focused on the issues of patient safety. Absent these mandates it is questionable how much real effort would have been devoted to patient safety in the past few years. On July 1, 2004, JCAHO mandated a new universal protocol generally known as the "time out." In this protocol, before the operation actually begins, there is to be a pause, lead by the surgeon, in which the surgeon, the anesthiologist and the scrub tech or nurse all agree on the patient, the site of the surgery and the plan of the surgery. All must agree before the case proceeds.

This is a major step; again a mandate that must be followed by all in order to maintain hospital accreditation. Surgeons, anesthiologists and nurses generally approve of this step and have rallied to its usefulness.

Thus far, this is the only major new mandate from the JCAHO related to OR or Perioperative patient safety. That said JCAHO has multiple long standing protocols related to monitoring patients in the PACU, monitoring patients after conscious sedation no matter where it occurs in the hospital, etc. Indeed, over 50% of JCAHO standards are directly related to patient safety, e.g., medication usage, infection control restraints to name but a few.

JCAHO is committed to improving patient safety and uses its accreditation process as a lever to achieve that goal. JCAHO believes there are five key elements:

- identify error
- root cause analysis of errors
- compile data on error frequency and root causes (a critical step in order to set priorities
- disseminate this information with intent that organizations will change their systems
- access effectiveness of new processes on a regular basis

JCAHO's National Patient Safety Goals were promulgated in 2004 and include: ensuring the identification of patients, improving communication, enhancing the safety of medications and infusion pumps, reducing the risk of infection and preventing patient falls.

JCAHO Sentinel Event policy – Each accredited organization is expected to detect sentinel events (those that actually or potentially cause serious harm to a patient,)

complete a root cause analysis and report to the Commission. JCAHO collates information and reports regularly to all hospitals lessons learned, such as avoiding high concentrations of potassium chloride in patient care areas.

Association of Operating Room Nurses (AORN) – AORN has many projects and programs related to patient safety. There are some joint programs with the American College of Surgeons being considered.

American College of Surgeons (ACS) – The College supports the JCAHO efforts, has published books on safety, and has a number of committees and task forces dedicated to safety. Further, it has spearheaded the study of surgical outcomes as related to preoperative parameters, the National Surgical Quality Improvement Program (NSQIP).

Anesthesia Patient Safety Foundation (APSF)– Anesthiologists have focused on safety for many years and, as a result, have brought down anesthesia mortality rates dramatically. As a result, many would consider anesthesia today "six sigma." This has come about first by reviewing closed cases with problems, then addressing near misses and also by eliminating explosive gases such as cyclopropane. The Foundation [APSF] serves as a clearing house for safety and quality issues in anesthesia.

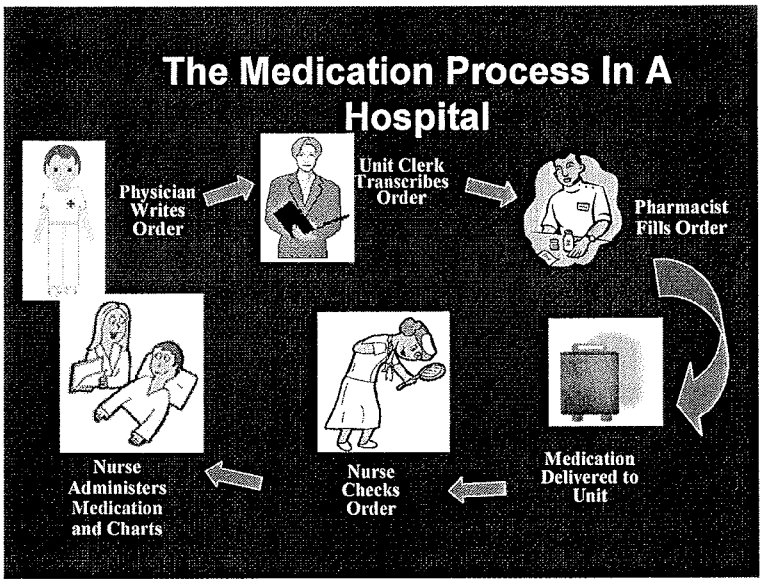
University Hospital Consortium (UHC) – UHC began an aggressive patient safety program about three years ago consistent with the needs and desires of its constituent hospitals. Included in this is an internet based system for reporting errors and near misses. The system is used in the perioperative setting as well as the rest of the hospital and has developed some much needed and useful information. However, given a lack of expressed interest by the constituent CEOs, there is no organized program within UHC related specifically to the issue of error and safety in the OR or Perioperative patient safety.

