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OPERATING ROOM AND PERIOPERATIVE SAFETY

A Beginning Roadmap for Action

Prepared for

Telemedicine and Advanced Technology Research Center

United States Army Medical and Materiel Command

Fort Detrick, Maryland

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OPERATING ROOM and PERIOPERATIVE SAFETY

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Executive Summary

Developing a roadmap for action in OR suite and perioperative safety.

The United States Army Medical Research and Materiel Command through its Telemedicine and Technology Research Center (TATRC) has embarked on a five year research agenda devoted to the Operating Room of the Future. The research agenda has five major elements, first among them being to enhance patient safety. TATRC wishes to advance the patient safety agenda and to do so requires a clear roadmap for its partners and collaborators.

In data from the American Hospital Association, 17 –30% of patients had one or more serious adverse events. Convert this to a typical 350-bed community hospital with about 14,000 admissions and 5,400 surgeries and there will be 4000 serious adverse events each year. By rank order in this hypothetical American hospital the following adverse or unexpected events will occur: 884 patients will have an adverse drug event, 816 a nosocomial infection (i.e., an infection acquired in the hospital), 696 a procedural complication, 544 an unplanned readmission, 408 a decubitus ulcer, 299 will die, 204 will have a fall and 163 will have an anesthesia complication. (Combining the procedural, anesthetic, surgically-related nosocomial infections and the surgically-related medication errors leads to the conclusion that the perioperative environment is the location for the greatest number of adverse events.)

The University Hospital Consortium began a self reporting system a few years ago. As of late 2004, 60 academic hospitals had recorded 71,000 events of which 6219 (8.7%) occurred in the OR environment. The most common errors were those related to a procedure (2200), a complication of a procedure (600), a break of skin integrity (180), an equipment issue (400) or a medication error (200). [Values rounded] Those related to the greatest ultimate harm were: skin integrity and complications of procedures.

What is to be done to prevent these types of errors from occurring? The Institute of Medicine (IOM) in a landmark publication in 1999 wrote that as many as 44,000 to 98000 Americans die as the result of avoidable errors in hospital each year. These are incredible numbers and many have disputed them. (A more recent study reported in July, 2004 suggested that nearly 200,000 Americans die each year of medical errors.) But even if only half or ten percent occur actually occur, it is way too many. The IOM report was entitled “To Err is Human,” a very apropos title since that is the basic problem. Humans make mistakes. Humans will continue to make mistakes. Well-educated and well-trained humans will make mistakes. Humans that double check will still make mistakes.

The author of this report has interviewed surgeons, anesthesiologists, nurses, hospital executives; reviewed literature; talked to leaders at organizations such as the University Hospital Consortium, JCAHO, Health Care Advisory Board and others. This has lead to s

report on the predisposing factors to perioperative errors, an understanding of the errors that occur and some initial thoughts on approaches to enhance patient safety. What follows are the author's thoughts, based on these interviews and reviews, on improving safety in the perioperative environment and what TATRC's partners and collaborators might do to engage this issue.

A successful approach to improving the safety of the OR and its environment will depend on attention to creating an environment of safety and then focusing on both human factors and technology factors.

Environment of safety refers to the commitment of the CEO and Board to safety, to the needed investments, to a nonpunitive environment, and to a reporting and analysis feedback system.

Human factors must include leadership, management, teamwork, information transfer, training and the creation of a culture of safety.

Technology factors can include: surgical/operating room information systems; video capabilities, identification devices for patient, staff, equipment, instruments and medications such as bar-coding and RFID; simulation approaches and robotics.

Information systems include not only the electronic medical record but the surgical system, the anesthesia system, the supply chain system and the PACS system – all interconnected, wireless, easy to use, with built in prompts and alerts, with built in “knowledge” and built in surveillance.

Video includes in room cameras for distant command and control of the OR suite, light source cameras to train, teach and record data and for teleconsulting and PACU/ICU cameras for electronic monitoring at a distance.

Identification devices – barcode and RFID – can be used to track equipment, supplies; to identify the patient and the intended site of operation and procedure; to track staff and to record, document, and bill and order post use of medication or device.

Simulators can enhance safety by training individuals for a particular procedure and for use of particular devices; by allowing the surgeon to preplan the best approach and procedure for the particular patient; to rehearse surgery and to provide team training in contingency planning and crisis management.

Robotics can enhance patient safety by, at least, integrating patient-specific data; allowing less invasive surgery (e.g., CABG), allowing more accurate surgery (e.g., craniotomy); developing preplanned and rehearsed surgery; and having built in alerts and detectors.

In summary, the perioperative environment is a high risk area with high velocity, high complexity and high stakes; OR errors lead to disproportionately more harm than errors elsewhere in the hospital. There is a need to create an environment of safety and then address both human factors and technology factors when designing patient safety initiatives. The environmental factors include an institutional commitment, resources, a non punitive attitude, data collection and root cause analysis and systems approaches. Human factors include especially leadership, management, training and teamwork. Technology approaches include information systems, identification mechanisms, video, simulation and robotics.

TATRC is anxious that its partners and collaborators actively engage in research to enhance patient safety in the OR and the perioperative environment.

Introduction

The United States Army Medical Research and Materiel Command through its Telemedicine and Technology Research Center (TATRC) has embarked on a five year research agenda devoted to the Operating Room of the Future. The research agenda has five major elements, first among them being to enhance patient safety. Despite the

prominence of this agenda item, most research efforts by TATRC's partners has, to date, been focused on other elements such as new technologies. TATRC wishes to advance the patient safety agenda and to do so needs a clear roadmap for its partners and collaborators. This report will set out the issues, directions for research, obstacles to success, and a proposed outline for future work. It includes the steps needed to initiate a functional and successful process for a program in safety;

will order the work from simple to more complex and from that doable with today's technology versus that which will need to depend on technology not yet fully operational; and will establish the benchmarks necessary to hold partners and collaborators accountable, including measures of success.

