Setting a Research Agenda for Perioperative Systems Design

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Perioperative care may be considered as a system amenable to industrial design approaches. The current care model is disjointed, prone to breakdown by failure of one component, and hostile to personnel. Moving a patient as a person and data set through the flow of perioperative care is not only possible, but it is essential for efficiency and safety. Perioperative systems design integrates the research agenda in technology, safety, informatics, and even telemedicine by putting all the pieces that constitute patient care into a cogent, flexible, and well-managed model.

When our workgroup assembled to create this white paper, we originally intended to focus on how the physical infrastructure of the surgical workspace supported the surgical procedures that occur therein. This scope proved to be less than satisfactory in complimenting the work of the four other focus areas. Consequently, we redefined our mission on several occasions and what arose was a broad set of issues integrated under a research framework we called "perioperative systems design."

Perioperative systems design describes a rational approach to managing the convergent flow of patients from disparate physical and temporal starting points (frequently home), through the operating room (OR), and then to such a place and time (home or hospital bed) where future events pertaining to the patient have no further impact on OR operations (Figure 1). This process for an individual patient can be envisioned as a nested set of timelines: a coarse-grained timeline beginning with the decision to perform an operation and ending when the patient definitively leaves the postoperative experience, and a fine-grained timeline encompassing the immediate pre-, intra-, and postoperative course. At each point, physical infrastructure and work processes impact the progress of patients along these timelines. Starting from this construct, perioperative systems design can be conceptualized, studied, and optimized like any industrial process in which many materials, actors, and processes are brought together in a coordinated workflow to achieve a designed goal.

We will present the current state of the art and technology with respect to the perioperative process. We will develop the notion of nested perioperative timelines, which illustrate how unexpected events pertaining to one patient have effects that propagate downstream and frequently affect global efficiency. We will set out a desired state of perioperative systems design for the OR of the Future (ORF). Next, we develop a research roadmap (essentially a set of specifications) for future research in perioperative systems design. Finally, we will set forth a research agenda for accomplishing the stated goals.

Current State of Perioperative Systems

Perioperative systems design in today's OR involves a complex interaction with (and often reactions to) physical infrastructure, changing technology, and human factors. Hospital processes are often defined by facility design, which is an architectural discipline rather than a discipline of production system design. Once hospital facilities are built, the processes they support are hardwired and difficult to change. Often, processes remain locked-in for decades due to the capital investment that is required to make changes.

New technology has been introduced primarily for intraoperative use; it is not focused on preoperative or postoperative processes, or aimed at infrastructure improvements. Often, new technologies actually disrupt the perioperative process because of their complexity and by creating competition for scarce equipment that has to be moved around and set up for use.

Patients and healthcare providers comprise the human factor in perioperative systems. The current perioperative systems tax the cognitive capacities of both. To lessen the cognitive burden, systems are created which ultimately subject all stakeholders in

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the process to a tyranny of "standard operating procedure."

The best perioperative systems highlight the potential for the application of basic principles of management and industrial design, coupled with emerging technologies, to smooth the flow of patients through future ORs. However, it has not yet been possible to assemble all of the available pieces in one project, and many pieces are missing altogether. Instead, today's pre-, intra-, and postoperative environments are characterized by

1. An array of ergonomic deficiencies;
2. Inefficient, ineffective, and redundant processes;
3. Fragmented communications and team integration;
4. Inflexible "systems" of operation,
5. Staffing shortages (nurses and technicians);
6. Varying levels of competency among perioperative personnel.

These factors contribute to an environment in which safety issues, frustration, and inefficiency must constantly be combated.

Current deficiencies are brought into sharpest focus when the intraoperative portion of perioperative systems design is considered. In today's ORs, teams are fragmented, while communications are by voice, landline telephone, and grease board. A team member who leaves the line-of-sight effectively leaves the team.

Significant energy is diverted from patient care simply to make the ORs and their equipment function. Supply and equipment deficiencies cause wasted time. Information systems are used to a limited degree. The personalities and work habits of individual surgeons are a strong factor in the OR's function. The complexity of work is unrelentingly high. The workload is highly variable and has intense peaks. Unplanned events occur frequently and in clusters, causing unpredictable responses and high stress levels. This stress affects patient care and contributes to a high employee turnover rate and burnout.

Example of the Current State of Perioperative Systems

The most technologically advanced ORs in use today allow us to glimpse the potential of the fully realized ORF, while highlighting some of the previously described problems. A specific example may be illustrative here. Recently, the Center for Integration of Medicine and Innovative Technology (CIMIT) developed a working ORF in concert with the Telemedicine and Advanced Technology Research Center (TATRC) and several industrial partners at the Massachusetts General Hospital.

The objective of the CIMIT ORF project was to bring the most advanced intra- and perioperative technology approved for use with patients together in a single OR, with a commitment to keep the installation at the forefront of available devices. Included in the project were major physical plant changes to allow drastic modifications in workflow aimed at improving OR throughput. Extensive personnel resources were made available, and the CIMIT ORF quickly exceeded expectations with respect to patient throughput. The average time between the departure of one patient from the OR and the subsequent patient being ready for surgery was almost immediately cut by 60% relative to comparable conventional