Health Care Advisory Board (HCAB) – The HCAB has done extensive work on medication safety and safety issues overall but nothing focused on OR or Perioperative patient safety. They find that their constituent hospital CEOs and COOs and even the VPs of Quality are not currently interested in OR safety and hence they have not engaged their work force on this area. They do find that perioperative managers and some surgeons have asked for help in addressing OR safety.

Agency for Health Care Research on Quality (AHRQ) – AHRQ has an extensive research program devoted to patient safety. Its first National Healthcare Quality Report was recently released for 2003. In its pursuit of quality, the report focuses on five major goals:

Reduce Medical errors
Increase evidence-based practices
Improve the systems for reporting errors
Encourage the use of electronic medical records
Improve patient protections

Medication Error Prevention as a Model for a Program in Perioperative Safety



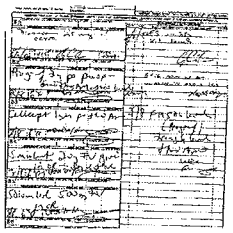
Since medication errors are the most frequent errors made in the hospital, much attention needs to be placed here. The process of medication delivery has three separate components, each with multiple subcomponents. First, the physician orders a drug for a patient; then the pharmacy processes the order and finally the nurse administers the drug. In actual practice, there are many steps and also multiple checks and balances to assure that errors do not occur.

Ordering

Physicians are famous for apparent poor handwriting. Whether or not the injunction is true, the problem accounts for a large number of errors or at least the need to check with the physician for clarity. In some hospitals, the orders are transcribed by a clerk for transmittal to the pharmacy. The clerk may be very careful but is not trained in drug therapy so an error from misreading handwriting is common. Generally, a nurse is to cross check the transcription before it is sent off but during busy times this may not occur or the nurse may misread the handwriting. Some 60% of all medication errors occur during this set of steps.

Physician Order As Received At Pharmacy

Paper Medication Order

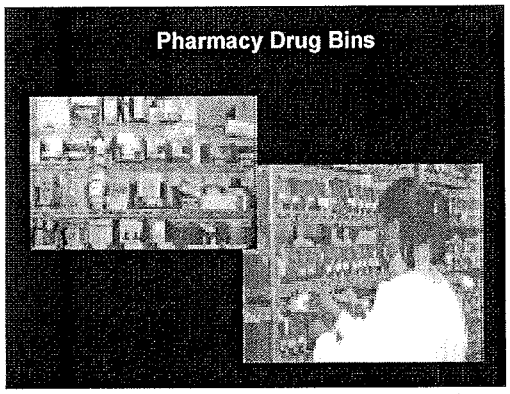


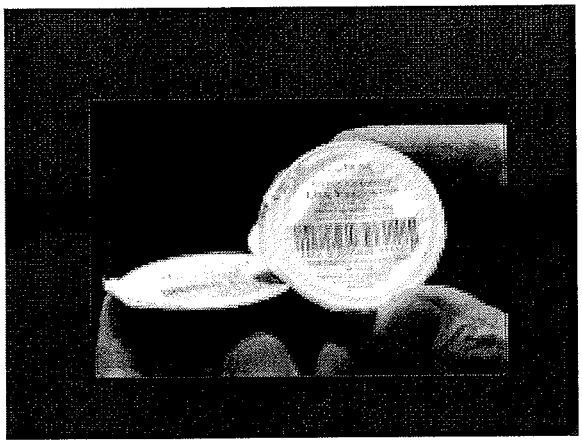
Preparation in the Pharmacy

Today's hospital pharmacy includes many checks and balances to assure safety but mistakes still occur. First is that the order is misinterpreted. Some hospitals avoid the clerk transcription error by faxing the physician's order directly. But it is not uncommon for the pharmacist to have difficulty interpreting the order. This leads to calls and pages

but if there is no immediate answer or if the pharmacist thinks he understands the order, it is prepared. [The graphic is for a patient about to go to the OR for kidney transplant.]