It is recognized that TATRC is inherently technology oriented; this report will nevertheless approach the problem in a broad sense looking at all of the issues and approaching the research agenda from a similarly broad perspective

This report is qualitative, being based on a review of the literature and interviews of officials at national organizations interested in safety issues plus interviews with a wide array of surgeons, anesthesiologists, nurses, others involved in the perioperative environment, hospital managers involved with safety agendas, executive level hospital managers and TATRC personnel. The next steps will need to be quantitative to develop the specifics data on errors in the OR and the perioperative environment and the process improvements that will be needed to improve safety. That said, there are some obvious approaches to improving safety now (better communication; team building; leadership; identification technologies like bar coding and RFID for patients, staff and equipment/instruments; robust surgical information systems with wireless capability and built in alerts and knowledge; simulation devices to improve training in high risk procedures; and robotics, to name a few.) These techniques can be begun even while more basic studies are underway to more fully define the safety problems inherent in the operating room and perioperative setting.

OR OF THE FUTURE TATRC FIVE YEAR STRATEGY PLAN

- PATIENT SAFETY
- TELEMEDICINE
- INFORMATICS
- ADVANCED DEVICES
- PERIOPERATIVE SYSTEMS DESIGN

iSetting the Stage

A gentleman in his 60's was discovered to have early stage prostate cancer, treatable by either surgical resection or by brachytherapy (seed implants into the prostate.) After much gathering of data from his physicians and personal soul-searching, he made the decision to go with brachytherapy. Through a friend who was a major donor to a particular cancer center, he chose that center due to its reputation for excellence in this procedure and overall excellence in care of patients with prostate cancer.

All was ready in the operating room. He was given spinal anesthesia while the urologic surgeon and radiation oncologist checked out their equipment. The procedure was to benefit from the use of a rectal ultrasound probe so that the team could be certain of where the seeds were placed in the prostate. Further, they were to use a device that held the needle in a fixed position that allowed insertion of the seeds with great accuracy. To their surprise, they found that the needle stylus was bent and certainly not usable. However, another full set of equipment was in the OR and ready for use. So they proceeded with the procedure using the stylus from the other set. At completion, they discovered that one seed was left behind in each of the many needles used. They then realized that the new set was a different model with a stylus that was shorter, hence leading to improper placement of the seeds. Since the procedure produces local inflammation and swelling, now was not the time when they could go back to inset the missing seeds; that would have to wait some weeks. Meanwhile, the patient was less than happy that he had chosen this institution only to have received a botched procedure for a serious disease.

What went wrong? Everything. Purchasing had not thought that the cheaper model would be of any problem and did not notify anyone that it was a different model. Biomedical and Central Sterile Supply did not cross check the new purchase with the prior equipment for compatibility. The scrub technician did not realize that he had two different models of equipment. And the physicians never thought to double check that they had identical equipment. So all the checks and balances that should normally assure safety were not effective; in short, there was no organized *system* in place to assure quality and safety.

The patient, by the way, chose to go elsewhere for followup therapy.

Overview of the Problem

We all assume that our healthcare provider will not make mistakes, at least not when treating us. But doctors, nurses, physical therapists, pharmacists, etc are all human and are endowed with a common characteristic, namely, they all make mistakes just like the rest of humanity. Certainly, no one comes to work in the morning determined to make a mistake; indeed, a lot of effort and energy goes in to not making a mistake – but it still happens.

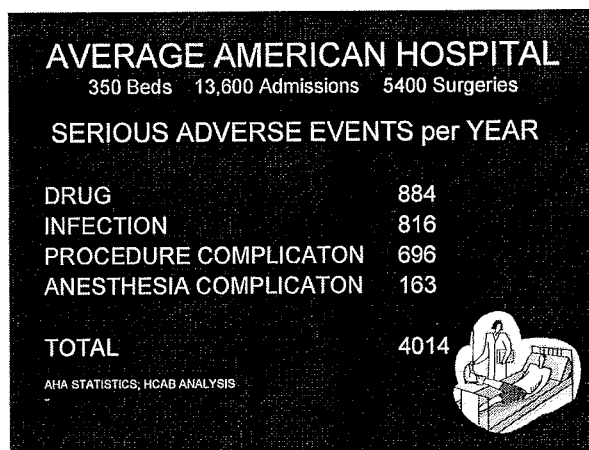
A study from Harvard Medical School published in the prestigious New England Journal of Medicine in 1991 by Leape and colleagues found that about one half of actual injuries

to patients at a major Boston hospital arose as a result of operative procedures and 20% were related to medications. Looked at differently, about 2% of all patients in the hospital had an operative complication, somewhat less than 1% had a drug-related adverse event with a total of nearly 4% of all patients having some injury secondary to hospital activities.

Another study of errors by Andrews and colleagues, published in the major British journal *The Lancet*, followed 1047 hospitalized patients on two intensive care units and one surgical floor. Unlike the Harvard study that found about 4% of patents had an adverse event, this group detected 46% overall had some form of adverse event and that 18% of patients had a serious adverse event. They noted that only 23% of adverse events were actually reported up the chain of command.

In data from the American Hospital Association, 17–30% of patients had one or more serious events. Convert this to a typical 350-bed community hospital with about 14,000 admissions and 5,400 surgeries and there will be 4000 serious adverse events each year.

By rank order in this hypothetical American hospital the following adverse or unexpected events will occur: 884 patients will have an adverse drug event, 816 a nosocomial infection (i.e., an infection acquired in the hospital), 696 a procedural complication, 544 an unplanned readmission, 408 a decubitus ulcer, 299 will die, 204 will have a fall and 163 will have an anesthesia complication. (Combining the procedural, anesthetic, surgically-related nosocomial infections and the surgically-related medication errors leads to the conclusion that the perioperative environment is the location for the greatest number of adverse events.)



Whether one accepts the lower numbers or higher numbers as more realistic of the typical hospital, the fact is that there are all too many lapses in patient safety in United States hospitals. Given the available data it is clear that the specific areas to address first in addressing the safety issues are: perioperative events, medication errors and nosocomial infections.

Further, in the operating room environment, it is critical to recognize that medication errors and the development of nosocomial infections are major aspects of perioperative patient safety approaches.