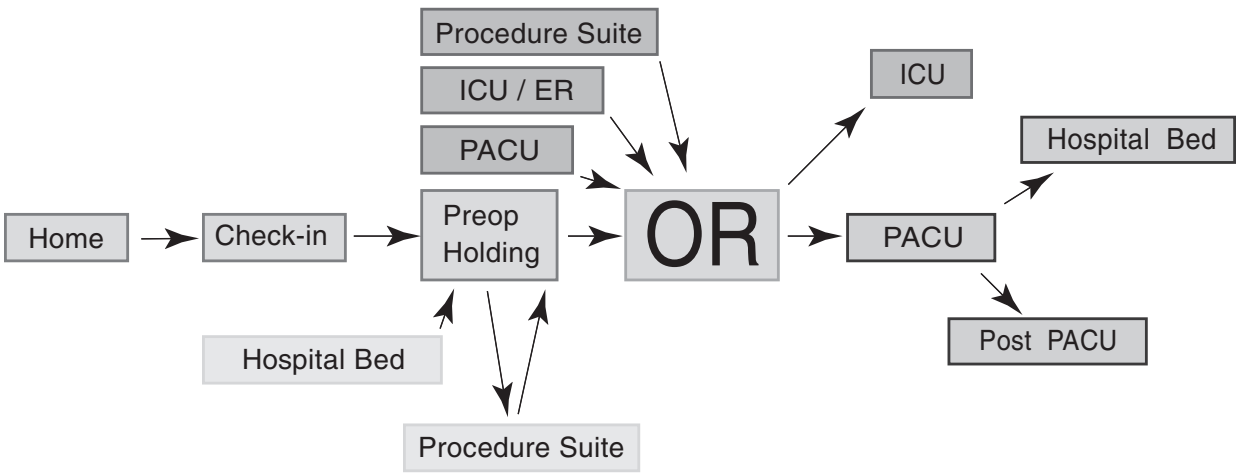

Figure 1. Graphic showing the perioperative movement of patients (PACU, postanesthesia care unit).

ORs doing similar cases (a mix of major intra-abdominal and routine laparoscopic procedures).

Three important qualitative observations arise from the early experience in the CIMIT ORF: First, improvements in one aspect of a perioperative system design highlight fragilities elsewhere in the perioperative system; second, the current state of technology is woefully unready for integration; and third, communication with team members "over the horizon" is still virtually impossible.

The dramatic enhancement in OR throughput has had the effect of adding a catalyst to the rate-limiting step in a multistep reaction: a new rate-limiting step appears elsewhere. For example, the organization and policies of the Massachusetts General Hospital preoperative clinic allow healthy patients to bypass a personal interview with the anesthesiologist. In such cases, the responsibility for discussing anesthesia plans and procedures and obtaining consent falls to the ORF team. This adds to the intraoperative team's workload and increases the likelihood of a day-of-surgery cancellation because of unaddressed anesthetic concerns.

Similarly, the inability to consistently ensure that presurgical documentation (consent, history, etc.) is in the patient's record prior to arrival in the suite interrupts the surgeon's work. Limitations of the postoperative phase of the perioperative system have also appeared. For example, high occupancy in the hospital has caused all of the postanesthesia care unit (PACU) beds to fill early in the day, which in turn, strands a patient in the ORF and brings the operation of the entire suite to a halt.

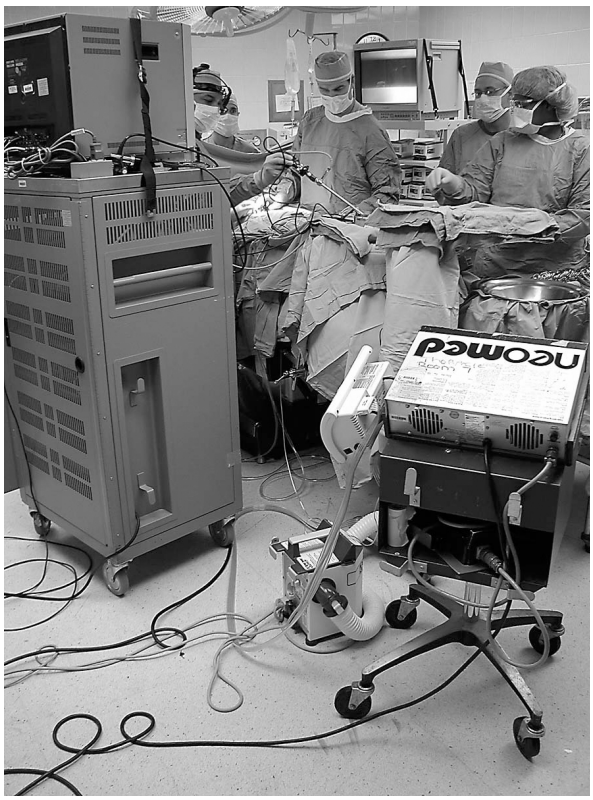

Figure 2. The design of today's operating room results in fragmented communication.

Integration of technology has been one of the major goals and persistent challenges in the CIMIT ORF. On the surgical side, integration of advanced surgical devices has depended upon cooperation between traditional competitors in industry. Enough progress has been made to appreciate the tremendous as-yet unrealized advantages full integration between devices would yield. Other systems are farther away from integration. For example, the anesthesiologist interacts with as many as four separate displays, each attached to its own computer: one for the hospital's patient information and order entry system, one for physiologic monitors, one for automated anesthesia record keeping, and one for drug and supply management.

Communication in the CIMIT ORF is still most effectively carried out face-to-face (Figure 2). This leads to extensive round-tripping by team members throughout the suite for planning and information gathering. Analog walkie-talkies and cellular phones have been rejected as being insufficiently secure for patient confidentiality and too awkward to use. When team members leave the suite, communication degenerates to beeper pages and messages on the main OR public address system. Landline telephones are used for all requests for supplies, technical support, and custodial service between cases, as well as communication with OR administrators and other physicians.

We suspect that similar sorts of system vulnerabilities have come to light during the development of other technologically advanced OR initiatives, and we cited the previous specific example to point out the potential difficulties of integrating changes in a particular facet of perioperative design within a larger system. Hence, perioperative systems must be considered globally when changes are made to one facet; in particular, upstream and downstream issues must be addressed in an effective perioperative systems design.

Perioperative Timelines

The CIMIT ORF experience illustrates that the perioperative process is actually a series of interconnected

events and in actual practice, many steps in the process are completely dependent on the successful completion of the preceding steps. This sequential structure makes it useful to conceive of the perioperative process as a set of two nested timelines (Figures 3 and 4). The overall perioperative timeline begins with the decision to perform a procedure and ends with the patient's departure from the postprocedure recovery area. Nested within this overall timeline is the intraoperative period, which begins when the patient arrives in the OR area.

