Field Research in the Operating Room

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The study of the operating room (OR) is hardly a new endeavor. In 1914, Frank Gilbreth used observation and motion picture photography of surgical procedures to revolutionize the work flow of the OR (Gilbreth & Gilbreth, 1917). In 1979, sociologist Charles Bosk embedded himself in a surgical team, observing surgeons’ behaviors in conference rooms, hallways, and ORs to illuminate the culture of surgery and surgical training (Bosk, 2003; Conrad, 2004; Williamson, 2004).

Today, nonmedical researchers continue to push through the OR doors to study topics such as teamwork (Sevdalis et al., 2009), communication (Gardezi et al., 2009), and efficiency (Farrokhi, Gunther, Williams, & Blackmore, 2013). However, these investigators face unique cultural and logistical complexities that must be understood and navigated for successful research. The purpose of this article is to outline these features as a primer for those planning research in the OR. We also share our experiences and insights from conducting multiple OR investigations, both on our own and in collaboration with colleagues from nonmedical disciplines.

In the complex environment of the OR, studying procedures and behaviors requires communication, clearance, and cooperation.

FEATURE AT A GLANCE:
The study of the operating room (OR) began over a century ago and has continued to advance. However, for nonmedical researchers, unique challenges present themselves that must be carefully addressed. We present an overview of the OR aimed at nonmedical researchers interested in studying the OR environment. Based on our extensive experience, we identify several key challenges and describe ways to circumvent them. With a respectable understanding of the OR environment, we can prepare a researcher to gather useful data. Such investigations have the potential to yield great insights about cost savings, efficiency, methods, processes, and general human interaction, among others.

KEYWORDS:
teams, health systems, medical products, health products, patient handling, organizational behavior, field methods

THE CHALLENGES OF RESEARCH IN THE OR

For any researcher, studying health and health care is inherently difficult. This challenge is even more acute for nonmedical professionals seeking successful research opportunities in the OR, for numerous reasons:

- To protect patient privacy, there is strict oversight of data collection.
- Sterility cannot be compromised, placing constraints on recording devices and limiting locations of direct observation by researchers.
- The emotional tenor in the room varies from tense and urgent to calm and instructional in a matter of moments – for every case, every day.
- High-stakes procedures and time-sensitive OR team coordination have the potential to create an unpredictable setting.
- Depending on the nature of the research, an OR team may be reluctant even to grant an “outsider” permission to enter.

Thus, not only is it a challenge for a researcher to gain approval to enter the OR, but it is also a challenge to navigate the room once he or she has gained access.

GAINING ACCESS

Institutional review board regulation in particular exists with research involving patient observation in the OR. Often, approval from additional regulatory boards (e.g., nurse leadership) may be required. For this reason, beginning this process as early as possible will benefit researchers.

To be granted permission to enter the OR, researchers first need to select an “OR ambassador.” This ambassador should be familiar with the culture, well known and respected among the staff, and able to dedicate time and resources to the research project’s success. The ambassador can assist with identifying appropriate surgical teams and cases, initiating regulatory training and necessary registration, navigating the OR suite, and accessing and interpreting the surgical schedule.
Before entering the OR, a researcher should alert the attending surgeon and anesthesiologist about his or her planned presence on a case. This notice can be accomplished on a case-by-case basis (e.g., via e-mail correspondence with specific physicians) or as a mass announcement (e.g., e-mail correspondence to all OR staff describing the research). If a mass announcement is used, it is still wise for a researcher to remind the surgical staff prior to surgery; the booked OR schedule may not reflect specific details and variations of each case, making open and continuous communication critical. In this case, a close connection with an OR ambassador who works directly with the surgical team may be even more essential for communication on the researcher’s behalf, as e-mails often go unanswered in a busy clinical setting.

**FAMILIARIZATION WITH SURROUNDINGS**

A greater understanding of the environment and challenges in the OR enables a researcher to more seamlessly integrate and utilize the setting. Figure 1 displays a common layout of the operating room, sterile zones, and key participants.