What is to be done to prevent these types of errors from occurring? The Institute of Medicine in a landmark publication in 1999 wrote that as many as 44,000 to 98,000 Americans die as the result of errors in hospital each year. These are incredible numbers

and many have disputed them. But even if only half or ten percent occur, that is way too many. The IOM report was entitled “To Err is Human,” a very apropos title since that is the basic problem. Humans make mistakes. Humans will continue to make mistakes. Well-educated and well-trained humans will make mistakes. Humans that double check will still make mistakes.

Why Focus on the Perioperative Environment?

We know from the studies noted above and others that errors in the perioperative environment are not only frequent but also prone to be serious and with long term consequences. In today’s civilian or military hospital, the OR is at the center of the action, both clinically and financially. If the OR suite runs poorly, the entire hospital is adversely affected. Operating Rooms have changed dramatically in recent decades but the management principles have not developed with the

**Current State of the Operating Room
General Mode of Operation**

- Teamwork - fragmented
- Communications - voice and grease boards
- Much energy - focus on function rather than patient care
- Surgeon personalities - strong factor in its operation
- Workload - highly variable with high peaks
- Complexity - high
- Time - wasted (Someone in the OR is always looking for some critical thing while the patient and surgeon wait)
- Information systems - limited usage

se changes. The acuity level and the complexity of operative procedures are much higher and rising. It is truly a “high velocity” environment “choked down” by the human inability to manage this level of complexity and tempo. Surgery has advanced to the point where humans cannot keep track of all activity. Nevertheless humans are routinely expected to overcome this level of

Response to Unplanned Events

- Unplanned events occur frequently and in clusters
- OR responds - one at a time
- As unplanned events increase, the OR response becomes more unpredictable and therefore more stressful
- Different people in the OR respond to stress in different ways
- High stress affects patient care as well as employee turnover rate

Effect of New Technology/New Procedures

- New technology - primarily intraoperative advances, not pre or post operatively or aimed at the infrastructure
- New technology - evaluated primarily on surgeon satisfaction or time saved
- New technology - must be very time efficient in order to be utilized under conditions of stress. Otherwise people revert to older learned methods
- Technology education - "on the job," gained by observation and is sporadic dependent upon manpower
- The balance between patient safety and other factors such as convenience or cost usually not explicitly defined

complexity on their own, yet it is simply impossible.

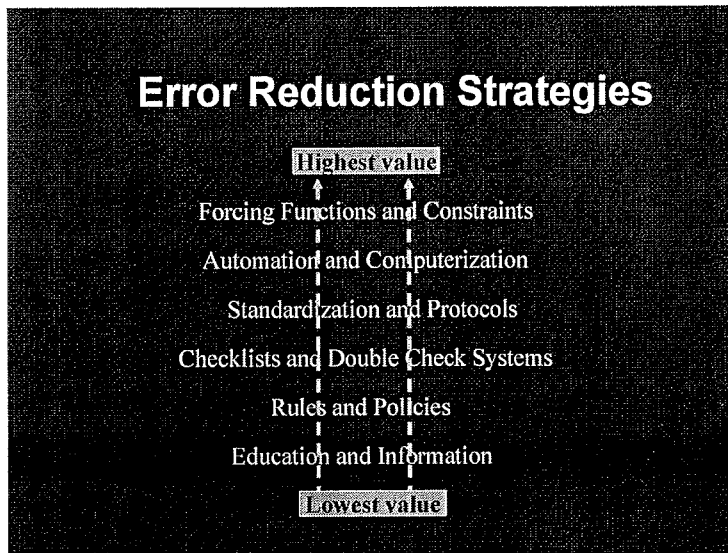
Improving patient safety will concurrently improve OR efficiency and effectiveness because the change in processes and systems needed to produce improved safety are the same as those needed to improve effectiveness and efficiency. Hence, improving patient safety in the perioperative environment will not only have a value in and of itself, it will improve morale of the staff,

allow better use of an expensive capital asset and reduce expenditures per case and per day.

Safety is often thought to start with education and training, both of which are critical. Although these teach basics, they do not necessarily reduce errors, the errors made by well intentioned and usually well trained individuals. System changes are the key to improved safety. The Table addresses the rank order of power of various approaches noting that forcing functions (e.g., requirement that all medication orders be entered only via computer with its built in queries on allergy and built in “knowledge”) are most valuable and education least important.

Whatever the final approaches accepted, it is clear that they will

definitely include the engagement of systems, methods and technologies already proven in other industries. They will need to be modified and adjusted to be acceptable and effective in the operative setting but will fundamentally be based on prior knowledge of industrial and management techniques, augmented by advanced technology. Among the latter are: 1) Approaches to positive identification - of patient, staff, equipment, instruments and drugs with appropriate new technologies such as bar coding and RFID. 2) Improved situational awareness using voice and visual technology along with advancements in tactile clues for the surgeon. 3) The electronic medical record and surgical information systems will be essential to integrating the myriad digitized information sources available. 4) Automation will be critical in records management, supply chain management, and sterilization procedures. 4) Further, advanced devices and technologies will allow not only better surgical outcomes but also safer surgery e.g., simulation, robotics, neuronavigation and intraoperative MRI. These are but a few of the keys to improvement. Common to all will be the extensive use of information technology.



General Concepts About Safety in the Operating Room

Of all medical errors about 20%, and probably more, occur in the operating room. The OR is fundamentally different from other elements of the hospital. Foremost is that the patient is asleep or sedated and therefore cannot assist in his or her own mitigation of hospital based errors. In short, the patient needs advocate(s.) Further the OR is a high velocity environment with increasing efforts at productivity enhancement.

This velocity increases the opportunity for error. The environment is also increasingly complex, increasing the opportunity for error and increasing the need for training and education.

