Published in final edited form as:
Hum Factors. 2024 March ; 66(3): 683–700. doi:10.1177/00187208211068946.

Human Factors Integration in Robotic Surgery

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Abstract

Objective: Using the example of robotic-assisted surgery (RAS), we explore the methodological and practical challenges of technology integration in surgery, provide examples of evidence-based improvements, and discuss the importance of systems engineering and clinical human factors research and practice.

Background: New operating room technologies offer potential benefits for patients and staff, yet also present challenges for physical, procedural, team, and organizational integration. Historically, RAS implementation has focused on establishing the technical skills of the surgeon on the console, and has not systematically addressed the new skills required for other team members, the use of the workspace, or the organizational changes.

Results: Human factors studies of robotic surgery have demonstrated not just the effects of these hidden complexities on people, teams, processes, and proximal outcomes, but also have been able to analyze and explain in detail why they happen and offer methods to address them. We review studies on workload, communication, workflow, workspace, and coordination in robotic surgery, and then discuss the potential for improvement that these studies suggest within the wider healthcare system.

Conclusion: There is a growing need to understand and develop approaches to safety and quality improvement through human-systems integration at the frontline of care.

Keywords

surgery; robotics; teamwork; workspace; task design

INTRODUCTION

Accidental patient injury in surgery remains a significant burden. There are an estimated 4000 “never event” claims per year (Mehtsun et al., 2013), while the full range of avoidable complications and accidental injuries is between two (Morris et al., 2003) and 20 times

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higher (Bismark et al., 2006). New technology is intended to improve safety, efficiency, and quality. When introduced to the operating room (OR), it can also generate a range of new intraoperative failure modes, inefficiencies, and unrecognized risks (Cook & Woods, 1996). Interrelationships between systems components are complex and adaptive, with new technologies frequently having far-reaching and opaque consequences for healthcare systems (Catchpole, 2011; Pennathur et al., 2013). In some cases, this adds cost, complexity, and hazard without clear benefit (Dhanani et al., 2021; Kim & Anger, 2010; LaMattina et al., 2018). As well as the “Ironies” (Bainbridge, 1983) and “Surprises” (Woods et al., 1997) of automation associated with many devices, their introduction into the OR also presents challenges for physical, procedural, team, and organizational integration (Catchpole et al., 2019), while often being unrecognized within a culture that has been slow to adopt systems engineering principles (Russ et al., 2013; Waterson & Catchpole, 2016).

Recent FDA guidance for medical device development (Food and Drug Administration (FDA), 2016) is intended to address some of these challenges, but there may be insufficient time, motivation, rationale, or methodology to fully assess integration of surgical innovations into everyday practice (Blandford, Berndt, et al., 2014; Blandford, Furniss, et al., 2014). Indeed, clinical adoption frequently outpaces evidence of safety and efficacy (Bolenz et al., 2010; Dahm et al., 2014). Systematic approaches to understanding and addressing the risks inherent in the introduction of new surgical technologies into the existing systems of work are often lacking (Barkun et al., 2009; Zorn, Gautam, et al., 2009). Without substantial attention to systems-level integration, surgical innovations are likely to generate unexpected patient injuries and present an ongoing public health burden (Parsons et al., 2014).

This paper aims to use the perspective gained from studying the introduction of one of the most pervasive and substantial changes in surgical technology of the last 20 years—the da Vinci robot—to consider the benefits, opportunities, and challenges of applying human factors principles for technology integration to deliver improvements in surgical care. Using the example of robotic assisted surgery (RAS), we explore the methodological and practical challenges of addressing unexpected implementation problems within a successful robotic surgery service. Our intent is not to explore the device designs, but rather determine how systems engineering principles can be applied to their integration and successful use. We also seek to understand where these devices may create new possibilities for failure that might eventually feedback into new designs. Unlike a systematic review, this narrative is driven through a combination of extant and influential literature published by leaders in human factors and robotic surgery, as well as more general observations from the embedded clinical work that supports it. In doing so, we will provide examples of how the adaptation of established approaches can lead to evidence-based improvements in a timely way, within an area of clinical focus that continues to evolve, and where there may be a gap between frontline experience and published studies. Finally, we will discuss the wider implications for systems engineering and clinical human factors research and practice.

THE ADOPTION OF ROBOTIC-ASSISTED SURGERY

Possibly the most ubiquitous exemplar of new surgical technology in the last 20 years is the *da Vinci* surgical robot. Before the introduction of RAS, complex laparoscopic operations were reserved for experts in laparoscopy, and could only be performed for specific procedures. In contrast, the robotic system provides enhanced wrist dexterity, allowing a wider range of surgeries to be conducted by a broad range of clinicians, not just expert laparoscopists. Providing improved access and instrument control, it has allowed a minimally invasive laparoscopic approach for many complex operations, with reported benefits including a reduction in rates of post-operative pain and blood loss compared to open procedures (Anderson et al., 2012), as well as a reduction in conversions from laparoscopic to open surgery because of inability to complete the operation laparoscopically (Feinberg et al., 2016). Consequently, the number of RAS procedures performed worldwide grew quickly (Barbash & Glied, 2010; Mirheydar & Parsons, 2013). In short, the *da Vinci* offers the potential for surgeries with smaller incisions and higher surgical precision, leading to fewer post-operative complications and better outcomes.