Researchers can expect fixed elements in virtually every OR. Typical permanent equipment includes overhead lights, storage units, and workstations. Mobile but large equipment, such as the surgical bed, anesthesia machine, and suction unit, frequently resides permanently in the room, whereas other large equipment may be wheeled in and out based on the needs of the procedure (e.g., cardiopulmonary bypass machine). These permanent fixtures and equipment can limit movement and lines of sight for observers and restrict placement of recording devices or sensors. When we insert new detection devices in the OR, we first test them in mock setups before live implementation (see the case studies in the sidebar).

All research activities must obey OR sanitation and sterility standards. Everything that comes into the OR must be clean; equipment is wiped down, traffic is limited, and all personnel wear the well-recognized shirt-and-pant uniform (“scrubs”), surgical masks, and hair and shoe coverings. In addition to being clean, the tools and personnel performing the procedure must also be sterile; that is, absent of microorganisms. Sterility reduces the risk of infection when sensitive body parts are cut or exposed, and most surgical procedures require this condition.

In the OR, the sterile field is designated by a set of drapes, typically blue or green, that surround the surgical site. Sterile surgical gowns are of the same color and are worn only by the personnel who will be performing the operation. These personnel cleanse their fingernails, hands, and forearms with antibacterial soap in a process known as *scrubbing in* prior to donning a sterile gown and gloves. Only those scrubbed in can touch the sterile field, which includes the surgical site, the drapes over the patient, and any steriley draped tables or equipment. Moreover, those scrubbed in cannot touch anything nonsterile, including their own gowns below the waist, without compromising the sterile procedure (Anderson et al., 2014; see Figure 2). The sterile field is generally located in the center of the OR, often distinguished by a line or color...
change, whereas the nonsterile personnel and supplies remain toward the periphery (Figure 1).

Despite the fact that nonmedical researchers are asked to wear scrubs, they will not scrub in. This is a critical consideration for a researcher, as it will limit his or her physical location in the OR. Being on the periphery of the OR has the potential to constrain an observer’s points of view, a factor that must be considered when planning research. Even being close to the sterile field can distract the surgical team, particularly the scrub nurse or surgical technician whose job it is to ensure the maintenance of sterility. Therefore, it is important to communicate with the OR staff and set ground rules about where an observer can and cannot stand prior to the start of the procedure. Some common areas of observation for a typical OR setup are shown in Figure 1.

Although comportment in the OR can be a challenge to the unfamiliar researcher, a dedicated OR educator is often available to help orient new staff members and also may serve as a valuable resource for researchers. In addition, many hospitals have institution-specific OR orientation documents that may be accessed by researchers.

THE CAST OF CHARACTERS

The surgical team may be composed of any of several members (Table 1) but, at minimum, includes a surgeon, anesthesiologist, scrub nurse or tech, and circulating nurse.

Identifying individuals can be tricky in the OR. Everyone is wearing the same base outfit, and the scrubbed-in team members are all wearing gloves and gowns. The researcher who enters a case midstream runs the risk of missing the early conversations and routines that would help sort through the different team players. Whenever possible, it is wise (and often required) to have a medically trained chaperone in the OR to help identify different team members. These chaperones can also interpret the action, but researchers must then also be careful not to let all observations flow through an interpreter for loss of their own insight.

As with any new interpersonal scenario, a researcher should introduce himself or herself to the OR team and reiterate the rationale for the intended research. The core members must be aware of and assent to his or her presence, as must any members who enter later in the procedure to give breaks (this exchange of team members is known as a handoff).

By “playing nicely” in the proverbial OR “sandbox,” a researcher has the opportunity to be an observer in an environment ripe with scholarly opportunity. By not doing so, one runs the risk of disrupting the strategic work flow or being dismissed from the OR.

Even if a researcher does successfully integrate into the OR, he or she must understand that data collection always comes second to patient care. Many states have regulations stating that the attending surgeon and anesthesiologist may eject anyone from the operating room for any reason, as patient care is the first priority. As a result, a researcher needs to build inevitable stops, starts, and dismissals into the study’s time frame.

With experience, researchers often develop an “OR sense,” which enables them to identify appropriate times for questioning staff or getting a closer look at a procedure. As a rule of thumb, when staff appear relaxed and are engaging in casual conversation, they will be most approachable. Conversely, when team members are working quietly or having terse, clinical interactions, they should not be distracted.

BUT WHAT ABOUT THE BLOOD?