In the representative set of perioperative timelines shown in Figures 3 and 4, milestone events are indicated below the timeline in rough chronological order with no attempt to represent the actual elapsed time between events. Events and conditions shown above the timeline denote points at which the perioperative process can be derailed. It

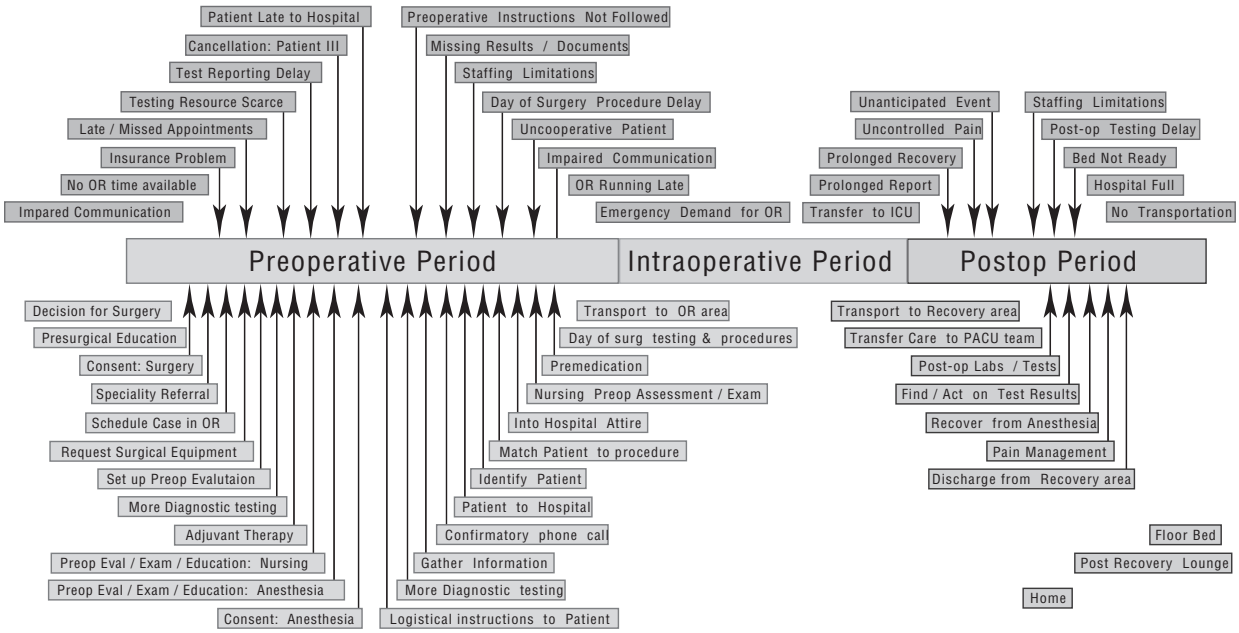

Figure 3. Timeline for perioperative period.

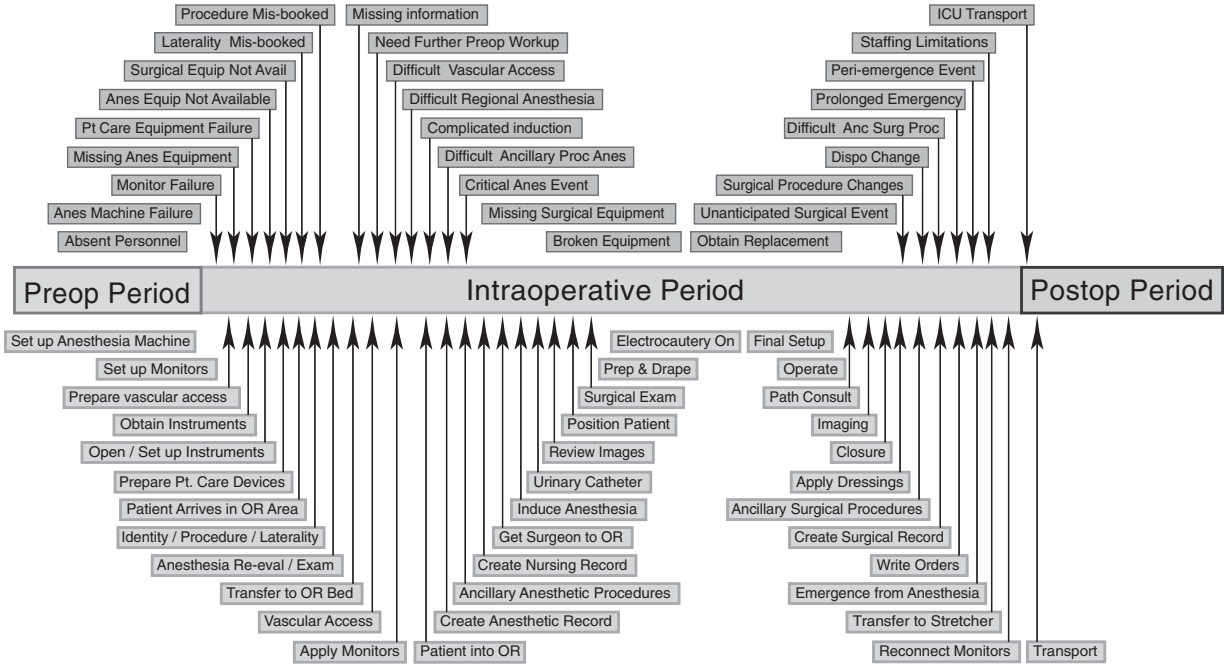

Figure 4. Timeline for intraoperative period.

is readily apparent that the perioperative process is extremely vulnerable to perturbations, particularly during the critical intraoperative portion, when delays in a single case propagate downstream and ripple across the OR as well.

The overall timeline shows that perioperative processes (and perioperative systems design) extend far beyond the OR, both in space and time. In fact, perioperative processes and their vulnerabilities are so distributed that the design of improvements will truly require a multidisciplinary and holistic approach. Any planned change in perioperative systems must be considered in the context of the entire system, and the timelines are a useful construct for this purpose. Furthermore, any proposed research and development effort in perioperative systems design should be evaluated in terms of its likely and potential favorable impact on the perioperative timelines.

Desired State for the Perioperative Systems

Today's ORs deploy an impressive array of standalone technologies. Current trends point to evergreater technological capability in diagnostic and therapeutic tools. We anticipate continued miniaturization of tools and equipment, more mature voice recognition and other communication technologies, and continued advances in robotics and imaging that will lead to more and more noninvasive procedures. We have moved from the network decade of the 90s to the age of sensors today, and in another leap, will move to the coming biotechnology decade as well as seeing the routine development and manufacture of nanoscale materials. These developments will allow the realization of the perioperative system design of the future.