Despite the rapid growth of RAS, there have been concerns about the speed of implementation. There has been a relative lack of clinical evidence supporting the superiority of robotic technology (Dhanani et al., 2021) and even suggestions of an elevated prevalence of adverse events and complications in RAS compared to traditional laparoscopy (Paraiso et al., 2011). Robotic malfunctions are documented in 2%–5% of RAS cases (Borden et al., 2007; Kaushik et al., 2010) though safety-related incidents are underreported (Cooper et al., 2013), making the burden of errors in RAS difficult to estimate. Patient safety incidents in RAS may be double that of traditional open surgery (Parsons et al., 2014). The FDA MAUDE database from 2000 to 2013 identified 1391 patient injuries, 8061 device malfunctions, and 144 deaths related to RAS (Alemzadeh et al., 2016). In another study, 2837 events were identified between 2009 and 2012, of which 7% were severe or fatal injuries (Gupta et al., 2017). Unintended injury in RAS has also been the focus of media scrutiny (Carreyrou, 2010) and legal precedent (Estate of Fred TaylorIntuitive Surgical Inc, 2015), which places the responsibility largely on the provider and health system, rather than the manufacturer, to ensure safe operation. Not until recently did systems engineering studies suggest otherwise undocumented complexity, RAS-specific risks, injury mechanisms, and strategies for mitigation (Ahmad et al., 2016; Cao & Rogers, 2004; Catchpole et al., 2016; Randell et al., 2015a, 2016; Tiferes et al., 2016; Yu et al., 2017).

Historically, RAS implementation has focused on establishing the technical skills of the surgeon on the console (Ahmed et al., 2015). The number of cases required to learn the psychomotor skills, procedures, and the management of multiple new instruments (in an absence of haptic or proprioceptive feedback) is around 50–100 cases, depending on case complexity (Lenihan et al., 2008; Woelk et al., 2013). However, this is still not clearly specified (Zorn, Gautam, et al., 2009) and over time has risen in some specialties to as many as 1600 cases (Mirheydar & Parsons, 2013). Moreover, there is a dearth of studies exploring this learning curve for OR staff, who also need new skills (Lenihan, 2017), RAS-specific technical expertise (Randell et al., 2016), and strategies to cope with increased task demands and workload (Weber et al., 2018; Yu et al., 2017). Additionally, there is a lack of cognitive aids, such as checklists, for specific procedures to support this work (Abdel Raheem et al., 2017; Raman et al., 2016). This places greater reliance on the training, knowledge, and expertise of the team, which is already under-specified and inconsistently developed.

Consequent difficulties with port placement, docking, instrument changes, and extra procedural steps, all contribute significantly to operative time (Catchpole et al., 2018), exacerbating risk of anesthesia that arises from placing the patient in steep Trendelenburg (supine on the table, head declined below feet, at an angle of roughly 16°) position (Campos & Ueda, 2014; Kaye et al., 2013). The physical separation of the surgeon from the OR team places additional demands on verbal communication (Randell et al., 2014; Tiferes et al., 2016), the most frequently cited cause of procedural error (Lingard et al., 2008) and surgical injury (Greenberg et al., 2007; Rogers et al., 2006). Moreover, the size and layout of an OR is known to affect clutter, obstructions, congestion from equipment and displays, organization of tubes and lines, unnecessary movement, distractions, team performance (Young & O'Regan, 2010), infection risk, increased threat of accidental disconnection of devices (Ofek et al., 2006), and slips, trips and falls (Brogmus et al., 2007). RAS has particularly acute effects on equipment congestion, the movement paths of staff, and the safe positioning of data and power cables necessary for function (Ahmad et al., 2016). The learning curve required to counter this multitude of systems integration challenges may continue in RAS well beyond 500 cases (Catchpole et al., 2016; Zorn, Wille, et al., 2009) and accounts for a steady increase in the experience recommended to achieve competency (Mirheydar & Parsons, 2013). Table 1 summarizes some of the new skills required.

Robotic-assisted surgery increases task demands for the OR team and increases reliance on vulnerable teamwork and communication, while exacerbating already challenging workspace issues; yet, organizations are left to identify and resolve these risks without formal guidance or available expertise (Catchpole, Bowie, et al., 2021; Russ et al., 2013). Even though these issues have been known for some time (Cao & Rogers, 2004; Webster & Cao, 2006), individuals, teams, and organizations have been left to identify these problems, and generate solutions with little support. These are considerable risks within clinical culture where systems thinking and safety science may still be misunderstood (Wears & Sutcliffe, 2019). As well as the imperative to address these specific problems, the observed exacerbation of known surgical safety risks makes RAS an ideal exemplar for understanding emergent risks in high-technology surgical innovation and integration.