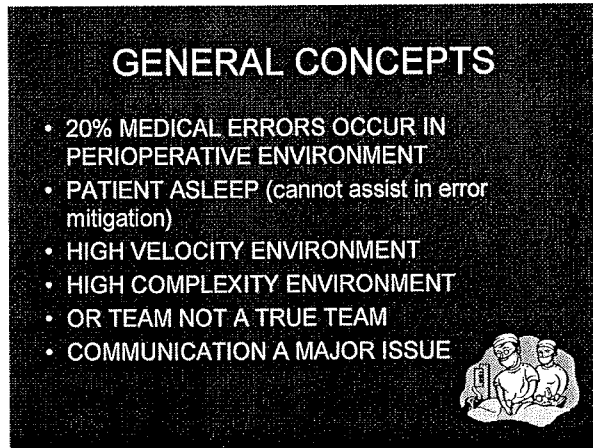
Interestingly, the team in the OR, typically the surgeon, anesthesiologist and scrub nurse or technician, is really not acting as a true team. They work together in the same location, sharing workspace, overlapping responsibilities and goals, but each has

distinct roles so in some ways they function separately. A critical issue is therefore to improve teamwork if only for the purpose of improving safety. Finally, the operating room is inherently a dangerous location for both patient and staff; the patient because of the potential for error and the latter because of the potential for injury from equipment or instruments.

Communication is often noted as not clear, and that there is not clarification that a request/communication was received and understood (i.e., similar to the “read back” approach in the cockpit or on a naval bridge.)

Every anesthesiologist will state that putting a patient to sleep is inherently dangerous; a matter of degree of risk for the patient versus the expected benefit or outcome of the procedure. Anesthesiologists often feel they have “divided attention” problems, i.e., they are checking the records and materials for the next case while giving anesthesia to the current patient. In part this is caused by the eroded preoperative examination [see below.] The anesthesiologist, surgeon and nurse/ technician are also relied upon too much to be ever vigilant. There is a growing need for sensors to detect rare but crucial events that can lead to patient harm.

Technology in the operating room suite is surprisingly behind the “power curve.” This is especially true for the electronic medical record and surgical informatics in general. These prove to be major issues as will be discussed later as part of the patient identification issues.



GENERAL CONCEPTS

- 20% MEDICAL ERRORS OCCUR IN PERIOPERATIVE ENVIRONMENT
- PATIENT ASLEEP (cannot assist in error mitigation)
- HIGH VELOCITY ENVIRONMENT
- HIGH COMPLEXITY ENVIRONMENT
- OR TEAM NOT A TRUE TEAM
- COMMUNICATION A MAJOR ISSUE

The OR suite is usually a profit center for most hospitals. As a result there is all too often a reluctance to confront safety issues. Further, since it requires gowning, most hospital executives avoid visiting the OR suite.

Specific Issues for Concern in the Perioperative Environment

The specific areas of concern in the operating room, many related to data and communication, are the following. Of major importance, and raised by many who work in the OR suite, is proper *patient identification*. This implies not only being sure the right patient is in the OR but that the team knows the patient's medical issues clearly in addition to knowing the planned site of the operation (left breast, not right) and the procedure planned (lumpectomy with sentinel node removal, not mastectomy with axillary dissection.) Absence of all of the proper data and information about the patient will lead to delays at best and frequently to errors, some serious with adverse consequences, at worst. Operating on the wrong site may not occur often but the stakes are very high. Further, the entire team needs to know what the plan of work is to be so that each can do his or her part effectively. Too often there is inadequate communication among team members on the planned procedure. Patient needs are often exacerbated by incomplete medical records which are rarely electronic, rarely can be rapidly obtained if not present in the OR. The result is that the team makes assumptions based on incomplete data.

Medication safety is a high priority just as elsewhere in the hospital but amplified by the fact that the patient is asleep. Patient identification procedures should have indicated if there are any allergies and this must be in written form available to all. A decision to start an antibiotic, for example, must be undertaken with knowledge that the patient is not allergic. Prophylactic antibiotics are a key issue in OR safety. These antibiotics need to be given and given at the start of the procedure, not later, if they are to be efficacious in preventing a post operative infection. The OR is a place where fluids of various types are used to irrigate the site, clean the skin, etc. These fluids need to be labeled. If the scrub technician is called out of the room or is busy with a retractor, it is possible for someone else to assume an unlabelled container to be other than what it is. A very unfortunate accident occurred in a Florida hospital when "saline" was used to irrigate the operative site. Unbeknownst to the surgeon, the unlabelled container he used was not saline but a combination of lidocaine and epinephrine, leading to the child's death.

Infection control is critical in the OR environment. The culture is such that no one would enter the OR without properly scrubbing and gowning but there is less attention often paid to the prophylactic antibiotics or whether the patient is infected or colonized with bacteria resistant to most antibiotics, i.e., needs special attention to avoid cross contamination. Post operative infections are only recognized later on the unit or after discharge; not adequately related back to an

SPECIFIC ISSUES

- PATIENT IDENTIFICATION
- MEDICATION ERRORS
- INFECTION CONTROL
- INTRAOPERATIVE ISSUES
- TRANSPORT AND "HAND OFFS"
- COMMUNICATION
- OR ENVIRONMENT

event that did or did not occur in the OR. Lax behaviors, perhaps again because the patient is asleep, may be one key to addressing this problem. Finally, emerging infectious diseases may be problematic such as West Nile or Avian flu.

Some specifics about infection control include skin preparation. There is good evidence that a clipper is less likely to lead to site infection than a razor but the razor has stood the test of time for most surgeons who are wary of change. Chlorhexidine, which is colorless, as a scrub is better than iodine-based scrubs. If the prep is done by an assistant before the surgeon enters the OR, the surgeon cannot “see” that the scrub has been done to his or her satisfaction so iodine scrubs are still preferred. Vascular access lines should, based on good studies, be inserted with full sterile prep (gown, mask, gloves and sterile drapes) but this is uncommonly done because “the supplies were not readily available” or just lax technique but otherwise well trained physicians. Blood sugar elevations enhance infection rates after cardiac surgery among diabetic patients. There are inadequate studies relating blood sugar and infection with other surgical procedures so that glucose levels may not be followed in other than cardiac surgery. There is data that reduced temperature can predispose to wound infection but OR temperatures are often kept cool for staff comfort in the bright lights with heavy gowns.