Preoperative Period

From a patient's perspective, the ideal perioperative system allows them to move from home to procedure and back to home seamlessly, comfortably, and safely. From a surgeon's perspective, such a design allows them to transition smoothly between procedures and other clinical activities with minimal frustration while ensuring the safety and comfort of their patients. For the remaining stakeholders in perioperative systems, the ideal design provides a rewarding work experience by minimizing frustration and wasted effort, absorbing the effects of peaks in workload and unexpected events, while ensuring the comfort and safety of patients and healthcare providers alike.

The perioperative system design of the future will put the patient at the center of the process. Starting from the decision for surgery in the surgeon's office, expert software will assist with medical decision making. Referring to comprehensive databases of the patient's medical history, as well as aggregate and surgeon-specific outcomes experience for the contemplated procedure in case-matched controls, decision support software will be able to suggest optimal presurgical testing, diagnostic studies, and interventions to minimize perioperative risk. Interfaced with the patient's calendar and testing facility schedules, these programs will suggest and schedule dates for indicated tests.

Scheduling a case will create a secure Website for the procedure to coordinate appointments, disseminate results to appropriate stakeholders, and keep the patient apprised of their progress along the perioperative timeline. The patient will be able to review educational material tailored for their specific procedure within the context of their intercurrent medical conditions. Again, guided by expert software, specific reminders, perioperative instructions, and information (eg, directions and drive time to the hospital under current traffic conditions) will be sent to the patient.

Practitioner-specific case lists linked to the individual patient and procedure sites will be available to anesthesia, surgical, and allied personnel sufficiently in advance of the contemplated procedure to allow final interventions to be easily made prior to the day of surgery.

Prior to the day's cases, automated supply management will dispense supplies for each case based on a moving window of the surgeon's past use of items for the booked procedure. A second rank of less commonly used supplies, and the items needed for the surgeon's most common "changes" to the booked procedure, will be identified by looking further back for infrequently used items. These will be readied in the background for rapid provision.

Expert workflow process software will use passive sensor technology, such as radio frequency identification (RFID) tags in conjunction with sensors in key portals (eg, doorways), to track and monitor the progress of critical supplies, devices, and actors. When an incipient bottleneck is developing, appropriate personnel will be alerted in time to avert the problem before its effects are felt in the OR. This technology, coupled with time-and-motion

data from more fine-grained sensors throughout the OR, will be used to detect the key events in each OR and infer the progress and projected end times in each room. These data will be used to balance the workload across the ORs by moving cases, when appropriate. Again, this system will rely on expert workflow process software to monitor the workflow and suggest interventions.

On the day of surgery, patients will participate actively in their own check-in process by using their Website to confirm the site and nature of the surgery. The patient will don a beacon device that identifies them and tracks their location within the hospital. It will also link authorized practitioners to the patient's medical record and to the hospital's information management and order entry system. Perioperative patients will also wear physiologic monitors that communicate through the beacon to the hospital information system. Physiologic monitoring will be continuous.

The anesthesia and surgical teams, and appropriate OR personnel, will be authorized to access the patient's electronic medical record and enter orders by RFID when in proximity to the patient and by more conventional means when working remotely. The interface will be a wireless hand-held device carried by the practitioner. Location and process-specific records, such as the perioperative nursing record (used to track personnel and equipment) and the anesthesia record (an information-dense accounting of a period of intense interventions) will be created and maintained automatically when advanced sensors detect key events and will be seamlessly integrated with the patient's hospital medical record. Hence, the user interface for these documents will be completely transparent to the practitioner.

Intraoperative Period

Real-time access to comprehensive medical knowledge databases will play a key role in guiding intraoperative management. For example, a system proposed by Gage will be operant: At the beginning of anesthesia, the anesthesia workstation will access worldwide aggregate anesthesia record databases and practitioner-specific databases.[1] As the anesthetic progresses, the case at hand and matched historical controls will be compared. Decision support software will use these comparisons to suggest optimal management. Moving beyond database connectivity, the anesthesia workstation will run physiologic models tailored to the patient's procedure and comorbidities. Divergence between model and patient behavior will intelligently activate alarms. Appropriate differential diagnoses of patient and equipment problems will be generated and displayed along with context-specific decision support information.

OR equipment, including surgical, anesthesia and ancillary patient support devices (ie, beds, warmers), will be fully integrated within and across categories. Equipment will be fully compatible at the software level, such that single controllers with user interfaces tailored for use by surgeons, anesthesiologists, and nurses can operate all of the relevant equipment. Conversely, this equipment will be fully modular at the hardware level. This allows the OR to be optimally configured to the case at hand, but capabilities can be rapidly enhanced to cope with unexpected complications, and individual devices can be hot-swapped in the event of failure. All of the equipment in the OR will identify itself and report on its condition to the perioperative record, thus creating another database that can be used for utilization and quality assurance purposes.

The ideal user interface will display critical information saliently, while allowing easy access to comprehensive data. Recording and equipment control functions will reside in the same device. Requirements for manual data entry will be minimized by (1) automatic recording from therapeutic devices (ventilator, infusion pump settings), (2) the use of advanced sensors to detect and record key events (intubation, incision), or (3) voice recognition technology to record spoken announcements (eg, drug, route, dose). The user interfaces for surgical, anesthesia, and nursing workstations will reside on devices that are fully mobile (ie, hand carried and wirelessly connected).

Voice communications in the OR will be hands free, wireless, and secure, and will use voice commands to configure the circle of participants to the needs of the moment. This technology will allow easy and instant communication with other personnel throughout the OR. A team member who leaves the OR will remain in the communication loop. Enhanced video capacity will facilitate "telesurgery" consultations.

Intraoperative supply chain management will be as intuitive to use as today's supply cabinets and chest-of-drawer workstations, but with deeper reserves, broader inventory, and software enhancements. For the user, obtaining an item should be as simple as removing it from its storage location. In the background, the system validates the user's authorization to access the item,

establishes the patient's identity and associates the patient with the item (allergy check or alert), documents use, registers the charge, and links to central supply to ensure replenishment as well as identify and ready likely follow-on items.