HUMAN FACTORS STUDIES IN RAS

Growing literature is available on human factors studies aimed at exploring a range of challenges in RAS. These studies have confirmed many of the concerns outlined above and have detailed the impact of robotic integration on everyday work, workload, disruptions, and efficiency in surgery. While many of these studies were recently reviewed in more detail elsewhere (Catchpole et al., 2019), for the purposes of this paper, we will focus on several more recent studies, while considering the broader context and implications of their findings.

Workload

Several studies have explored the impact of surgical technology on both physical and mental workload. Although RAS may reduce physical workload for surgeons, it has the potential to increase cognitive load (Abdelrahman et al., 2017), while simultaneously increasing both physical and mental workload for other OR team members (Weber et al., 2018). Others have explored the physical ergonomics surrounding the robotic console and the strain experienced by surgeons (Craven et al., 2013), suggesting ergonomic training (Franasiak et al., 2014) or specific surgical pauses (Park et al., 2016) to avoid musculoskeletal problems present with laparoscopy. In terms of mental workload, particular challenges for the operating team include the docking process, instrument changes (via the manipulation of the robot arms, rather than the traditional manual method), and staying alert to and anticipating the needs of the surgeon. For anesthesia, the need to position the patient in steep Trendelenburg (to provide more space to work in the lower abdomen) leads to specific physiological challenges in the management of hemodynamics and ventilation. This further increases the cognitive challenge. Another concern about positioning the patient in this way is that it can limit access to actions necessary in an emergency, such as placing a central line. In some cases, less experienced anesthesiologists will require a line to be placed prior to surgery, delaying the process for the rest of the team. Thus, the cognitive work for anesthesia to maintain a safe physiological balance will impact both preoperative and intraoperative strategies.

Communication

A range of communication-related studies has revealed environmental and physical challenges, such as noise and console-to-bedside communication problems (Schiff et al., 2016), as well as non-verbal and gestural problems that reduce the ability of the team to anticipate requests (Randell et al., 2014). This also relates to a range of other team-related behaviors that appear to be associated with poor performance in RAS, including (i) decreased engagement in procedure and awareness of processes of the bedside team members, (ii) repeat communication, (iii) clarity about the receiver of a message, (iv) the team cannot communicate directional cues, gestures, movements, eye contact, or face-to-face, (v) inability for the surgeon to see the operating table; the patient; the robot; or the rest of the room, and (vi) surgical ‘tunnel vision’, which helps concentration but can reduce overall awareness. All of these require specific verbal communication strategies to be adopted by the surgeon, bedside surgical assistant, anesthesiology team, and scrub team. Furthermore, because the surgeon is not scrubbed when at the console, they are less able to respond rapidly to urgent needs at the bedside, but rather rely on the bedside team to respond to potential events (such as bleeding) earlier. This is compounded by the inability for the rest of the team to see and respond to the surgeon’s actions or non-verbal cues, which are especially important for understanding if the case is progressing as expected (Schreyer et al., 2021).

Workflow

The workflow and operative efficiency have been found to vary with surgeon experience, the inclusion of residents, and specific procedure type in RAS (Catchpole et al., 2016). Flow disruptions (Alfred et al., 2021; Cohen et al., 2016; Koch et al., 2020; Weigl et al., 2020) or deviations in the progression of the surgical task, can be used to understand the mismatches between work demands and the abilities of those required to do the work. This methodology has been successfully applied across a broad range of surgical contexts (Cohen et al., 2022). The most common disruptions tend to be coordination, communication, training and equipment issues. In some cases, flow disruption rates are sensitive to specific robot models and patient characteristics (Catchpole et al., 2016). This form of data collection has also allowed further analysis, identifying repeated utterances; additional supply retrieval; fogging of or matter on the endoscope lens; and procedure-specific training as particularly disruptive (Catchpole et al., 2018). More recent observations are described in Table 2.

Workspace

It is also increasingly acknowledged that workspace design in the OR can have significant impacts on surgical flow, performance, teamwork, and safety. The effects of the work environment have become a topic of interest to a broader range of experts, including those focused on design and architecture. In all ORs, design issues include ventilation, temperature, humidity, noise, acoustics, and lighting (Joseph et al., 2018). In other surgeries, it has been possible to study the effects of workspace on flow disruptions, and more critically, escalation effects (where small problems can concatenate to become more serious) (Joseph et al., 2019). Many ORs were not originally designed with today's technologies in mind that are not only more numerous, but have also increased in size. However, our initial studies in RAS suggest that this relationship might be more complex than first thought. A recent analysis of six operating rooms across two hospitals found that disruptions increased in relationship to room size (so larger rooms had more disruptions) during the set-up phase of the operations. This was due to problems with wires, cords, equipment causing congestion, and the need for increased movement around the OR (Kanji, Cohen, et al., 2021). Conversely, during the docking stage, smaller rooms created more problems, with equipment rearrangement and robot docking being easier in larger ORs. Studies of room layout in RAS support this view, and suggest that around 50% of OR staff movements could be avoided with better OR layout (Ahmad et al., 2016).