There are a host of critical *intraoperative factors* to consider. As to anesthesia, there have been substantial improvements over the years especially in drugs, monitoring and preoperative evaluation. But safety is being eroded by the pressures to have faster production and fiscal effectiveness. Further, new technologies if improperly introduced can exacerbate the “divided attention” noted previously. Anesthesiologists might consider utilizing various monitors and sensors to detect unexpected events as a way to maximize their vigilance needs. There is an interesting European study that demonstrates the utility of “autopilot” technology to aid in anesthesia control and safety.

The OR is an inherent hazard zone for the patient with opportunities for electrical, chemical or other injury. Drug reactions, falls, burns, pressure, nerve injury, thrombosis and or blood clots can occur while the patient is asleep. The OR is inherently poorly managed for these issues, not because people don’t pay attention but because the OR is complex with major opportunities for error.

The patient must be properly positioned to prevent pressure and hence damage to a nerve or tissue. Since the patient is asleep, he or she cannot tell the team if the position feels wrong. Peroneal nerve damage is uncommon but a real risk in OR setup. If the operating table is not properly set up, in some instances, it can collapse leading to a fall for the asleep patient, obviously a serious risk. Electrical instruments must be properly grounded to prevent sparking and ignition of anesthetic gases. There is an increasing number and variety of devices that deliver energy to patients by one means or another. It has become increasingly difficult for Biomed departments to verify the correct function of these devices because of inherent complexity – field testing is often impossible – and a simple electrical test may tell little about energy delivery to a patient. Fire safety is more important than most think. There is about one fire in an OR in the USA each week,

usually due to gases being trapped under drapes and ignited by a device either unwittingly due to cauterization equipment or the spark of a faulty piece of equipment. Lasers are of immeasurable benefit to today's operations but they are inherently dangerous and need to be treated as such. New endomechanical devices that aide the surgeon dramatically, such as staplers and suturing instruments, can misfire. Imagine doing a laparoscopic procedure on the kidney only to have the stapler misfire and penetrate the aorta; it has happened, due to malfunction.

Also during the case, there is a need to monitor critical variables. Not only heart rate, blood pressure and respirations but also, for example, blood sugar. During a coronary artery bypass (CABG) case, watching blood sugar on a diabetic will prevent it from rising too high thus increasing the risk for a sternal wound infection after surgery. More and more parameters are being monitored today but monitors often do not integrate with one another (there are no standards for integration.) Coordination among devices is needed as is an ergonomic design to enhance the ability of the team members to see data without neglecting other patient needs. This might include positioning, duplication or heads-up display devices.

Imaging is done more and more frequently in the OR and is of major assistance to the surgeon in planning and progressing on the case but with it comes the need for imaging safety. Staff knows to protect themselves with lead lined gowns or to leave the room, but it is also important to remember that the patient is at risk too. Yes, it is just "one shot" but the eyes, thyroid and reproductive organs need to be shielded nevertheless.

Finally, the "standard" protocols for sponge and needle counts are key. There is nothing worse than having a patient with persistent pain after surgery whose abdominal X-ray shows a retained clamp, missed at the end of the case. Apparently, retained foreign bodies are more common than may be believed.

Post operatively, *patient transport* is a vulnerable time with some areas ripe for fairly frequent error. Not locking the stretcher wheels before transferring the patient to the bed may lead to a patient on the floor, possibly with a broken bone. Similarly, airway management of this patient who is still groggy at best needs to be attended to. Losing the endotracheal tube during transport can be a calamity. Patients are frequently not monitored during the brief trip to the PACU, ironically the highest risk period for the slightly awake patient. Lacking pulse oxygenation monitoring, many if not most patients are placed on nasal oxygen whether needed or not; an expensive "work around" by staff when the hospital avoids the expense of the monitors, or an over use of a technology needed for only some patients.

The *post anesthesia care unit (PACU)*, previously known as the recovery room, has, like the OR, a more rapid pace of care, greater complexity than the past, and often serves as a temporary surgical ICU while the patient awaits a regular ICU bed to open. This requires a new level of expertise and experience by staff along with technology advances to aid in patient observation and care. For example, the introduction of pulse oxygenation monitoring in the PACU has been a major advance in safety.

There is much opportunity for error in the whole “*supply chain*.” As with any complex environment, logistics are critical to functionality. Today’s OR is filled with equipment, monitors, instruments, imaging technology and the like. Each case is different and has its own required set of materials. All too often the supplies are incorrect. Perhaps the surgeon’s preference list was not checked, perhaps there is a broken or bent instrument, or even a critical implant is not available for the case. Most of the time it is possible to improvise or use something slightly different. An aortic graft that is one size greater or smaller than desired is not much of a problem but the wrong size aortic valve is a show stopper. When that happens, in addition to a tense surgeon and a frantic search for the correct item, there is breakdown of teamwork and harmony. Consider this example: a patient is having open heart surgery to replace a valve. At the critical moment it is realized that the valves available for insertion are all the wrong size. No others can be found after a frantic search of the storeroom. Calls go out to other hospitals nearby that do valve surgery (not many.) One has the right size. A nurse takes a cab to that hospital and races back with it while the patient remains on the bypass pump. Finally the case is completed; no one apparently the worse for the experience except that the patient has a much longer time on the bypass pump than should have been necessary with all of the potential complications that extra time engenders. If nothing else, this example shows how trained professionals can be pulled away from their core competencies of patient care.

Communication is a critical factor in the OR and better communication is essential to reducing errors. Many interviewees stated that most errors have as their root cause a lapse in communication. Inadequate “read back” is common and not part of the culture of the OR (as it is in the cockpit or on the naval bridge.) All of the patient identification issues discussed above are really about good communication such as having the right information at the right time in the right place and getting it to all of the right people. There are many “hand offs” from nurse to nurse, nurse to tech, surgeon to tech, etc. These are information handoffs and are part of the communication problem. Many safety checks are left to the last minute – is the consent in the chart and signed? Are the laboratory tests back and acceptable? Is there a prothrombin time report for the patient who has been on anticoagulants? Plus there are issues of complete documentation of more occult problems – does the patient have mild pulmonary or cardiac disease that will manifest itself as the result of the stress of surgery and anesthesia? Again it is important to recall that the patient is asleep so he or she can no longer be asked; all the more reason why it is so important to “know” the patient.