Postoperative Period

Recovery personnel will have access to all information relevant to their patient's intraoperative course and preoperative issues prior to the patient's arrival in the postanesthesia care unit (PACU). All patients will travel fully monitored from the operating room to the PACU, and the PACU record will simply be an extension of the anesthetic record.

Flexible spaces will be rapidly reconfigured to meet the recovery space needs. What sets the PACU of today's OR apart from any other unit in the hospital includes a cadre of highly skilled nursing personnel and physicians, piped oxygen and vacuum, physiologic monitors, and specific supplies. Due to their high cost, the availability of monitors is frequently the largest infrastructure impediment to adding PACU capacity.

In the PACU of the future, patients will arrive wearing their monitors. Equipment miniaturization will have developed to the point that a source of electricity and access to a wireless local area network (LAN) is all that will be needed to support a mobile "PACU workstation," including oxygen, vacuum, a display for the monitors, and supplies. This mobility of infrastructure will make it possible to reshape flexible spaces into traditional PACU bays, ambulatory recovery space, overnight critical care beds, or ambulatory PACU spaces, based on the projected needs from the day's workload.

Smart scheduling software will predict periods of peak demand for PACU services and schedule personnel appropriately.

Summary

The ORF will be characterized by intuitive communications and sensor technologies that reduce or eliminate medical errors; provide complete 24-hour situational awareness to clinicians, support staff, and management; and support the creation and nurturing of highly trained and cohesive teams. These environments will be scalable.

In the future, the patient's surgical environment will be the primary focus, and the healthcare facility will use technology to improve both the efficiency and effectiveness of the delivery process. This includes the flow of people, information, and materials, and the integration of human systems into these technologies.

Recommended Research Roadmap

The Perioperative Systems Design Workgroup agreed that safe and efficient perioperative systems are critical to both military and civilian contexts. However, today's complex perioperative processes, sometimes perceived as chaotic, unwieldy, and frustrating, have grown up without direction in response to developments in surgical practice and technology. Consequently, inefficient perioperative systems have dampened the benefits of new surgical techniques and high technology.

Research and development is now needed in several areas that defy easy sorting into specific projects; accordingly, we present two schemas for organizing this research effort. The first is based loosely on categories of effort within perioperative systems design, and might at first glance lend itself to the evaluation of technological innovation in perioperative systems. The second research schema invites researchers to consider their work in terms of the overall goals of perioperative systems design. This second, goal-oriented schema is meant to provide an encompassing framework for the critical evaluation of research within the global context of an entire perioperative system.

Category Research Roadmap

Our Perioperative Systems Design Workgroup identified eight major categories for research: safety, integration, connectivity, information, equipment, outcomes, facility design, and personnel. Some of these categories also drew the attention of the other four workgroups, in some cases forming the bulk of their efforts. They are re-treated here for the sake of completeness and to stress the idea that perioperative systems design encompasses the complete care of the patient, from admission to discharge. The research categories identified by the other workgroups that are most relevant to the multidisciplinary focus of our workgroup are highlighted below in the first six items:

Safety

The Patient Safety Workgroup viewed safe care as a precondition and first priority in surgical settings, and we took this to include all patient settings considered in perioperative systems design. The Patient Safety Workgroup pointed out that ensuring safety was consistent with patient-centered care and achieving optimal outcomes. The group also recognized that most errors result from poorly designed systems and clinical processes, and are not the fault of individual clinicians. The Telemedicine Workgroup advocated the use of teleconsultation to broaden the resources brought to bear on intraoperative processes as well as the use of high-resolution recording of complete intraoperative data for later analysis of critical events.

Integration

Both the OR Informatics and Advanced Devices Workgroups focused on equipment data stream and information integration as areas for development. Both workgroups commented on the impressive capabilities of stand-alone equipment and lamented their lack of integration with each other. The Advanced Devices Workgroup focused on the increasing number and types of sensors that clinicians monitor and control. Pointing out the limitations of human ability to capture, process, and integrate raw data streams, a call was made for research into data capture and use, optimized for both real-time analysis and after-the-fact interpretation. The Informatics Workgroup called attention to the fragmentation of medical information from clinical resources such as labs, medical records, and databases.

Connectivity

The Advanced Devices Workgroup stressed the importance of device interconnectivity. Current devices neither communicate with each other nor with common interfaces. All devices in the future should be able to be seamlessly plugged into a network for control, data capture, and safety. A DICOM-like standard needs to be created for all equipment that is used in future operating rooms; furthermore, this standard needs to provide interoperability in both civilian and military environments.

Although the Advanced Devices Workgroup focused primarily on surgical equipment, its position on connectivity logically applies to all devices used in perioperative systems, especially since some devices, such as procedure surfaces, fall within the control of multiple OR stakeholders. Connectivity was also a focus of the Medical Informatics and Telemedicine Workgroups, again, primarily for intraoperative devices.

Information

The Telemedicine Workgroup commented on the tremendous amount of information that passes through the typical operating room without being captured or recorded, and called for the development of technology to capture, broadcast, and record surgical procedures. The Advanced Devices Workgroup called for developing technologies and methods to extract relevant information from voluminous data both for intraoperative guidance and postoperative analysis. The Informatics Workgroup emphasized the need for "smart" software to assist with decision making for complex data sets and the development of standards for information management to make complete medical information fully accessible.

Equipment

Both the Advanced Devices and Informatics Workgroups touched on the need to improve the OR worker's user interface. The Advanced Devices Workgroup couched this discussion in terms of managing data streams and integrated device control for surgeons. The Informatics Workgroup extended this notion, calling for research to design and test the optimal user interface (UI) for surgeons, anesthesiologists, and nurses to input and access clinical data. The optimal UI will support multimode access, where clinicians are able to use mobile devices (such as the PDA or tablet computers), Internet browser access to Intranets, and adequate remote access through secured Internet connections.

The Perioperative Systems Design Workgroup embraces the need to rethink and reconfigure the user interfaces for all OR workers, with an emphasis on integrated data capture, real-time analysis, access to patient records and medical knowledge, coupled with device control.