Coordination

Planning, leadership, coordination, and the mutual support required for RAS is above and beyond traditional surgery. The docking process, recently studied in more depth (Cofran et al., 2022), particularly illustrates the coordination challenges in RAS. During docking, particular strains have been observed in room organization, retrieval of supplies, positioning the patient, and maneuvering the robot. Expert teams organize the layout of the room prior to docking to avoid problems with power cords, movement of staff (who are often busy retrieving supplies or instruments at this time), and overhead hazards such as booms. Foreknowledge of the surgical procedure will also influence strategies associated with patient positioning, and the location of the robot and other devices. Observations revealed that moving the robot towards the patient can lead to collisions with equipment (such as monitors, booms, IV poles and drips, anesthesia devices, and power cords). This is particularly challenging for the 'driver' (usually OR staff) who may not have a clear idea about where the surgeon plans to dock the robot, so they must listen to their commands. Our own observations of this process have revealed damage to the robot and other equipment;

minor injury to team members; and frequent delays (Cofran et al., 2022). A poor docking process can create a range of problems later in surgery and relies on multiple people with a shared understanding of the process and goals.

Despite considerable work and growing interest, however, these studies have remained at the periphery of RAS, and have been frequently published in human factors and, ergonomics, and specialist clinical journals. These have mostly focused on observable challenges or those with the potential to be assessed intraoperatively, and have not addressed the broader organizational context necessary for successful RAS function. More recent studies extend across multiple sites (Cofran et al., 2022; Cohen et al., 2022; Kanji et al., 2021). Our own observations and those of others suggest that RAS instrument designs affects sterile processing, for example (Alfred, C., et al., 2021), yet we are unaware of any formal studies of this. However, most critically, while these studies explore work as done in considerable detail, and make multiple recommendations for improvements, few have made and studied those changes. Unless the systemic challenges with RAS are addressed, they will continue to create risks and workplace challenges for patients and clinicians.

TOWARDS IMPROVED ROBOTIC SURGERY PERFORMANCE

While careful design would reap benefits for future attempts at high-technology surgery, there is also a need to address the current challenges. Indeed, surgical innovation often precedes a thorough understanding of safety and systems implications. Given the complexity of surgery, it seems likely that all devices would benefit from some form of human factors considerations during implementation. In order for human factors approaches to be valued by healthcare systems, clinicians, and patients, we need to be able to move from the detailed studies of the problems, challenges and unexpected complexities of surgical robots, to practical, evidential, and sustainable solutions that can be spread and replicated across organizations. There is no single approach that will fit all organizations and contexts, but there are similarities in both challenges and solutions.

Our literature review (Kanji, Catchpole, et al., 2021) identified a significant gap between identified problems with RAS and solutions. The review identified 30 articles. Seven (23.33%) implemented and evaluated interventions, while the remaining 23 articles (76.67%) provided suggested interventions but did not test them. Our study is currently developing ‘proof-of-concept’ interventions involving three commonly applied approaches —team training, checklist development, and workspace redesign (Kanji, Catchpole, et al., 2021) - that we hope will generate an evidence base that will demonstrate the value of human factors analysis and intervention within surgical robotics. Here, we consider those approaches in more detail within the context of our current studies, in order to explore the work necessary to develop, implement, and evaluate solutions to the observed challenges with RAS.

Teamwork Interventions

Teamwork and team training interventions are now some of the best recognized approaches to safety and quality improvement in healthcare, with a considerable evidence base, much of which was established in surgery (Hughes et al., 2016). Teamwork development can take three general forms: (i) The comprehensive TeamSTEPPS approach, which consists of 21 generic themes (Guimond et al., 2009), which is the de facto standard for a broad range of team-related skills, but is not specific either to surgery or RAS; (ii) Non-technical skills frameworks, which have been specifically developed for surgeons (Yule et al., 2008), anesthesiologists (Fletcher et al., 2003) and scrub-techs (Mitchell & Flin, 2008) and have gained considerable traction with surgeons, but may not address the specific challenges of RAS; and (iii) Team resource management training (Musson & Helmreich, 2004) based on aviation-CRM skills, which falls somewhere between the first two, covering both non-technical skills and broader team configurations. The interactive and problem-based approaches favored in this type of training may result in RAS-specific teaching, but may be highly trainer-dependent, and tends not to be systematically derived or repeatable. Some RAS programs now acknowledge the importance of team skills (Ahmed et al., 2015; Sridhar et al., 2017). However, it has also become increasingly clear that generic team training approaches belie the complexity of the interactions between tasks, teams, and technology in different surgical contexts (Catchpole et al., 2008; Robertson et al., 2014). RAS modifies the factors that are required for successful teamwork (Randell et al., 2015a), so TeamSTEPPS may fail to appropriately impact RAS team performance without technology-specific adaptation (i.e., focused content, streamlined delivery) to improve efficacy. Similarly, the standard non-technical skills frameworks that are successfully implemented outside of RAS would likely benefit from specific RAS considerations. Studies focusing on RAS have promoted the inclusion of tactics like standardized communication (Abdel Raheem et al., 2017), non-verbal actions (Sexton et al., 2017), and additional strategies to improve non-verbal communication, situational awareness, and team coordination (Schreyer et al., 2021).