It is important to remember that surgery is a graphic endeavor, particularly for those unaccustomed to the sights and smells of the human body. By its very nature, surgery will involve blood and other bodily fluids, harsh sounds from equipment and devices used to treat the patient, and unfamiliar smells of medicines, anesthetics, and human tissue. During the preparatory phase of the case, patients may be moved into unusual positions necessary for the procedure, which may be jarring for researchers. In addition, though uncommon, some high-risk surgeries may result in significant complication or mortality.

It is not uncommon for observers to feel light-headed – a sure sign they should sit down or excuse themselves; better to miss some data collection than become a second patient for the OR staff. It is also important that researchers remember that we are all human – having trusted contacts with whom to discuss anonymous OR events may help researchers process upsetting circumstances.

WHAT TO EXPECT FROM TRADITIONAL OR WORK FLOW

Although every surgical operation is unique to the patient and disease, nonoperative work flow is relatively standardized (Figure 3) and includes the following:

- **Room is prepared:** This step requires a team of environmental service specialists who decontaminate the room. Instruments and equipment needed for the procedure are prepared, and the bed and equipment are properly situated. Items that are needed for a particular case and surgeon are listed on a preference card and are delivered to the room on a case cart. A member of the anesthesia team will also ensure the anesthesia drugs and equipment are ready.
- **Patient enters:** The patient will usually be awake and is often apprehensive about the procedure and the foreign environment of the OR. He or she may have been given medication to diminish anxiety or may be sedated. Researchers must be respectful and discreet.
- **Patient is transferred:** The patient is transferred to the operating table, and monitors and sensors are connected to ensure the patient’s safety during the procedure.
Table 1. Roles in the Operating Room (OR)

<table>
<thead>
<tr>
<th>Role</th>
<th>Sterility and Location</th>
<th>Training</th>
<th>Duties</th>
<th>Key Insights</th>
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<tbody>
<tr>
<td>Circulator nurse</td>
<td>Nonsterile; anywhere in or out of the room, perhaps the most mobile job in the OR</td>
<td>Nursing school (associate or bachelor’s degree in nursing), completion of nursing exams</td>
<td>Responsible for keeping patient safe before and during operation, documenting care, and handling communication with those outside OR; also helps prepare room and get additional supplies outside of the OR during the procedure as needed</td>
<td>Circulators can help the researcher get situated in the OR (e.g., where to stand or sit). They are good sources of information about supplies, communication in the OR, and patient flow management.</td>
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<tr>
<td>Scrub nurse/surgical technician</td>
<td>Sterile; standing at the sterile field, assisting surgical team</td>
<td>Nursing school (see above) or surgical technology training program</td>
<td>Responsible for managing all tools and sterile items during the case as well as ensuring that no items (e.g., needles, sponges) are left in the patient at the conclusion of surgery. Scrubs also set up the room and supplies and then assist the surgical team during the case.</td>
<td>Scrubs are often very knowledgeable about the steps in the procedure. They also have insights into instrument and supply utilization and can describe how surgeons may differ in their approach to procedures. The best time to interact with the scrub is during down time or after the case.</td>
</tr>
<tr>
<td>Scrub nurse/surgical technician trainee</td>
<td>Sterile; standing at the sterile field assisting surgical team along with a preceptor</td>
<td>In nursing school or surgical technology training program</td>
<td>On-the-job learning assisting with surgery; in direct contact with sterile tools and sterile field</td>
<td>The nurse/scrub-in-training can provide information about the educational environment of the OR. It is important to remember that this individual is still learning, and it is best not to distract him or her during a case.</td>
</tr>
<tr>
<td>Attending anesthesiologist</td>
<td>Nonsterile; standing or sitting at anesthesia machine</td>
<td>4 years of medical school 4 years of anesthesiology residency</td>
<td>Responsible for maintaining patient level of consciousness, monitoring vitals, and keeping patient safe during the procedure. Must give permission for researcher to be in the OR</td>
<td>Anesthesiologists have important insights on OR work flow and management, drug utilization, patient sedation, and patient safety.</td>
</tr>
<tr>
<td>Certified Registered Nurse Anesthetist (CRNA)</td>
<td>Nonsterile; standing or sitting at anesthesia machine</td>
<td>Nursing school 1 year experience in acute care setting 2–3 years of specific training for master’s/doctoral degree</td>
<td>Often as the sole anesthesia provider in the room, works with an overseeing medical doctor anesthesiologist. Same duties as above</td>
<td>CRNAs have important insights on OR work flow and management, drug utilization, patient sedation, and patient safety.</td>
</tr>
<tr>
<td>Anesthesia trainees</td>
<td>Nonsterile; standing or sitting at anesthetic machine</td>
<td>4 years of medical school</td>
<td>On-the-job training under an attending anesthesiologist</td>
<td>Anesthesia trainees often have insights on medical management of patients, variations in anesthetic practices, and educational environment in the OR.</td>
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(continued)
Anesthesia starts ("induction"): This step may involve local anesthesia (patient is fully awake but the area to be operated is numbed, such as in extremity surgery), sedation (partially asleep, may respond to commands), or general anesthesia (fully asleep, unresponsive, and connected to a ventilator/breathing machine).