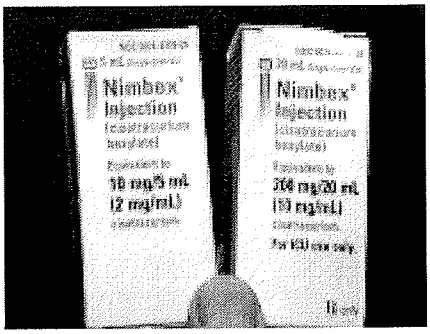
Many drugs today come from the manufacturer prepackaged in what are called "unit doses" or packets that are consistent with common prescribing practices. This eliminates error in measuring liquids. Readers are all familiar with the little packages of cream cheese that are served today in restaurants instead of a slab. For the restaurant this reduces waste and assures that the product is clean when served. In the pharmacy there are





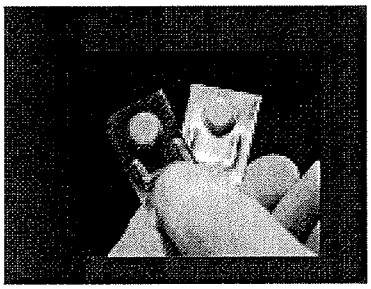
bins, alphabetically arranged with unit doses of various liquid drugs. Imagine that the physician orders metachlopramide for a patient, three times per day. The pharmacist goes to that bin and pulls out three containers, checks the labels and puts them in a tray that will go to the patient's floor. Unfortunately, many of these packets look alike and are easy to mistake. Imagine that the patient gets the packet from the next bin by mistake – milk of magnesia. After three doses of that today, he will be an unhappy camper tomorrow. Not the worst of errors but still a problem.

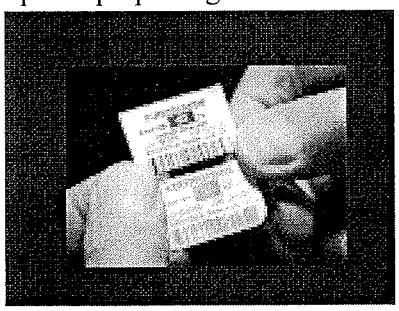
Other drugs must be placed into an intravenous solution. This requires taking the drug from the shelf in its vial, inserting a needle on a syringe to withdraw the correct amount and then injecting the drug into the intravenous fluid in a bag. Here an error that has been frequently recognized is that the drug may come in various concentrations. A pharmaceutical manufacturer always wants to have all of their packaging look alike – their brand. But a look alike package is potentially deadly if a higher concentration is pulled off the shelf by mistake; an equal amount of fluid removed from the vial might mean a dangerous or even fatal dose into the intravenous bag. One approach on medical floors is to simply not allow high, i.e. dangerous, concentrations of drugs on the floor where less trained but enthusiastic staff might make a mistake. For example, high concentrations of potassium if not diluted properly can cause the heart to stop when given intravenously. So it is best to just not have the high



concentration vials around where someone might misread the label. This simple step has led to big reductions in this error that, unfortunately, was not all that rare.

Pills are often also packaged in "unit of use" plastic bags with a label. The pharmacist can then select the proper pills for a patient without having to open and count from a large container each time. Alternatively, the pill is prepackaged in individual "blister' packs by the manufacturer and come with a label noting name and strength. The packaged pills or capsules are placed in bins just like the unit does of liquids noted above. Of course the same errors can occur. Consider two pills that look much alike. It is all too easy to select the wrong package. Yes, they each have a label but sometimes the eye just does not "see" the mistake.