Observations and analysis of specific RAS tasks has lead us to focus on (i) team readbacks, (ii) specific verbal and non-verbal communication, (iii) use of names, (iv) implementation of pre-briefing and post-operative debriefing, and (v) establishing shared awareness through procedural call-outs, especially in the docking phase, for safety-critical moments, (vi) focusing on specific communication protocols between surgeon and anesthesiologist (to communicate existing and expected progress) and between surgeon and nurse (for expected instrument changes). One of the challenges with implementing teamwork-related interventions involves the disruptiveness associated with taking time away from clinical work, which is often difficult to negotiate. An approach that has worked in previous studies (Catchpole et al., 2014) for addressing the training need within organizational constraints is through a short training package that can be delivered via small group teaching in successive one-hour meetings after hours or in scheduled unit meetings. Our prior work also suggests that this benefits from in-situ coaching, reminding the team of teamwork-related behavioral suggestions at the start of each operating list, offering encouragement and helpful critique after each procedure, and debriefing toward the end of the day.

Task-Related Interventions

Task-related interventions focus on defining and allocating tasks among team members to improve workflow and efficiency. Checklists, which have proven extremely popular (O Connor, Reddin, O Sullivan, O Duffy, & Keogh, 2013; Urbach et al., 2014) in healthcare over the last decade, are a task based intervention that may be particularly suited to technology-oriented surgical tasks in RAS. A number of checklists have been developed for RAS, and several evaluated. These include a team-based checklist for open conversion (i.e., changing mid-case from robotic to traditional incision due to inability to complete the surgery robotically) in partial nephrectomy (Zattoni et al., 2017) and radical prostatectomy (Jing & Honey, 2016). At least one has been computerized (McCarroll et al., 2015), while others have been developed but not necessarily tested (Ahmed et al., 2013; Wastler, 2015). Our own work with OR turnover—that is, cleaning the room after a case and preparing it for the next—using checklists supported by other team structures—demonstrated sustained improvements through task definition, sequence, and allocation principles (Souders et al., 2017). However, healthcare has had an uneasy relationship with checklists, which have had variable impacts and effects (Urbach et al., 2014). In some cases, their forced use or misapplication has led to checklist fatigue and cynicism amongst staff (Catchpole & Russ, 2015). This means that the development has to be carefully considered, conducted from the "bottom up" working collaboratively with staff, and be evaluated specifically along perceptions of utility to staff before considering benefits on process or outcome. In addition to adapting turnover task cards for implementation at an additional site, we are working with OR staff to develop a docking checklist and a RAS preoperative briefing process between the surgical and nursing team to review the surgical plan prior to the start of the case.

Workspace Interventions

The benefits to workflow and safety of room size and layout have rarely been evaluated, and the acute effects of a surgical robot on the OR offers an ideal opportunity to conduct more comprehensive evaluation. Simulation studies in other types of surgery have proven valuable for studying architectural questions in advance of new builds (Bayramzadeh et al., 2018a) but may not always be feasible to conduct specifically for robotic surgery, which is usually limited by the size of existing ORs- ORs that are often shared with non-RAS surgeries at other times. Summarizing these observations and the growing literature in this area has led us to focus on specific challenges to the team related to (i) management of power cables, (ii) keeping primary movement pathways clear, (iii) ensuring enough room for the team at the bedside, (iii) managing the location of overhead booms, (iv) focusing on the specific docking paths of the robot, (v) attention to overhead hazards, and (vi) attention to storage of trash cans, equipment and occasional-use objects (such as stools).

Integration into the Work System

In specific cases such as docking, combining multiple intervention approaches may be beneficial. Coordination of the docking process would benefit from (i) training as a team, not-withstanding the organizational challenges of doing that, (ii) preparing to dock with a briefing that includes a reminder of the docking sequence; role allocation; patient positioning requirements; necessary clear paths; and the final position of the robot and equipment and overhead challenges, (iii) a key word or phrase that can halt the process in case of damage, threatened injury, or other process issue, (iv) readbacks or call-outs at the start of the docking process; the completion of key tasks; and verbal acknowledgements, and (v) specificity in the language associated with docking and positioning. Workspace layout considerations include placing equipment in places appropriate for the case prior to docking (or just post-docking), clearing paths for staff, equipment traversal and overhead hazards, and managing power cables.

The operationalization of these improvements is the next challenge. Certainly, the growing range of human factors and systems analysis can deliver different, new, and better ways to train; but training is expensive, the benefits may be limited, and the time available for training staff is already compressed. Placing knowledge in the world, rather than in the head, might be a good place to start. This is one attraction for a checklist; however, in order to be effective and used, that checklist has to be accessible to the team at the right time and in the right place. We aim to experiment with different approaches. For example, a docking checklist that is attached to the robot and visible to the individual driving the robot would allow access at the right time. Similarly, electronic checklists have shown promise (Mainthia et al., 2012) or those that are "pop-ups" in the electronic health record (Long et al., 2018). Other suggestions include alteration of the physical space—for example, the implementation of hooks for the power cables–or other room or device markings (de Korne et al., 2012). All have advantages and disadvantages which need to be carefully balanced and studied "as done" in the wild with clinical teams, iterating towards the best solutions, while generating the experiential and statistical evidence base for their use.