Patient is prepared: The patient may be moved to a specific position on the OR bed, a Foley catheter may be inserted, hair may be removed from parts of the body, and a sterile solution will be applied to the surgical site.

Time-out commences: At this point, the presurgical checklist is completed (Leonard, Graham, & Bonacum, 2004; Lingard et al., 2005).

Surgery begins: This section will vary dramatically depending on the type of procedure. It may involve multiple surgeons, staff shift changes, and equipment retrieval. A dynamic operational map, an example of which is demonstrated in Figure 4, can represent the common substeps and various roles of team members in the flow of a surgical case.

Surgery concludes: At this point, the team has a debrief during which pertinent items of the case and recovery are discussed.

Instruments/supplies are counted: Toward the end of the case, surgical technicians and circulator nurses will count both instruments and supplies to ensure that all items have been removed from the patient. They may not be interrupted during this time.

Anesthesia concludes: The anesthesiologist awakens the patient ("emergence"). Once he or she is comfortable, the patient will be moved to the recovery room, often known as a post-anesthesia care unit, or PACU (Ahmed et al., 2013).

Room is "turned over": As described more thoroughly earlier, trained personnel clean the OR, and incoming OR staff prepare for the next case.
Researchers must remember that despite any instinct or interest they may have in participating in the case or in simply helping, they must not. The doctors, nurses, and technicians described in the work flow are intensely trained over years to understand the complexities of the OR. Involvement from an inexperienced, albeit well-meaning, onlooker may distract or even disrupt the case. Even seemingly straightforward tasks related to equipment, bed positioning, or securing the patient are done systematically to avoid injuries.

As mentioned previously, researchers who frequently visit the OR will develop a sense for when it is appropriate to ask questions, take a step closer, and so on. Until then, it is best for a researcher to stand quietly in an appointed area of the OR.

TOOLS AND THEIR PACKAGING

Whether or not one’s research involves OR supplies, the abundant materials that are utilized in the OR are another important factor (Table 2). As one of our collaborators stated, “Surgery occurs in a sea of stuff” (Figure 5). There are metal tools (instruments) as well as disposable items. These items are crucial to a successful outcome and must remain sterile and in their assigned place. If anyone who is not sterile accidentally touches any sterile tools or the sterile field, he or she must alert the scrub team immediately to ensure patient safety. All of these precautions and rules are in place to achieve the very best surgical outcomes.

The process of planning and delivering surgical supplies varies by institution but generally follows a common flow (Figure 3). The instruments and disposables needed for the case are dependent on the surgeon and procedure as well as patient factors. A pick sheet (or preference card) is a list of these items to be picked for the case.

RISKS OF COLLECTING DATA IN THE OR

A skilled researcher will be aware of his or her potential effect on the outcome of a study by the very nature of conducting the study itself. Researchers need to be wary of how their presence may spur uncommon teamwork and communication among OR staff, thereby introducing challenges when conducting these studies (Nurok, Sundt, & Frankel, 2011). As such, data collection must be conducted with an understanding of certain risks.