The *operating room environment* creates its own set of potentials to foster errors. The staff is rather insular. Nurses and technicians come to work, put on scrub outfits and remain in the OR suite for the entire day. They eat lunch there, take their breaks there and socialize there without leaving until their shift is over. Since it requires donning scrubs to enter, few personnel from elsewhere in the hospital visit the OR. The staff of the OR is thus less likely to be aware of changes occurring in other units of the hospital and is less likely to embrace change.

The OR today is very technology driven so the staff must be familiar with many new pieces of equipment. Greater sophistication of equipment means increased cognitive burden on the OR staff and more opportunity for error.

The OR today is productivity driven. It is important in today's financial climate that these highly capital intensive suites are maximized and made as efficient as possible. While this can make for safer and more effective care it also means more opportunity for error. Add to this the high velocity, high complexity, tense environment with a strong hierarchy and you have the makings for error generation.

Hierarchy or a culture of hierarchy can have an adverse impact on teambuilding and teamwork. But, putting a patient to sleep and operating on them is an awesome responsibility. This said, it is equally important for all team members to recognize the responsibilities of each team member and to understand the ultimate responsibility of the surgeon for the patient's welfare. There is obviously a balance between the authority of the surgeon to direct the procedure and the requirement of each team member to effectively voice concerns for the patient's benefit.

All of this can lead to a tense environment. Sometimes it is exacerbated by inappropriate behavior due to inadequate support systems, supply chain breakdowns, instrument processing glitches, inaccurate scheduling, and changes in the day's work schedule at the last minute, technology malfunction or unfamiliarity with the technology in use.

ORs are usually profit centers for hospitals. Hospital management is therefore loath to confront surgical behaviors even when it may be detrimental to patient care/ safety. [An example is that of a senior cardiac surgeon who was in solo practice and grossly overworked but unwilling to accept the reduced income consistent with adding a partner. The result was a major increase in the risk of infection for his patients late in the week compared to the first case on Monday morning. Hospital management did not want to confront the issue because of his high productivity but eventually, when a hospital epidemiologist presented specific data, were forced to intervene due to patient safety concerns.]

On the other hand, hospital management must also recognize the totality of needs and agendas of the surgeons; those needs are not only related the operating room. Private and academic surgeons have somewhat different agendas. Management must recognize that both have office practices to attend and academic physicians have other pressures from their School of Medicine responsibilities. Hospital management must be responsive to these needs as one element of enhancing patient safety.

Also inherent to the OR environment are some basics related to experience, training and also to alertness. Less experienced surgeons are more likely to make an error. Surgeons using new technology without adequate training are prone to more errors. Inexperience in

other team members is also an issue – such as working with an inexperienced scrub, circulator or anesthetist. Assistants may lose alertness during lengthy cases. There is a need for mechanisms to regain alertness at critical times in the case (ala the B2 bomber pilot who flies from Iowa to Afghanistan and back; needs to be especially alert when on the bombing run over the target site but can and should rest at other times.)

Available Data on Patient Safety

On first glance it might seem remarkable that, given the potential of error, there is such a paucity of data available on patient safety in the OR setting, but such is the case. This lack of data also inhibits national organizations and individual hospitals from taking a more proactive stance related to safety in the perioperative environment. Instead, most hospital effort has focused on medication errors, nosocomial infection, blood product administration and other areas where data is more easily accessible and for which data is available today.

Hospitals have long used incident reports to keep track of problems and issues. They are sent up the chain of command for review and for changing procedures to help prevent such an incident in the future. Of interest, incident reports from the OR tend to focus on equipment failures, instruments missing from the set, supplies not available and occasionally on retained instruments or sponges in the site. Rarely do they address medication errors or technical errors on the part of the anesthesiologist, surgeon or nurse. As a result, the frequency of technical errors or errors related to the majority of issues enumerated above is simply unknown.

Twenty years ago the Maryland Hospital Association (MHA) began, with seven participating hospitals, a process of collecting, analyzing and reporting back data on quality indicators. This has grown to now include over 1400 participating hospitals worldwide in a system known as the Quality Indicator Project (QIP) operated for MHA by its subsidiary, the Center for Performance Sciences (CPS.) The indicators (such as unscheduled returns to the emergency room, documented falls, unplanned returns to the OR, etc) were designed to be “value free,” that is, they are meant to offer guidance as to where an institution might want to place emphasis in addressing quality. So a high or low incidence of Caesarian section is not intrinsically “good” or “bad” but rather a marker or comparison with others to offer guidance. Among over 290 acute care measures available to hospitals, certain measures have proven to be especially valuable in addressing not only quality but specifically safety: administration of antibiotic prophylaxis, unscheduled return to the intensive care unit, unplanned returns to the OR, etc. These tend to have a relationship between the care process and a high likelihood of error for which there is a published association.

The JCAHO-mandated ORYX core measurement concept allows use of the QIP system as one of its core measurement techniques; it has become the most widely used of all core measures in the country.

When the University Hospital Consortium (UHC) looked at the literature of OR safety a few years ago it was found to be “incredibly data poor.” Anesthesia was in the lead in documentation but the emphasis was on the single catastrophic event, ala an aircraft crash or power plant failure. Anesthesiologists did do root cause analyses which have led to major improvements in anesthesia care and safety but there was less attention to “near miss” reporting. There was little or no data from the surgeons and hospitals, overall, did not focus on OR errors. UHC set up a hospital-wide PC to Internet-based error event

UNIVERSITY HOSPITAL CONSORTIUM

PATIENT SAFETY DATA COLLECTION

- WEB-BASED, COMPUTER INPUT, EVENT REPORTS
- STAFF CHOICE TO REPORT
- 71,000 EVENTS FROM 60 HOSPITALS OVER 2 YEARS
- 8.7% (6219) FROM PERIOP ENVIRONMENT
- DISPROPORTIONATE % OF HARM FROM PERIOP EVENTS

UHC DATA: JUNE, 2004

reporting system. Their initial lessons were that this elective collection of data greatly improved reporting. Hospital department managers would access and use the data directly in real time rather than waiting for a monthly or quarterly report to be sent back. Managers and others could also do data mining such as looking for the frequency of reported falls. The system does have some deficiencies, perhaps the greatest being that those who enter data do so with their own biases as to what constitutes a reportable error. Reporters are not trained observers but

they do tend to be enthusiastic. So, it is imperfect but a very usable and useful data base. In late 2004, with over two years of reporting by more than 60 university affiliated hospitals, there were over 70,000 events in the data base of which 6219 (8.7%) were from the OR perioperative environment. The most common OR errors proved to be: errors related to procedures, complications of procedures, equipment issues, medication errors and loss of skin integrity.