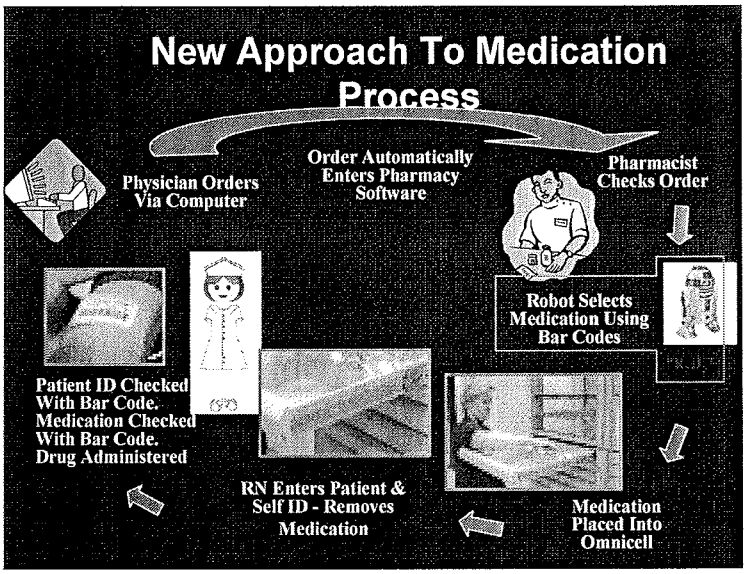


Delivery to the Floor and Administration of Medications

The prepared drugs are delivered by the pharmacy to the individual floors or units in the hospital. Each patient has a tray or drawer in a chest that is stationed in the hallway near where the nurse is working. All of Mr. Miller's medications are in that tray. The tray may be divided into front and rear compartments to separate what he is definitely to be given today and what he may have if he wishes or needs (e.g., sleeping pill or pain medication.) The nurse is expected to check her medication order card and select the proper medications from the tray. She also has a notification on her medication card about any allergies or other potential medication issues. She will double-check this against the drugs that she is about to administer to be sure that nothing will cause the patient a problem. Her medication card also indicates the dose and route as transcribed from the physician's order. If anything doesn't match up, she will double check the original doctor's order or call the physician if she has a question or concern. Once checked, she takes the medicine to the patient and then marks down that it was given. Depending on the patient and the drug, she may stay with the patient to actually observe that it was taken. At the end of the day or shift there should be nothing left over in the front half of the tray. All of these steps are set up to assist with patient safety related to medications. But errors can still occur. A drug gets into the wrong tray or the nurse opens the wrong tray to take out a medication. It looks correct and it is given. Or, the nurse misses the fact that the patient is known to be allergic, just as the doctor did when signing the original order. Or something has happened to the patient's kidneys and the original order is no longer appropriate but the adjustment has not yet been ordered. Will the nurse know or not?

New Approach To Improve Safety of Medications

What can be done to reduce these errors? Humans will still make mistakes so just more training and admonitions to be careful are not enough. The various checks and balances built in now are good but not good enough. Here is a new way of approaching medication safety.



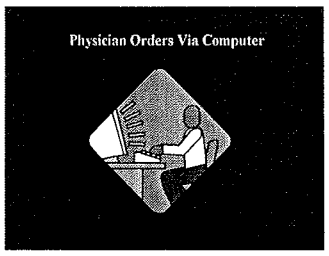
First, address the environment of safety by getting commitment from the top of the organization including the Board of Directors that safety is critical and that the needed resources will be forthcoming. Banish the culture of punishment for making an error and replace it with a culture that embraces reporting safety concerns. Collect the information, analyze it, do root cause analyses and report back to the involved staff on new approaches and systems.

Second, be sure that the pharmacy is directed by a true leader with vision and commitment to safety. He or she must also have the requisite management skills and ability to team with doctors and nurses. Begin training programs for the staff up and down the chain of medication ordering, preparation and administration.

Initiate some changes that attack human factors as a third step. For example, eliminate high concentrations of potassium chloride from patient care areas, improve labeling of medication bins in the pharmacy and keep drug packages with different dosages separated from each other.

Then, as a forth step, begin to introduce technologies that will assist the staff in this new approach, which is described below.