Implementation Science

Engineering approaches also need be explored in terms of their implementation within the wider system of care, and how they may be affected by staff attitudes or changes to the system. The success of safety-related interventions is dependent on the method and context of implementation within the culture, organization, and clinical work systems. This can be understood and documented to improve spread and replication. Quantitative methods alone cannot explain the multi-level impacts of individual, departmental, organizational, and community factors influencing outcomes. Through direct observation, interviews with key informants, and process evaluation, it is possible to explore the wider effects of our interventions or technology on the delivery of care. There is also a need to understand barriers to implementation, particularly of distal influences (S. J. Russ et al., 2015) or where staff may not always be supportive. Implementing and sustaining improvements requires an ongoing involvement of stakeholders across organizational levels and boundaries (Dixon-Woods & Pronovost, 2016). We also need to study more complex adaptive behaviors (Braithwaite et al., 2015) within the wider systems context of healthcare education and safety (Vosper et al., 2018). This benefits from the evaluation of different outcomes at multiple levels of a system across multiple study sites (McCulloch et al., 2015), and from the growing movement around implementation science.

As with engineering approaches, there are many frameworks to choose. Two leading approaches are the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) and the Reach–Effectiveness–Adoption–Implementation–Maintenance (RE-AIM) framework (Glasgow et al., 1999). Both have arisen from the quality improvement movement, based on the recognition that spreading improvements in healthcare have a range of organizational, individual, and practical challenges. CFIR considers 5 domains of influence: (i) process (ii) individuals, (ii) inner setting, (iv) outer setting, and (v) intervention. It helps to describe the implementation process and has been used extensively across a range of healthcare contexts. REAIM focuses more on the life cycle and spread of an intervention, and less specifically on the challenges of getting it into place. Reach considers the number of people involved (and their potential to adopt or resist change). Effectiveness considers the importance of the intervention on outcomes (both those important to individuals, such as ease of use, and those for patients or organizations, such as cost and outcomes). Adoption refers to the number of staff who are willing to participate; implementation to the number of staff who adopt the new approach (i.e., deliver as intended); and maintenance to the extent to which the program becomes adopted and supported by the organization.

A FUTURE APPROACH TO HEALTHCARE HUMAN FACTORS INTEGRATION

This move from human factors recommendations “as imagined” to implemented system changes “as done” exemplifies what is now described as embedded Clinical Human Factors practice (Perry et al., 2021). This suggests a growing need to understand and develop approaches to safety and quality improvement through human-systems integration at the frontline of care. At present this is somewhat distributed, sporadic, and uncoordinated. It is time to consider a healthcare technology human factors integration framework, not just in the operating room, or acute care, but across the healthcare system.

The first requirement for a consolidated healthcare human factors integration approach is a systems framework. Here, the Systems Engineering Initiative for Patient Safety (SEIPS) model has been extremely successful. It has become familiar and respected not just within human factors or systems engineering but to a far wider range of clinicians across different contexts. The recent SEIPS 101 publication (Holden & Carayon, 2021), which turns this theoretical model into a set of practical tools, also demonstrates how SEIPS needs to be complemented by practical approaches. The implementation science frameworks such as CFIR and REAIM, which address how changes can be developed, implemented, spread, and sustained, are also valuable and complimentary, especially for human factors or systems engineers who may not have extensive experience with organizational change.

As models of surgical processes have improved, it has been possible to observe reliably (Parker et al., 2010) the disruptive effects of systemic deficiencies on intraoperative performance in multiple specialties (Feuerbacher et al., 2012; Shouhed et al., 2014; Wiegmann et al., 2007), their downstream impact on mortality and morbidity (de Leval, Carthey, Wright, & Reason, 2000), and effects of different interventions (Catchpole et al., 2014, 2021b; Morgan et al., 2015). This has opened the door to performance evaluations that, while not specifically addressing patient outcomes, are evidenced as being effective through process, teamwork or other proximal outcome measures that are growing in acceptance within the clinical community. Multi-level metrics that are complimentary, potentially overlapping, and based on recognized theories defined, for example, through realist review (Randell, Greenhalgh, et al., 2015), can provide a coherent evaluation across a range of systems dimensions, as defined within a systems framework (Catchpole et al., 2021b).