One common research concern is the Hawthorne effect—the phenomenon whereby workers’ behaviors change when they realize they are being observed (Landsberger, 1958). Although skilled researchers understand this risk, the concept has been directly examined in the OR as it relates to turnover time (the time between the end of one case and the beginning of the next). The significance of the Hawthorne effect is debatable, but researchers should be sensitive to what and who is being studied, especially as it pertains to human subjects (Collar et al., 2012). The OR staff may not realize the motivation behind such actions; however, instituting a period of desensitization (observers present but no data collection), collecting data over extended periods, and educating subjects about the anonymity of the data are ways to minimize the risk (Nurok et al., 2011).

Another information-collecting bias is the tendency for researchers to focus on primarily high-action areas and
high-status team members. Researchers new to the OR can understandably be drawn to the patient's bed, the surgeon's techniques, the instruments changing hands – they are perceived to be the exciting parts of the case. Remaining sensitive to and curtailing this human tendency in such an experience is key. A researcher must remember that the specific research focus will largely dictate which aspect of the OR and which team members are important to observe. Avoiding this focusing or magpie effect can be accomplished by training observers with videotaped encounters and standard observation forms or by delegating specific individuals for each observer to monitor (Nurok et al., 2011).

It is often desirable to have multiple observers in the OR. When multiple observers are used for a study, interpreter reliability must be considered. Depending on their preexisting knowledge and level of preparation, observers may have varying levels of knowledge and perceptiveness. Competency evaluations, systematic training, and repeated assessments of inter- and intrarater reliability can help to ensure high-quality observational data collection (Carthey, 2003).

ENSURING ACCURACY IN DATA COLLECTION

For any researcher embarking on a study of a rich environment full of stimulating information, implementing a system to capture data accurately is key. Video recording can be helpful in ensuring accurate data collection (Carthey, 2003) and has been used for teaching of surgical techniques (Guerlain, Turrentine, Adams, & Calland, 2004) as well as for improvement in quality measures (Weinger, Gonzales, Slagle, & Syeed, 2004). The use of video capture in the OR raises significant legal and ethical concerns, impeding its routine use for research purposes.

Video recording can be helpful in ensuring accurate data collection (Carthey, 2003). But when using video data, it is important to avoid the focusing or magpie effect. This can be accomplished by training observers with videotaped encounters and standard observation forms or by delegating specific individuals for each observer to monitor (Nurok et al., 2011).

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The most promising attributes of OR research are the expanse of preexisting data sources. Technology has had an increasing presence in the OR. Rooms are outfitted with multiple overhead cameras, and many minimally invasive procedures are also conducted using cameras. Documentation of procedures in the electronic medical record is becoming more extensive, as quality reporting guidelines require more data elements (Cevasco & Ashley, 2011). In addition, hospitals are increasingly interested in reporting quality measures in response to demand by savvy consumers of health care (Minami, Dahlke, & Bilimoria, 2015).

OR management software systems contain details about expected case length, required instruments and supplies, and patient data. Modern anesthesia machines can continuously track vital signs and gas-flow parameters. This abundance of

<table>
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<th>Table 2. Types of Operating Room Materials</th>
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<tr>
<td><strong>Category</strong></td>
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<tr>
<td>Equipment</td>
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<tr>
<td>Instruments</td>
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<tr>
<td>Devices</td>
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<td>Supplies</td>
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<tr>
<td>Implants</td>
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<tr>
<td>Tissue</td>
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The antisocial OR

Patient and staff privacy are of utmost importance when conducting research. Photos and recordings of staff, patients, and their information should be acquired only when explicit permission has been given and only for the purposes of research. Any information captured in the operating room is off limits for social media. Being present during surgical care delivery is a special opportunity and must be treated with appropriate reverence and respect.

The research opportunity

We have focused on some of the challenges of conducting research in the OR, but we also want to highlight the incredible opportunity that exists in this largely unstudied environment. One of the most promising attributes of OR research is the expanse of preexisting data sources. Technology has had an increasing presence in the OR. Rooms are outfitted with multiple overhead cameras, and many minimally invasive procedures are also conducted using cameras. Documentation of procedures in the electronic medical record is becoming more extensive, as quality reporting guidelines require more data elements (Cevasco & Ashley, 2011). In addition, hospitals are increasingly interested in reporting quality measures in response to demand by savvy consumers of health care (Minami, Dahlke, & Bilimoria, 2015).
information can supplement any data collected in person or serve as the primary source for data.