The physician does all ordering via the computer. He or she signs in with name and password and then scrolls to his patient's record. Only the appropriate physician has access to actually creating or changing a medication order for this particular patient. . Others can see the order but cannot make changes. The physician now writes the medication, including dose, route, and number of times per day. The computer will query the reason for the order. For example, an antibiotic is ordered for pneumonia. If the patient is known to be allergic, the computer will not accept the order. If the dose is inappropriate for the patient's height and weight it will challenge the order or assist the physician to calculate the correct dose. If the patient's



kidneys are malfunctioning (known to the computer because the blood tests of kidney function are also incorporated into the system) it will alert the physician to adjust the dose and, again, assist in that calculation. If the patient is receiving other drugs that might interact adversely with the new drug the computer will so inform the physician. If the antibiotic chosen for pneumonia is not among those usually used for pneumonia the computer will also query the doctor, even suggesting alternatives. All of these steps will be instantaneous and convenient.

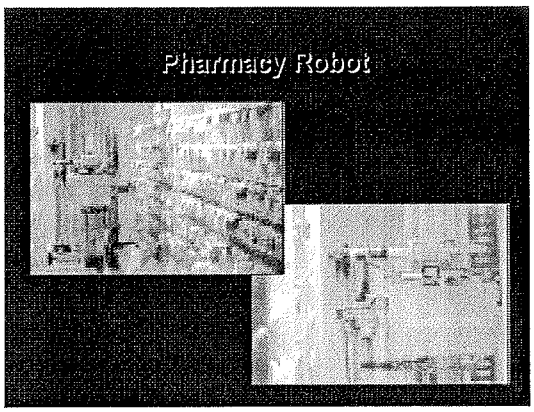
There are some problems. First, these are new systems and they are constantly being updated and upgraded. The basics work well but the added elements are still developing. Clearly, such a system eliminates the handwriting error. It eliminates the allergy error. So mistakes will be much lessened. By adding in "knowledge" such as drug-drug interaction, kidney function and choice of antibiotic, the physician is given much additional help and is "taught" all at the same time. The training comes at the perfect moment. Doctors learn best when faced with an issue, such as what is the best antibiotic to prescribe right now for pneumonia, not some other time such as when the doctor is reading at home about pneumonias from a textbook.

Drug Preparation in the Pharmacy

If the order comes from the physician via the computer there is no chance for misreading handwriting. That is a big first step that reduces errors immensely. The pharmacist can review the order, see how it has been adjusted or not for kidney function, other drugs being administered and dosed for weight and height. The computer can set up alerts and alarms to the pharmacist for any order that was sent despite the computer's "advice." The pharmacist does not have to enter the order into the pharmacy computer; it is done automatically.

Drugs can be selected from the bins described above and then scanned with a bar code just as in the supermarket. This not only records that the drug was placed in the patient's tray but it cross checks the selection as being correct. Is it the right drug, right dose, right number of doses for the day? If the pharmacist or pharmacy technician selects the wrong (e.g., higher, more dangerous) concentration of the drug, the bar code reader alerts the computer which in turn stops the process. This will dramatically decrease the chance for taking higher concentrations of a drug and mistakenly under or over diluting it for addition to an intravenous bag of fluid. Further, the computer, having checked the concentration of the drug in the vial and knowing what is needed to add to the IV solution now prompts the pharmacy technician with the correct amount to withdraw.

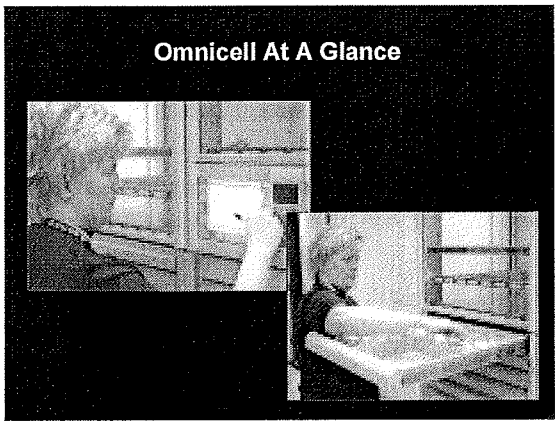
Perhaps better yet, an infusion robot is utilized to select the proper compound, add diluent, remove the required amount and inject it into an infusion bag for delivery and administration. The computer provides a label which gives the drug name, dose, , diluent, the date and time for administering and the rate it is to be administered to the patient,