Outcomes

A recurring theme from the other workgroups was the need to demonstrate return on investment from

potentially expensive ORF research initiatives. For example, from the Advanced Devices Workgroup comes this mandate: In order to fully capture the purported benefits of the components of the ORF, as well as the efficiencies of systems integration, it is necessary to model, predict, and then measure the effect of different patient flow schemes, different staffing models, and room functionality in the presence or absence of its various components. Only by performing such a detailed analysis can one justify the potential added expenses of such a sophisticated OR environment and identify areas of waste that should be modified or eliminated from the design.

The Patient Safety Workgroup chose to focus on outcomes measurement from a quality assurance perspective. They advocated using the sophisticated data collection capability of a realized ORF to identify the true incidence and prevalence of adverse events, to determine the cost of adverse events and to demonstrate the cost-effectiveness of initiatives to ensure safety.

Two additional general issues pertaining to the ORF and identified by the Perioperative Systems Design Workgroup are facility design and personnel.

Facility Design

The pace of technological innovation will only continue to accelerate. Thus it is likely that disruptive technological breakthroughs will occur more than once during the lifetime of the buildings erected to house the ORF. Thus, hospital facilities of the future must be designed to support and nurture technological innovation. In conflict with this notion, today's hospitals grow by accretion and renovation, rather than creation from scratch. Research in perioperative systems design should include a consideration of how spaces can be made more accommodating to new technology, and how new technologies can be used to extend the capabilities of existing space.

Personnel

The ORF will accelerate the onslaught of new technologies and their associated cognitive load on the people who work there. Without proper attention to the care of individuals (caregivers and, to a lesser extent, patients) using the workspace, future ORs may exceed the capacities of their designers. This issue encompasses but goes beyond ensuring the safety and comfort of personnel. New technologies may require completely reconfiguring the OR workforce, redefining work roles and redistributing tasks. Ironically, in future ORs, it may be surgeons whose capacity for work is exceeded, as improved perioperative systems quicken the tempo of patient flow through the perioperative timeline.

Goal Oriented Research Roadmap

Perioperative systems design cuts across all aspects of the care of the surgical patient. It intersects all of the issues addressed by the Safety, Informatics, Telemedicine and Advanced Devices Workgroups. Research critical to improving perioperative systems design may not lend itself to organization under the category schema described above. For example, research into advanced devices to automatically select and deliver supplies to the OR in a timely fashion will touch on safety, equipment, connectivity, information, integration, and facility design in the category schema, but it might more easily be described as an effort to improve readiness in the OR. To address this we have developed a second research schema by defining four broad concepts pertaining to the fundamental goals of perioperative systems design research. These goals encompass the "why" of perioperative systems design research, and any proposed effort must be critically evaluated with respect to how it impacts them:

Readiness

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

Workflow

Addresses the optimal design and deployment of resources and processes associated with the pre-, intra-, and postoperative timelines.

User Expectations

Addresses the needs of those who use the surgical environment, including patients, the surgical team, and other aligned clinicians. Expectations may range from the emotional (eg, reducing frustration, increasing satisfaction) to the physical (eg, reducing

fatigue and stress). In addition, expectations may emanate from awareness of technological progress in other industrial and cultural settings (eg, use of wireless bar-coding in retail, robotics and machine-assisted tasking in manufacturing, and customer service models enhanced through connectivity with the internet).

Training

Addresses the enhanced competency of the perioperative team—individually and collectively—before, during, and after the surgical process, and the development of a learning environment in surgery.

Summary

The issues involved in designing and deploying optimal perioperative systems are multidisciplinary, and will draw input from the following fields: industrial engineering and systems engineering for production system designs, workflow design, systems analysis, and quality assurance; human factors and ergonomics for workplace layout, safety, and training; computer science and human-computer interaction for user-centered information systems and easy-to-use computer systems; and management science for staffing, retention, and organizational behavioral analysis.

Given the breadth of the topic, it is easy for research to occur in apparent isolation, based primarily in one of the disciplines listed previously. Hence, a central goal of the Perioperative Systems Design Workgroup is to create a basis for a cohesive and mutually supportive academic and industrial engineering community focused on the surgical environment. To facilitate this goal, the workgroup created two schemas for research and solution development, one based on broad categories, the other based on goals of the perioperative process. The Perioperative Systems Workgroup advocates that any research pertaining to the ORF be considered in light its impact on the perioperative timelines and in terms of the goal orinted schema. For example, a new technology based in one of the eight categories may be developed to address specific user expectations; however, if this technology requires skilled operators, unique supplies, or any other scarce resource, it is likely to have a negative impact on overall readiness. This may be mitigated if sufficient attention is paid to workflow issues during development and deployment of new technology. New technologies should always be developed with an eye to training, if only to maximize their ease of introduction and realize their full potential. We believe that these schemas will facilitate research programming and funding to target operational goals relevant to most stakeholders in the surgical environment.

Recommended Research Agenda

In the previous section, we laid out eight major topic areas for ORF research and established a framework for considering which perioperative systems design goals specific research projects might address. To accomplish the creation of the desired state of technology in future perioperative systems, a concerted research effort in several more specific areas must be undertaken. These are laid out below. In some cases, the divisions between the topics seem almost artificial, because the topics are so closely related and draw so heavily upon each other.

A major workflow goal throughout the research effort must be directed at reducing the number of user interfaces that healthcare personnel must address, and equally important, making these interfaces more transparent. Here, we define “transparent” as a combination of being intuitive to use and requiring minimal interruption in the user’s primary activity, patient care.

Facilities

The rate of change in medical technology will only increase. Robust demonstration of a new technology’s effectiveness through outcomes projects will increase the urgency of its widespread deployment. This will lead to increased pressure on hospital facilities to provide a reconfigurable infrastructure. Future hospital design should focus on providing spaces designed for maximum flexibility and anticipating the need to reconfigure the space. For example, interior partition walls should be devoid of wiring or plumbing, with impervious surfaces pre-applied, and engineered so that, like furniture, they can be added to a large, finished space. Reconfigurable partitions can be achieved by inclusion of services in ceilings and accessed by pendants (electricity

and gases), while wireless connectivity and portable, battery-powered user interface devices will obviate the need for LAN connections or telephone connections in many walls. This research effort can be expected to pay large dividends for the life of a successful building in terms of workflow and user expectations. Developing and testing the basic concepts for a flexible hospital space should be a short-term undertaking.