Direct observation remains the best way to assess variations in the surgical process and the impacts of system design on individual patterns of work (Catchpole et al., 2017). Studies of flow disruptions and the like have been shown to be sensitive to different intraoperative technologies, surgical errors (Koch et al., 2020), surgical experience, room layout (Bayramzadeh, Joseph, San, et al., 2018; Kanji, Cohen, et al., 2021), checklist implementation (Morgan, New, et al., 2015), and the effectiveness of the supporting team (Catchpole et al., 2008). The significance of flow disruptions lies in their ability to provide a hitherto unavailable perspective on the quality and efficiency of the system. This allows for a systematic, quantitative, and replicable assessment of risks in surgical systems, evaluation of interventions to address them, and assessment of the role of technology in exacerbation or mitigation. Our team has also been utilizing observational data collection techniques that might facilitate the collection and classification of these data and eventually put tools in the hands of clinicians to help them collect actionable data themselves.

At a minimum, these assessments need to go beyond either traditional clinical skills or patient outcomes alone, and will need to be developed across a range of clinical stakeholders. This work must involve a multi-disciplinary collaboration, engaging not only the clinical stakeholders—surgeons, OR staff, anesthesia—but also those in preoperative and post-operative care, materials management, sterile processing, device representatives, and leadership. This, in turn, benefits from embedded HF practice, either with human factors or systems engineering professionals working at the frontline in clinical environments, or with clinicians, supported by these experts, who have developed the core sets of skills necessary for the task.

It will be necessary to demonstrate methods that close the gap between the “work as imagined” in which technologies are developed and “work as done.” These approaches can take many forms, and should pull from a wide range of engineering, human-centered design, quality improvement and other approaches, which requires new ways of thinking. This is especially true considering that understanding or measuring the problems does not directly indicate the solutions. Combined, this work needs to address not only established clinical implementation science approaches—which emphasizes the attitudes, evidence and organizational barriers and drivers to adoption – but also the engineering required for the integration of complex clinical technologies into even more complex clinical sociotechnical systems. In essence, this calls for an engineering science for clinical implementation. It is exciting to consider what this might be, and the implications for the human factors, engineering, and clinical professions.

DISCUSSION

The first surgical robot was introduced in 2003. Nearly 20 years later, many operating teams are still struggling with the changes that the technology has brought, despite being well documented and observed worldwide for 15 years (Cao & Rogers, 2004). This is for a variety of reasons, not the least of which is the fact that systems thinking is still not a de facto feature of clinical work; and because it is only relatively recently that human factors engineering approaches have gathered momentum; while interventions that demonstrate generalizable improvements are remarkably rare.

This is not just an engineering problem. Traditional clinicians and clinical scientists may have been surprised that the learning curves for robotic surgeries have not been as smooth, or as clearly delineated as those for lower-tech surgeries. It was not a surprise to find that clinical performance in RAS is not only related to the skills and experience of the surgeon, but also to the RAS skills of the rest of the surgical team, and the support of the organization. The "blame and retrain" attitude to clinical improvement has hampered systems-based learning and improvement (Wears & Sutcliffe, 2019). There remains a tendency to attribute device failures only to technical or engineering problems, rather than explore how failures in decision making or communication might be predisposed by technologies. There is consequently a lack of data, and a means to collect it, associated with these failures. This has also led to a limited dissemination of the methods to address the challenges described here and best practices.

We have not reported on the designs of the devices. Even though this is obviously a key role for human factors engineers that will also benefit from research, integration with the clinical system is always necessary post-design. Despite the best device designs, it seems likely that we should expect similar "surprises" when introducing other technologies into surgery specifically and healthcare in general. A plethora of methods exist to analyze these challenges, while a growing range of solutions can address them. We need to develop practical, integrated methodologies for understanding not just the theoretical and observable problems, but how that understanding can lead to deployable solutions to address them. One role for human factors expertise is in selecting the right assessment methods, while another, arguably newer and more challenging role, is in implementing and evaluating solutions. Wherever possible, we should be helping to develop an evidence base to demonstrate both methods for improvement and methods for successful implementation of those improvements. This would benefit from more formal integration into clinical work systems, rather than peripherally on a by-project basis. This, in turn, means we have to ally with designers, manufacturers, users, clinical scientists, and clinicians, and support the long-term embedded approach to human factors at the intersection of research and practice. This will be all the more important with the rise of AI automation, which is not a feature of the Da Vinci system.

This paper is a reflection on human factors integration in robotic surgery. It is an attempt to "join the dots" between what we know about the specific challenges faced by operating teams as a result of the introduction of robotic surgery, and the future that this might suggest for human factors considerations in high-technology surgery. In an attempt to bridge the research/practice gap we aimed to conduct a narrative review, linking recent prior studies with ongoing practical frontline work. Although much of the work mentioned is our own, and we did not take a systematic approach to the literature, we have included what we see as the key studies across independent and collaborative research groups in at least three countries. A more specific limitation is that our work has generally focused on intraoperative issues. We know that sterile processing (Alfred et al., 2020) and organizational issues such as personnel management and robotic surgery "block times" (Shinder et al., 2017) are important too. However, these, to our knowledge, have not received as much attention from human factors or systems engineers. Methods for studying the organization implications for surgical technologies are also less well defined, though there would be immense benefit for doing so. The challenges of introducing human factors and systems thinking into healthcare have been well elucidated (Russ et al., 2013) and progress has been slow, at least in part due to stiff resistance from the clinical professions to important non-clinical influences and perspectives (Wears & Sutcliffe, 2019), so we should be careful in anticipating what may yet transpire. Nevertheless, we feel that there are a range of important lessons that might be valued for the future of patient safety.