Pills, capsules, and liquids packaged in unit doses or units of use can be stored and retrieved by a pharmacy robot. The robot is given directions by the computer that in turn is following the doctor's orders, as checked and verified by the pharmacist. The robot selects the ordered drugs, checks its bar code and delivers it to the patient's tray. Basically, the robot has a special arm that grasps the package and moves it to the tray. The process actually starts by having the robot "stock" a location with multiple sets of the bar coded prepackaged drug, The robot "knows" the location and will return there when it needs that drug for a patient. But it still double checks by reading the bar code on the drug package before proceeding. If somehow a drug got into the wrong location, the robot will pick it up and put it into a discard tray.

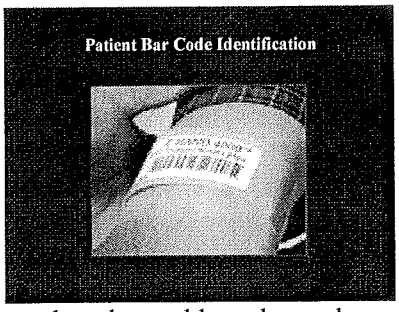
Another robot, designed for delivering supplies to hospital units can be modified to deliver medications. It is programmed to take its stock from the pharmacy, and like

R2D2, travel down the hallway, onto the elevator (which it "calls" by wireless technology) and to the nursing unit. On arrival, it states "I have medications for you" and the nurse with the appropriate password opens the robot's cabinet and removes the drugs, perhaps placing them in the distribution cart discussed next.

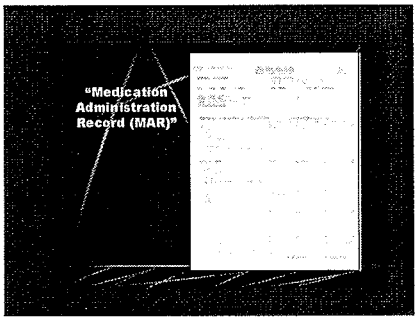


Another new step in protecting the patient is a special distribution cart or case on the hospital unit floor. Instead of a cart with multiple drawers or trays that can be opened by anyone, the new system has multiple built in features. First, the robot or pharmacy technician loads the cart with the various patients' trays. The cart is connected with the computer that knows the patient's order and what the pharmacy has prepared. The nurse goes to the cart but cannot open it. Instead, she must first sign in with her name and password and the patient's name. A nurse from elsewhere in the hospital not assigned to that floor will not have access to this cart. Next, the nurse indicates which drug she wishes to withdraw. The computer and nurse co-verify the choice and the patient's drawer (and only that patient's drawer) opens automatically. The nurse removes the desired medication, swipes it across the bar code reader on the cart to verify both that it is correct and that it was removed.

She then goes to the patient's room, swipes the patient's bar code enhanced wrist identification band and gets an approval from her wireless computer which is, in turn, connected wirelessly to the hospital clinical information system including the medication ordering software. Once the approval is posted, the drug is given and the system registers the transaction as completed eliminating that paperwork from the nurse's routine.



From end to end there is a continuous check on the order; continuous record of who was involved (doctor, pharmacist, pharmacy technician, nurse;) continuous record of any changes made, why and by who and with whose approval; assurance that the right drug got to the right patient at the right time in the correct dosage and route; and a record of when the medication was actually administered or swallowed. In addition, if mistakes were made and the computer issued a correction or alert, there can be a record of these as well.



The latter is an interesting issue. Consistent with the airline pilots' agreement to report errors and near misses with the promise of anonymity, it might be best to keep this data unconnected with the individuals involved. As a result, physicians, nurses and pharmacists become willing to use the computerized system without fear of reprisals yet the institution can collect very valuable data to edit so that recurrent errors can be dealt with by added system changes. Of course it would also be valuable to learn that a particular doctor repeatedly made the same mistake. In this instance, he or she could be offered some form of remediation but this would break the anonymity.