Communications

Communications can be (somewhat artificially) divided into person-to-person voice and person-to-group nonverbal blocks. Both will retain their utility in the perioperative system design of the future, and both require significant research and engineering effort to realize their full potential.

Voice communication will continue to be a mainstay for conveying instructions and data, and for synchronizing the information state and plans among team members. What will be different about the ORF is that people will communicate with equipment and the medical record in much the same way as they communicate with each other: by voice. All of this functionality must be delivered without restricting the mobility of personnel. Hence the need for the continued development of ergonomically perfect, wearable, hands-free, wireless voice communications devices.

Other forms of communication that are currently in use must gain new functionality to fulfill their missions in the ORF. For example, the ubiquitous "dry-erase" white board is likely to persist, if only because it is so effective for broadcast communication and providing visual organizing cues. Research in areas of nonvoice communication must focus on capturing the data that people put on such "big-picture" devices so that it can be used by decision analysis programs. Basically, people must be able to communicate with software and databases via the white board. Similarly, the software and databases must be able to use the same device to communicate with people without destroying its functionality.

In a related area, paper documents have a representational value of the big picture. Current software designed for the electronic recording of data that is traditionally represented graphically on paper must be engineered so that this graphic information is returned to the display of data.

As the cost of sophisticated equipment falls and technology continues to develop, we anticipate that significant steps toward the desired state in communications can be achieved in 3 to 5 years, with major benefits to the intraoperative timeline in terms of workflow, readiness, user expectations, and training.

Patient Monitors

Today's conventional physiologic monitors require miniaturization and the application of short-range wireless technology to make them full-time wearable and free of leads. "Put them on once, always on" wireless monitors for patients should be a short-term research focus. Once in the perioperative environment, vital signs should always be monitored, and they should be monitored without tangled, contaminated leads that must be removed and reapplied with each change of location. Creating this monitor architecture allows the patient to be monitored wherever there is a display, since the monitoring hardware and software will be on the patient, rather than the wall. We expect that this level of technology could be achieved in 3 to 5 years, with modest improvements in perioperative workflow but a dramatic impact on perioperative readiness (the ability to anticipate and react to physiologic perturbations foreshadowing catastrophic events).

Effective monitors of each of the major anesthetic interventions: hypnosis, analgesia, and paralysis would be beneficial and merit further research. Two of these three monitors are available in some form, while the third (analgesia) remains a long-term goal. Having all three integrated and consistently deployed could yield significant improvements in perioperative workflow.

An advanced sensor to detect, identify, and quantitate drug administration would be beneficial, in that it would remove the need for human involvement in documentation. Such technology is probably a longer-term goal (ie, 10 years).

Perioperative Medical Informatics

The ideal perioperative system in the ORF depends entirely on having complete information about the patient, disease, surgeon, procedure, anesthesiologist, etc, all available in the same place for use by people and expert software. Much of the required information is already gathered and stored in today's perioperative systems, but not always electronically and never in a single database.

Hence, we endorse the research agenda set forth in the White Paper on Medical Informatics. Related areas of research necessary to use the accumulated data prospectively and effectively are:

Standards for Database Connectivity

Proprietary standards for databases have grown up for a variety of reasons. Although it may suit the purposes of the developers and owners of today's medical databases to limit their connectivity, the ORF will not be realized if such silos of information are allowed to continue. Establishing the framework for a single access point for all patient information, as well as the required data about practitioners, will require a basic science effort by academic researchers coordinating with the research work done by industrial developers. The necessary standards are not likely to grow out of a competitive marketplace, so a regulatory contribution to this effort is likely to be required.

Finally, legislative work to protect the privacy of patients and practitioners in an era where complete data about both are known and readily accessible will be necessary. This aspect of the research effort should be accomplished in the short term.

Although standards for connectivity will have little direct impact on perioperative timelines, they are a required step for enabling much more dramatic improvements through ready access to information.

Expert Software

We anticipate that several areas in the perioperative systems design of the future will require decision assistance provided by expert software. Such software has been described as having "knowledge inside" and will be used in three overlapping sets of circumstances: (1) to optimize decision making when the number of variables affecting the decision exceeds human cognitive capacity (eg, scheduling), (2) to bring aggregate medical knowledge (historical and prospective research) and patient-specific data into the decision-making process, and (3) to make lower level decisions autonomously in the background (eg, picking supplies for routine cases). Scheduling software, both for day of surgery and for the entire perioperative period will remove much of the apparent chaos found in today's ORs, and will smooth out the effects of unanticipated events by quickly adjusting schedules to accommodate new circumstances. To do this, such software will need access to complete data about all of the actors. Wide application of expert software depends on standards for information sharing and seamless access to complete data. Once achieved, huge improvements in perioperative readiness and workflow are likely. However, this is likely to remain an intermediate-term goal (5 to 7 years) while the prerequisite steps are accomplished.

Voice Recognition

Voice recognition for the purpose of controlling devices and software has the obvious advantages of allowing the user's hands to be doing something else and of preventing contamination of the user interface. Voice recognition for the control of devices, query of databases, and use of software will be a near-universal feature of perioperative systems design in the desired state of technology. Research in the areas of informatics, information standards, and expert software should all proceed with the assumption that the voice will be the mode of instruction input. Initially, the direct impact of voice-recognition devices on perioperative timelines may only be a modest improvement, or may even be counterproductive; however, as voice recognition establishes itself as a part of intuitive, easy-to-use interfaces, its impact on workflow will become more positive.

Single User Interfaces Optimized for Target Users

To create an environment where clinicians focus on the care of the patient rather than on the control of devices, interaction with medical equipment must become intuitive and transparent. Redundant actions must be eliminated and all relevant information and control elements placed within easy reach of the user. The intraoperative user interfaces might ideally reside on a tablet computer-based device. Key features will be wireless connectivity and mobility within the OR, and the ability to tolerate high-level disinfection between cases. Perioperative personnel will also need a smaller, PDA-like device for interacting with patient medical records, the hospital order entry system, and imaging displays for use in the preoperative and postoperative periods. Such a device should be hand held and fit in a pocket.