The application of human factors principles allows for an optimistic outlook for RAS. Although we have observed flow disruptions extensively, surgical robots have revolutionized the field of laparoscopy and many patient outcomes are much improved over open approaches. However, RAS has a range of issues that may be recognized at the frontline, but have not necessarily reached leadership within organizations, nor within the wider clinical community. Human factors studies of robotic surgery have demonstrated not just the effects of these hidden complexities on people, teams, processes, and proximal outcomes such as operative duration, but also been able to analyze and explain in detail why they happen and offer methods to address them. These methods are amenable to evaluation, and thus can be used to form an evidence base for the value of human factors and systems engineering in the integration of surgical technology. This combination of evidence base, analytical and interventional methodologies, and frontline implementation will undoubtedly contribute to a better overall understanding of and engagement in the application of human factors principles in healthcare.

CONCLUSIONS

Broader considerations than surgical training alone are important to maximize the value and reduce the risks associated with the introduction of new surgical technology into the OR. There is much that can be learned from the experience of robotic surgery about the challenges of integrating new technology into acute care systems. Healthcare has struggled to embrace systems thinking, and while evidence-based practice is held in high regard, a lack of evidence-based approaches to systemic integration, and a lack of standardized approaches to address the systems challenges associated with surgical technologies, means that some organizations and teams have developed effective techniques, while others have not addressed the inefficiencies and risks nearly as well. Understanding the causes of and solutions to recurrent, technology-induced challenges, and recognizing the need for formal intervention approaches, including system considerations associated with teamwork, task design, and workspace use, are important steps towards improving the safety, efficiency, and efficacy of future surgical technologies. Developing methods and an evidence base that supports findings that systems thinking improves processes such as disruptions or duration and outcomes such as length of stay, blood loss and adverse events, will further enhance this value for clinicians, administrators, device designers, and patients.

ACKNOWLEDGMENTS

This project was funded under Grant Number HS026491-01 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services (KC, JA, TC). The authors are solely responsible for this document's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ.

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KEY POINTS

- Robotic surgery requires new technical, team, and workspace organization skills for the surgeon, the operating room team, and the anesthesiologist while also requiring new training and staff development practices.
- Limited systems thinking in healthcare means it has taken nearly 20 years of robotic surgery use to study and reveal these effects, and there remains no formal acknowledgement or approach to addressing them.
- We outline approaches to teamwork training, task design, and workspace management that might successfully address this gap when implemented carefully into the wider clinical system.
- Recognizing the need for formal intervention approaches and human factors engineering is an important step towards improving the safety, efficiency, and efficacy of future surgical technologies.

TABLE 1:

Examples of new skills required for surgical robotics

New surgeon skills	Basic console operation
	Physical ergonomic understanding
	New psychomotor skills
	New procedures
	New instruments
	Multiple instruments (w/o proprioception and haptics)
	Engaging/disengaging instruments
	New cognitive strategies
	Awareness
	Communication
	Scheduling and sharing resources
	Coordination of staff
	Emergency conversion procedures
New OR staff skills	Docking
	New instruments
	Instrument changes
	Instrument maintenance
	Emergency conversion procedures
	Fault analysis
	Increased mental workload
	Use of space
	Maintenance
	Turnover
	Communication
New anesthesia skills	Patient positioning and associated potential complications
	Emergency conversion procedures
	Increased mental workload
	Specific anesthetic management strategies
	Communication

TABLE 2:

Examples of disruptions observed across four hospitals

Phase	Disruptions	
Pre-Op/Wheels In	Preparation failures	Instrument defects
	Anesthesia delays	Confusion about setup of the room
Docking	Varying levels of experience	Damage to/from booms
	Confused communication	Power cable problems
	Equipment “clashing”	Patient positioning problems
On console procedures	Repeat communication	Equipment blocking sightlines
	Unacknowledged communication	Camera fogging/clearance problems/insertion/control
	OR staff slow response	Breaking sutures
	Confusion about what is happening	Equipment unavailable
	Unclear decision making	General lack of team skills
Off console procedures	Undocking sequence and levels of experience	Confusion about what equipment is needed for procedures that take place here (e.g., cystoscopy)
Closure and Wheels out	Mixed learning	Post-Anesthesia Care Unit (PACU) delays that result in waiting in the OR until PACU team is ready
	Same problems repeating	Lost needles/sponges (Raytechs)/4 × 4 s/caps/etc (coordination of X-ray into the room for lost items with additional robotic surgery equipment)
Post-Op/Turnaround	Slow/variable turnover	

Source: 77 full case observations across four sites.

Cases observed: Hiatal/inguinal hernia repair, hysterectomy, sacrocolpopexy, nephrectomy, prostatectomy.