This model for medication ordering, preparation, delivery and administration is "technology heavy" yet utilizes people (physician, pharmacist and nurse) for their expertise and skills while eliminating opportunities to make an error or by detecting errors as they occur. Further it incorporates "knowledge" into the system thereby teaching as a byproduct of the work done by each. Finally it can be used as a data collection tool to address common near misses and common error pathways so that patterns of error can be recognized and further systems can be put in place to prevent those errors as well.

Summary

The OR can be approached in a manner as done for medications. First, create the environment of safety with high level commitment and provision of resources. Initiate a training program, eliminate the culture of punishment for errors, and begin a mechanism

to collect, analyze and feed back information on errors and near misses with the intent to correct or change processes.

In addition, assign a strong leader with excellent vision; appoint an effective manager and work together to empower all involved to immediately "speak up" about perceived errors or problems. To this new environment introduce technologies to further improve safety: the electronic medical record, a surgical information system that actually assists the professional staff, video, simulation, robotics and patient, staff and equipment identification devices. Any one will aid the staff to reduce errors; together these approaches can have a major impact to enhance safety.

Closing Comments

Dr Sherwin Nuland, a highly respected surgeon at Yale New Haven Medical Center writes in the New England Journal of Medicine of his introduction to surgical safety. As a third year student on his surgical rotation he is suddenly finds himself as a subintern for a week. Assigned to assist a well known senior private surgeon, he is left alone at the end of the operation to close the wound. Of course he is a novice and makes the mistakes of a novice, which lead to a wound infection some days later. Now, many years later, he reflects that so many errors were made that day. The senior surgeon should have determined his assistant's skills before leaving; the student should have identified himself as such; the nurses and anesthiologist should have objected that the surgeon planned to depart; the surgeon should have had a less "packed" operative schedule that day. Had any one of these errors been avoided, then Nuland's surgical error that led to infection would have been prevented. Nuland closes his commentary that systematic approaches are important but that it is essential that each person must be watchful, "alert to failures of human compensatory mechanisms."

Recommendations to TATRC – The Roadmap

What follows are the author's recommendations that TATRC should consider in advancing the OR and perioperative patient safety agenda relative to the entire "OR of the Future" initiative.

First -Develop a strong understanding and underpinning of the patient safety issue among TATRC staff, collaborators and partners and among other Department of Defense agencies. Involve, invest and include participation and discussion with leaders of the hospital community, regulators, government agencies and others with an interest in patient safety.

Do so by initially organizing a national invitational strategy meeting (IRT) to discuss OR and perioperative patient safety parameters and, from that discussion, develop the outlines of a roadmap for future work.

The IRT should address the three key elements of: 1) the environment/culture of safety, 2) human factors and 3) technologies. Despite TATRC's commitment to technology advancement, the safety agenda must encourage attention by its partners and collaborators to environment/culture and human factors as well.

Second- Write and publish white papers on the key issues to be addressed as a result of the strategy development from the IRT.

Third- Given that the data on OR and perioperative errors and near misses is inadequate, immediately propose a set of linked contracts to carefully and thoroughly determine the nature of errors and near misses as they currently occur in the perioperative and OR setting.

Fourth- Encourage all collaborators and partners to engage in the patient safety strategy by specifically proposing research projects that address safety as the primary aim and build upon the information developed above.

Some greater detail:

The proposed linked projects (contracts) to observe and define the error and near misses in the OR settings are outlined below.
Proposed Project # 1

There is currently limited, unbiased, comprehensive data available on the types, causes, incidence and severity of errors and "near misses" that occur in the perioperative environment.

However, before embarking on a project to measure the common and serious near misses and errors in the OR and perioperative environments (Proposed Project #2), it is critical to first more fully understand the nature and types of potential and actual errors in this setting. The process should begin with a better understanding of the "patient pathway" through the operating room and beyond. This needs to be elucidated during the entire pre, during and post operative event beginning with the patient evaluation by the surgeon.