Further, the Pennsylvania Patient Safety Authority (PSA, www.psa.state.pa.us/psa) has purchased the UHC system via ECRI and has mandated its use to monitor over 420 health care facilities. Its program is now (April, 2005) in its tenth month of operation.

The state of Minnesota mandated that all serious errors (based on a predefined set of 27 criteria which in turn were based on a National Quality Forum list of events that “never” should occur to a patient in a health care facility) were to be reported to a central agency which in turn would make the data public. The first report was issued in January 2005 and covers 16 months of initial data.

Combined, all hospitals in Minnesota reported 99 events of which 52 or just over one half were surgically related. These included 13 operations on the wrong body part, one operation on the wrong patient, the wrong procedure performed on five patients, a foreign body left in 31 patients and 2 unexpected surgically related deaths. The actual incidence was low as these cases, disturbing as they

Minnesota Adverse Events Report
State Wide Surgical Events
378,544 Surgeries

• Wrong Body Part	• 13
• Wrong Patient	• 1
• Wrong Procedure	• 5
• Foreign Object	• 31
• Death	• 2
• TOTAL	• 52

are, were drawn from 378,544 surgeries. This is one more instance, however, that serves to emphasize the types of errors that can and do occur in the OR. The major deficiency of the Minnesota program is that near misses are not reported. How often were errors detected and corrected before actual harm occurred? It is from near misses, which are much more common than actual serious events, that trends and implications can be developed with resultant changes in procedures and systems can be implemented.

In short, there is much data on quality available hospital-wide including some data on the perioperative environment but relatively little information on the most frequent types of errors, both near misses and errors leading to serious sequela in the OR and perioperative setting. It is the author's belief, based on interviews, that this scarcity of data is due to two causes: First, most hospital managers do not enter the OR suite because it means "gowning up" and as a result they avoid the issue of OR safety. Second, there has been little data collected in the perioperative setting by trained observers who can watch for errors of omission and commission, errors of knowledge, training and technique in addition to those that tend to be reported now such as major errors of wrong site or procedure along with instruments not delivered, equipment malfunctions, other supply chain mishaps, etc.

Conceptual Approaches To Developing A Program To Enhance Safety

Medication errors, listed as the most common safety concern by the IOM, are a logical first place to begin a program of patient safety in a hospital and indeed most hospitals have started there. It is sort of a "lubricant" for the whole institution to address the basics of safety. A successful program will address human factors, cultural issues, technologies, a non punitive environment, robots, bar coding, packaging and storage and information technology. All of this can be a means to a more general end of advancing patient safety. Further, medication errors are a major element of all medical errors and so are very important in and of themselves. Obviously, physician input and involvement is essential to a full and completely effective medication safety program but if physician interest cannot be generated early on, there can still be great progress with work by nurses and pharmacists along with medical records staff, clerks and others.

The operating room suite is fundamentally different from other areas of the hospital and as a result patient safety must develop in a manner somewhat different from the rest of the hospital agenda. However, the lessons learned from medication safety can be a stepping stone.

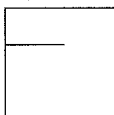
In the OR, the physicians, both surgeon and anesthesiologist, in addition to the nursing staff, are critical to advance the safety agenda and their commitment and support of the work must be achieved before progress can be made.

Any substantive research program must enumerate what happens. But it is important to differentiate between numerator and denominators. To say that 16 serious adverse events occurred seems like a big number. But if there were 3000 cases then the incidence of

errors is quite low. But try to explain that to the one person who was injured, or their relatives or lawyers. The challenge is to separate accurate measurements from a “political” set of issues. Numerators will make the data look alarming; denominators will make it look less so. The real issue is what is happening and how can it be prevented or significantly reduced. To do this requires accurate monitoring mechanisms, mechanisms that are not present in ORs today.

Studying adverse events, fairly uncommon, may not yield great dividends although a root cause analysis of each is important. But evaluating “near misses,” which are not uncommon, may yield large rewards by demonstrating weaknesses in processes and systems.

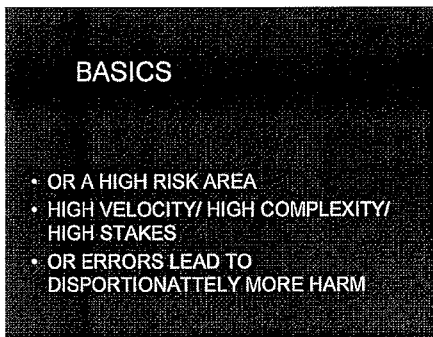
The changes needed will be the outgrowth of process improvement programs since improvements will depend on the improvement of processes. Consider a box representing all procedures. A small box within the box at the upper left corner represents the cases of errors and a smaller box still inside the second box represents the adverse events resulting from those errors. Some advocate focusing on the adverse events, others on all errors since they are the forerunner of adverse events. Either approach has its advocates but critical is to have a formal measurement system that fully enumerates all errors and all adverse events, something lacking at essentially all hospitals today.



The evaluation of reported errors and adverse events will require getting a team of surgeon, anesthesiologist and nurse (minimum disciplines needed; probably will want to add logistics, biomedical, pharmacy, information technology, etc). The team will need an observer dedicated to the program that can observe and collect data on processes and the resultant errors. The observer or another person on the team must be trained and skilled in evaluation and process analysis and redesign so as to assist the team in their planning for corrective actions to change systems.