However, surgery still remains a very human endeavor, with little of the activity automated or readily captured. We must continue to open the doors of the OR to experts in business operations, behavioral economics, and performance psychology to help improve efficiency and outcomes. As we continue to adapt no-touch sensors and ambient recording tools to the sterile environment, we may also see the former challenges of codifying human activity give way to a new era of surgical analytics. It is incumbent upon those of us who work daily in the OR to facilitate research in the OR and help make these advances possible.

**OUR APPROACH IN ACTION**

We have successfully conducted multiple studies of the OR, for both academic and quality improvement purposes. The following case studies are examples of OR investigations that highlight ways to address and respond to OR research challenges.

**Studying individuals (Challenge: Finding right time to collect the data).** We were interested in how well surgeons could predict which instruments they required for a case and whether there was a learning curve regarding prediction. We had surgeons select instruments from a tray identical to the one that would be used for their case and had them tell us which instruments they would “definitely” and “possibly” use. Our analysis was case specific (we were comparing the surgeons’ predictions with what they actually used), and surgeon predictions needed to be collected before the case.

Because of their busy schedule and the unpredictability of the OR, it was difficult to make appointments ahead of time. We also did not want to disrupt work flow by introducing a nonsterile duplicate tray into the OR itself. In observing staff activities around the time of cases, surgeons would most reliably be outside the OR at the scrub sink prior to the operation. We therefore set up our dummy tray on a table near the sinks, so the surgeons could make their predictions as they were preparing to scrub in.

**Studying teams (Challenge: Navigating research protection for multiple human subjects).** We partnered with design students to investigate information flow among team members in the OR with the goal of identifying novel solutions to improve team communication. Adequate data collection required multiple researchers to be present in each case, and although the data collected would be anonymous, there were many potential staff members “subjects” who might be present on any given day. We therefore began with announcing the initiative, type of data to be collected, and purpose of the research via e-mail to all physicians, nurses, and staff. The study was also discussed at staff meetings leading up to the research period.

We obtained explicit permission from the attending anesthesiologist and surgeon in the days prior to the procedure and obtained the patient’s permission on the day of the procedure. During the time-out, the entire team was reminded of the research and given a no-fault option of asking researchers to leave at any time. When handoffs occurred, the new team member was given the same information. To ensure anonymity, no protected health information was collected on the patient, including the date of surgery, and no names of any staff members were collected.

**Studying work flow (Challenge: How not to disrupt it in the process).** We were interested in the impact of surgical instrumentation and supplies on OR work flow and costs. It was more difficult than originally expected to collect data by visual observation alone, so it was often necessary to ask the circulating nurse and scrub technician specific questions (e.g., “What instrument is that?”). The challenge was obtaining data from these team members during the procedure while minimizing interruption of the OR work flow. It started with establishing a good relationship outside the OR by meeting with team members before research began. During these meetings, we highlighted the potential benefits of the study to work in the OR – enhancing buy-in – and answered questions about the study.

Before each case, the researcher reintroduced himself or herself and reminded the team members of the purposes and protocol of the study. If the researcher had a question for the staff, he or she would wait until the staff member was not engaged in an activity. We then gave feedback to the staff on our results, with the hope of maintaining future willingness to participate. Ultimately, once we had collected enough information from the OR, we moved our data collection out to the supply center and decontamination suite, where the instruments were prepared to be resterilized.

**Introducing novel technology (Challenge: Prevalidating research equipment for the OR).** We were interested in developing a no-touch, automated method for studying the ergonomics of scrubbed team members during surgery. The Microsoft Kinect (Microsoft Corporation, Redmond, CA) is an infrared-based sensor used for interactive gaming with built-in recognition of limbs and joint positions, but at the time, it had not been used routinely in the OR. The device first had to be cleared by our hospital’s clinical...
engineer to ensure that it would not interfere with other OR equipment. We then worked with collaborators to set up a series of environments for testing, including a mock OR table in a dry lab, which enabled us to determine the feasibility of data collection during optimal conditions.

We then used an actual OR after hours to identify placement of the devices. The OR has many obstructions, lights, booms, tables, and large equipment that can potentially interfere with videos and sensors. We ultimately required three devices triangulated in the OR to account for blocked sightlines. Only after we had conducted several successful simulated tests did we then begin studying live operating rooms.

REFERENCES


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