The initial output of the project is to create a "process map" of the patient's pathway. This will include determining the processes that underlie this entire pathway , such as registration, preoperative evaluation, risk analysis and identification, supply chain for instruments and equipment including sterile processing, the operative procedure itself, time in the post acute recovery unit (PACU) or intensive care unit (ICU), transport form OR to PACU or ICU, the" handoffs," etc.

Critical to this analysis is to assess the "risk points" in the process, those points where human error is most likely.

In general, it is envisioned that TATRC will select a contractor that will create a "Process Map" based upon close evaluation of four to six institutions with large operating suites (defined here as ten ORs or more) with 40 or more procedures per day, preferably among those academic medical centers that are currently participating in the OR of the Future agenda with TATRC.

The selected contractor must demonstrate familiarity with

Process mapping
Large (academic) medical institutions
TATRC "OR of the Future" agenda
Organizations with complex interpersonal activities
Organizations with complex programmatic operations

Proposed Deliverables

Process Map of Perioperative environment
Recommendations, based on the process mapping, for
Assessment of the key risk points along the process map
Suggested immediate safety interventions based on mapping outcomes
Human and Technology factors that could lead to improved safety
Selection of best currently available monitoring methods to assess patient safety in the perioperative environment (e.g.,University Hospital Consortium internet based process for error data collection and analysis; Center for Performance Sciences Quality Indicator Project, etc.)

Proposed Time Line

Six months from receipt of contract until completion of process mapping at 4 to 6 institutions
Two additional months to complete recommendations and prepare report

Proposed Project #2

There is currently limited, unbiased, comprehensive data available on the types, causes, incidence and severity of errors and "near misses" that occur in the perioperative environment.

This project aims to study the perioperative environment for the types of errors that are both most common and most serious, as defined in Proposed Project #1, using the currently available, recommended monitoring system(s) identified in Project #1.

In general, contractor will

Study the perioperative environment for errors, adverse events and near misses
Employ the monitoring system(s) identified in Project #1
Enumerate specific errors and classify them as to level of potential importance (i.e., near miss, error, adverse event, serious sequalea)
Relate errors to the number of procedures preformed to develop incidence rates

Complete limited root cause analysis of the
Most common errors
Most serious errors
So as to recommend early actionable approaches to reducing errors

It is anticipated that the contractor will
Utilize trained individuals to directly observe for errors and near misses
Enter the data into the selected monitoring system(s)
Work with the monitoring system vendor(s) to analyze the data to achieve the goals noted above.

Data Collection
Data is to be collected from 4 to 6 institutions with large and active ORs (see Project #1), each preferably chosen from current TATRC partners and collaborators.

Proposed Time Line
From receipt of contract
Three months to
Acquire IRB approvals
Select and train observers
Nine months to
Complete data acquisition
Twelve months to
Complete analysis and prepare report

Notes:
It is suggested that it not be the intention of TATRC that this project will elucidate all errors in all possible OR procedures but rather will identify with sufficient rigor the *common* errors and the *most important* errors (i.e., those causing the most severe or adverse consequences) across a broad range of operative procedures.

In the course of the research, it is anticipated that
Broad trends will emerge and be recognized
The monitoring system(s) will be tested and modified as appropriate
Critical lessons will be learned about the actual incidence of errors and near misses, plus the factors that most likely predispose to their occurrence.

It is suggested that it be the intention of TATRC that these lessons learned will be the basis for
Review of results with the participating institutions and TATRC staff
Presentation(s) at appropriate meetings
Publication(s) in appropriate venues

Further it is suggested that it be the intention of TATRC to utilize this material to

Stimulate a national dialogue on patient safety in the OR

Encourage its partners and collaborators to propose future research projects on patient safety

Assist national organizations (e.g., Joint Commission on Accreditation of Healthcare Organizations (JCAHO), American College of Surgeons (ACS), Association of Operating Room Nurses (AORN), Anesthesia Patient Safety Foundation (APSF), others) to develop their agenda and mandates related to patient safety.

Finally, it is suggested that TATRC look to the completion of this project for information that will point to technologies in the TATRC portfolio such as simulation, robotics, video, and information management/technology that could appropriately be directed toward enhancing patient safety.