The development and testing of optimal user interfaces for each member of the perioperative

team should be a primary goal in perioperative systems design. This research goal touches on the previously mentioned informatics, standards, expert software, voice recognition, and communications research topics, and echoes a primary research goal of the Informatics Workgroup. Because the optimal user interface depends on achieving all of the information connectivity previously described, and the plug-and-play device architecture described next, it is probably farthest from realization. However, research in this area will contribute significantly to meeting user expectations and improving workflow.

Plug-and-Play, Modular Operating Room Equipment

The creation of a single-user interface implies taking over control of devices and receiving data from sensors remotely and independently from whatever user interface was supplied with the device. Realization of an optimal, unitary information and control interface requires the creation of technology to allow software-level seamless integration of all OR equipment in such a way that another device can invoke all of its functionality. Because technology will continue to be acquired and deployed piecemeal to avoid the cost of replacing usable equipment that is not obsolete, hardware modularity and interconnectivity should become engineering and design objectives.

The drive towards modularity will also be supported by the need for flexibility in how equipment is deployed from case to case. What we are describing is the creation of a plug-and-play environment for OR equipment similar to the one that is just coming to fruition for personal computing. This will require traditional competitors to collaborate, or at least cooperate, and might best be sponsored by creating a government–user–industry consortium to develop the necessary standards to support the needed interconnectivity.

Development of plug-and-play OR equipment reiterates a major research goal of the Advanced Devices Workgroup and extends it to encompass all of the equipment used in perioperative systems. Developing plug-and-play perioperative technology is a prerequisite to constructing optimal perioperative user interfaces, and should be made an urgent short-term priority with an expected deployment time frame of 3 to 5 years for all OR equipment. Moreover, as it becomes available, plug-and-play modular equipment will yield significant improvements in readiness, workflow, and user expectations in its own right.

Perioperative Advanced Devices

Advanced devices for supply chain management and process monitoring await research and engineering development. Perioperative supply chain management is waiting for the application of robotics and expert software to completely automate the picking and delivery of supplies for surgery, anesthesia, and ancillary patient care, both preoperatively and intraoperatively. Research and engineering in this area should focus on creating secure supply delivery with a completely passive, transparent user interface.

Robotic picking, delivery, and dispensing of drugs and supplies, assisted by expert software for decision assistance and autonomous decision making, should be a research focus. Machine-learning algorithms could be applied here in conjunction with historical data mining to predict what supplies will be needed and deliver them to the therapeutic location preemptively. As with all of the other perioperative technology implemented in the perioperative systems design of the future, these elements should be developed as software-integrated hardware-modular plug-and-play devices.

These technologies will have major positive impacts on readiness and workflow. In many cases, the technological hurdles have been cleared in other fields such as manufacturing, and what is needed is an effective transfer to perioperative systems. This could be accomplished in a 3- to 5-year time frame.

Part of the optimal user interface for any procedure-based practitioner is the interface device's ability to infer where in the process the system is at the current time and to offer an intuitive, context based, focused set of next moves on the control side, while automatically recording complete data and displaying that which is most relevant. The user should have minimal intrusions on their attention to the patient from both the control and recording sides of the user interface. To achieve this capability to infer system states and procedure progress, the perioperative user interface devices that are developed will require inputs from advanced sensors. For example, such devices might include advanced optical sensors and image analysis software to infer, in conjunction with data from the gas analyzer, when intubation has occurred during the induction of anesthesia, or when the penultimate suture of a given type has been removed from the scrub table,

prompting the delivery of another. These technologies will have major impacts on readiness, workflow, user expectations, and training; however, huge amounts of processing power and connectivity will be required as well as development of the sensors themselves. Thus, they are more likely to be deployed on the 7- to 10-year time scale.

Suggested Collaborators for Perioperative Systems Design Research

The application of new technologies to perioperative systems designs for the ORF must be driven by the organizations that will use them in order to accommodate the unique features of the deployed locations. Ideally, this will be a collaborative effort led by the users, rather than work done in isolation.

Industry will play a key role in the development of perioperative technologies. Equipment manufacturers have the critical masses of engineering talent and production capacity to design, develop, and build new technologies. Clearly there is a role for ORF implementation projects to push technology and systems to the limits of their designs, pointing the way for future development. These projects should also serve as test beds for potential new technologies and systems.

Umbrella organizations like CIMIT, TATRC, and the Defense Adavanced Research Projects Agency (DARPA) will play key roles in (1) facilitating the interaction between users and developers, (2) identifying areas of mutual interest between traditionally isolated parties, and (3) bringing various stakeholders together. Finally, standards organizations with broad representation from all parties will play a strong role in developing the needed software and hardware standards for interconnectivity.

Conclusions

We begin by restating an essential definition. Perioperative systems design describes a rational approach to managing the convergent flow of patients from disparate physical and temporal starting points, through the operating room, and then to such a place and time where future events pertaining to the patient have no further impact on OR operations.

In contrast to the notion of perioperative systems design, today's complex perioperative processes have grown up without direction in response to developments in surgical practice and technology. Consequently, the benefits of new surgical techniques and high technology have been dampened by inefficient perioperative systems. Perioperative processes are so distributed, and their vulnerabilities are so pervasive, that their reconstruction will truly require multidisciplinary and holistic approaches.

We have presented two schemas for organizing the research effort in perioperative systems design. The first is based loosely on categories of effort: safety, integration, connectivity, information, equipment, outcomes, facility design, and personnel. The second research schema is meant to invite researchers to consider their work in terms of the overall goals of perioperative systems design: readiness, workflow, user expectations, and training. Our goal-oriented schema encourages critical evaluation of research within the global context of an entire perioperative system.

Referring back to the perioperative timelines, it is clear that perioperative processes are extremely vulnerable to perturbations, particularly during the critical intraoperative portion. Making the perioperative system more robust and fault tolerant is a key goal. Any proposed research and development effort in perioperative systems design should be evaluated in terms of its impact on the perioperative timelines, ie, what is its likely contribution to improvements in readiness and workflow, meeting user expectations, and enhancing training in the OR of the Future.

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