It is essential that all members of the team be involved and be invested. Leadership from the chief of surgery and chief of anesthesiology is of obvious importance but to get physicians truly invested and committed requires that the process be data driven. Physicians are all scientists at heart and want to address problems from a scientific perspective. Absent such an approach, the physicians will remain on the sidelines, at best, and will undermine the effort at worst. Hospital managers frequently make the mistake of assuming physicians will not participate or that they always doubt the information presented. It is again essential for hospital managers to make the data available and then be prepared and willing to rework the data or collect additional data to satisfy the medical team members. Once this is done, the medical staff will be responsive and responsible.

Approaches to Enhancing Patient Safety in the Perioperative Environment



A successful approach to improving the safety of the OR and its environment will depend on developing an environment of safety and on attention to both human factors and



technology factors. The agenda is to create a high reliability performance organization.

Environment of Safety

Creating an environment of safety is the first and critical step to an overall program on safety in an institution. This includes building a culture of safety within the institution, having intensive and recurrent training, developing organizational learning and creating optimized structures and procedures. There is much about patient safety in the OR that can be migrated from other programs in the hospital. But most of what happens in the OR is simply different from the rest of the hospital and thus needs its own agenda and focus. The closest contemporaries are the other “high hazard” areas such as ICUs, so to the extent that safety work is proceeding there, it can be transplanted to the OR. This requires commitment and buy in from the top of the organization, notably the Board, CEO and executive management. Absent this and no program on safety will flourish because of the cultural changes that need to occur and the commitment of resources that are necessary.

It is a simple fact of life that most hospitals, like most American institutions, operate in a punitive style. Staff members are expected to be careful and not make mistakes. Those who do make mistakes must be identified and punished; they must accept accountability. In our litigation prone society, hospital risk management departments and lawyers will advise professionals not to admit to errors to patients or family, nor even to offer apologies as that may be considered tantamount to admission of guilt in a malpractice case to come later. Although understandable, these are essentially opposite to what is needed for of an effective approach to reduce errors.

Humans make mistakes; this is a deficiency that we all have and always will have no matter how well educated or trained we are. "To Err is Human" was the title of the initial Institute of Medicine report for a reason - it is simply the fact. Given this fact, we need to



develop appropriate methods to deal with this natural human tendency. Without question, chastisement, punishment, and the like are counterproductive; this just leads to underreporting of errors and near misses since no normal individual will want to subject themselves to punishment. The key is to develop a non punitive environment where it is considered the norm to report error and near misses, either directly or anonymously. It is important to note that non punitive does not imply non

accountable. We must all be accountable for our actions. A patient or his family must be compensated if harm befalls him. But the patient deserves to be told of the error, whether harm occurred or not, and the institution needs to know of the error and be capable of responding to it effectively.

Errors that lead to patient harm need to be recognized and reported. Equally important is to recognize "near misses," those errors that were "caught" in time but which, if left unattended, could have led to harm. Most hospitals do not have an active system in place to capture error and near miss reports. In a nonpunitive environment it becomes feasible to institute an error reporting system and assume that with time staff will embrace it. Reports need to be fed into a data base that is regularly analyzed to determine frequency of error types, patterns of errors, etc. Critical to staff involvement is to get feedback regularly and to act on findings.

A systematized process for reviewing errors needs to include root cause analyses or what factors were present that:

- encouraged the error to occur (e.g., short staffing, complex environment)
- prevented early error recognition (lack of monitors/alarms)
- did not actively function to prevent error (non functioning alarms)

Unsafe practices occur because a process works for a person; asking them to change is essentially impossible. People will always gravitate to the lowest energy approach. Rather than try to change the person, instead it is critical change the environment so that a safe practice results. Changing the environment often requires resources. The safe path must be the only path available, if so, it will be the path followed. The needed resource may be a wall, a new technology, or tracking the patient in a new manner such as RFID.

Here are a few examples of creating such a "pathway": Computer Physician Order Entry (CPOE) at the Massachusetts General Hospital (MGH) requires the physician to use the

computer to order a medication; it is impossible to order a drug without using the computer system. Further, the system will not accept an order until the allergy fields have been completed. The result is that the physician uses the advantages of the computer with its allergy checking function. Another example, also from MGH, is a new anesthesia billing system which forced real time documentation by the staff anesthesiologists. This led not only to the better collections for which it was installed but also to much better documentation with improved safety and a significant reduction in errors.

The institution must commit to the process improvement approach and commit to a standardized approach to reporting and analysis of error and near misses. Examples of systems available are those of the Center for Performance Sciences Quality Indicator Project (QIP™) and the University HealthSystem Consortium Error Reporting System.

The QIP™ was initiated twenty years ago for the benefit of Maryland hospitals but now serves over 4000 hospitals across the country and many overseas. Hospital quality staff input specific outcome data which is assembled at CPS, analyzed and compared to local and national norms. Indicators include frequency of Cesarean sections, unexpected return to the OR, ICU or Emergency Room, death following cardiac surgery, etc. Each institution can choose the indicators it wants to utilize. Certain indicators are satisfactory for the JCAHO Oryx requirements. The advantages of the QIP are that trained individuals enter data; the disadvantage is that they do so based on chart review rather than real time observations. The data are submitted in batch to CPS and results are tallied on a quarterly schedule.

The University HealthSystem Consortium program was initiated a few years ago to benefit its membership of over 100 university affiliated hospitals. The system uses any computer with internet access to submit an individual report of an error. Any staff member (physician, nurse, etc.) with a password can submit a report, usually in real time or shortly after an incident occurs. The system queries the submitter for information as to the nature of the incident, the location, some patient demographics, whether and what harm may have occurred and what the causative factors might have been. The advantages are that an incident can be reported in essentially real time by the individuals involved or who witnessed the incident. The local manager can access their institution's data any time and compare to the current averages for all participating hospitals. The disadvantage is that reporting is neither mandatory nor done by trained observers. Thus the results are dependent on the willingness of staff to self report errors as they occur.

Human Factors and Patient Safety

Human factors include leadership, management, teamwork, and the creation of a culture of safety.

Any program of patient safety must start with leadership. There is a need for a surgeon, anesthesiologist and nurse leader to create the vision, inspire all to a higher level and to establish ground rules for work and behavior. But while leadership from anesthesia and