Human Factors in Robotic Assisted Surgery: Lessons from Studies 'in the Wild'

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ABSTRACT

This article reviews studies conducted "in the wild" that explore the "ironies of automation" in Robotic Assisted Surgery (RAS). Workload may be reduced for the surgeon, but increased for other team members, with postural stress relocated rather than reduced, and the introduction of a range of new challenges, for example, in the need to control multiple arms, with multiple instruments; and the increased demands of being physically separated from the team. Workflow disruptions were not compared with other surgeries; however, the prevalence of equipment and training disruptions differs from other types of surgeries. A consistent observation is that communication and coordination problems are relatively frequent, suggesting that the surgical team may need to be trained to use specific verbal and non-verbal cues during surgery. RAS also changes the necessary size of the operating room instrument cleaning processes. These studies demonstrate the value of clinically-based human factors engineers working alongside surgical teams to improve the delivery of RAS.

Keywords: Surgery, Robotics, Human Factors, Automation, Workload, Error,

Abbreviations:

RAS	Robotic Assisted Surgery
SURG-TLX	Surgery Task Load Index
SEIPS	Systems Engineering Initiative for Patient Safety
IMUs	Inertial Movement Units
EMG	electromyography

1.0 INTRODUCTION

Human factors research in Robotic Assisted Surgery (RAS) offers an opportunity to revisit, in healthcare, the often-observed truism that new technologies demand new knowledge and skills, create new cognitive demands, require management of the technology as well as the task, require new ways to coordinate people and technology, change situational awareness, and can create new opportunities for both success and failure (Bainbridge, 1983; Woods et al., 1997). Barriers to adoption and more widespread use of surgical robots include the overall expense of operating the robot and the efficiency of use, the learning curves required for both surgeons and the team, the difficulties of integrating this new technology into the existing systems of work within the organization, and the potential for serious incidents. Moreover, the significant costs of initial investment ($1-2.3 million), annual maintenance ($100,000-150,000) and the costs per case in disposable instruments, may eventually threaten the existence of robotic services as a viable treatment option which makes the study of efficiency, safety, and quality of RAS even more important. By providing the human-centered sociotechnical systems perspective that is still relatively new to healthcare, human factors studies can help to identify, understand and address these issues.

While controlled laboratory or simulated environments are necessary for assessing usability prior to implementation, they do not always represent the complexity of the time-pressured and resource-constrained surgical environment. We summarize a range of studies which have explored RAS 'in the wild' (Blandford et al., 2015) that considerably extend our understanding of the effects of robotic surgery on surgeons, teams, and organizations and which otherwise may have been missed in traditional laboratory research or conventional usability testing. Features of these studies are (i) multi-disciplinary teams carrying out studies embedded in clinical work, identifying "work as done" rather than "work as imagined", (ii) looking beyond the traditional focus of surgical skills, process efficiency, or outcomes, (iii) framing clinical work within human factors models, in order to generate potential solutions to process, safety and efficiency problems, and (iv) exploring otherwise hidden complexities and risks associated with surgical technologies. These are not new approaches for ergonomics and human factors professionals, but they are less familiar approaches within clinical science or evidence based medicine.

An especially strong feature of the studies reviewed here are that they have been conducted "in the wild" - with real operating teams, performing operations on real patients – rather than in simulation. Given the often unrevealed complexity of healthcare systems, this emphasizes the importance of exploring the real work as it is done, rather than the approximations of simulation or non-clinical user trials that can be useful, but inevitably suffer from under representing genuine clinical challenges and variability. In other words, these studies all demonstrate the challenging realities of working within complex health systems to deliver RAS. The other particular feature of this work is the partnership between human factors specialists, and clinicians – especially surgeons and operating room staff. This demonstrates both specific findings largely ignored by the clinical community, suggesting methods and approaches that may lead to safer and more efficient RAS, and also the general value brought by HF studies conducted in the wild.

2.0 SYSTEMS ENGINEERING APPROACHES AND MODELS

Human Factors and Ergonomics Engineering provides a variety of methods with which to understand and support cognitive, physical and socio-technical work in complex, risky work environments. The cognitive systems triad provides a theoretical basis for understanding and studying complex work systems such as RAS. The triad is comprised of the work system itself (i.e., the system to be controlled, as well as tasks, goals, situations); agents that act upon that system; and artifacts or technologies that mediate the relationship between agents and the work (Roth et al., 2002; Roth and Woods, 1998). Within RAS, the work system consists of the patient, type of surgery, surgical goals, tasks in support of those goals, mitigating health or other patient related factors, and situational factors such as time pressure. A variety of human agents act on this work system throughout a surgery, including surgeons and other clinical staff (e.g., anesthesiologists, nurses, surgical assistants). Artifacts and technologies include the robotic technology (i.e., instruments, cameras, and displays), other laparoscopic and surgical tools; and the medical devices, sensors and displays related to the maintenance of patient health under anesthesia.

The Systems Engineering Initiative for Patient Safety (SEIPS) models offers a further useful perspective on healthcare-related sociotechnical systems (Holden et al., 2013). Working from the users at the center of the system, the SEIPS models describe the interactions between people, tasks, technologies, environment and organization. From a RAS perspective, this helps to understand how surgical technologies change the skills required for the entire surgical team; changes the tasks that they do; changes the optimal size, design and layout of the OR; and changes the necessary training and professional development of the team and work periods and work rosters. SEIPS thus serves as a useful framework for considering the wide range of system components that influence, and are influenced by, RAS.

As compared to traditional or laparoscopic surgery, the robotic system as a mediating technology presents new challenges. From the surgeon's point of view, the system defines the "window" to the work system – the surgical field. Their view is provided and constrained by the camera field of view, angle, and orientation. The technology also has a direct impact on the manner in which the human agents interact. While traditional laparoscopy may disrupt some non-verbal cues, this is exacerbated in robotic surgery. Surgeons seated at the robotic console (with his or her gaze directed into the console, at the display), are not collocated with patient nor others on the surgical team, creating new challenges for communication and task coordination. Physical movements and gestures made by other team members are no longer visible to the surgeon. Likewise, the range of physical movements of the surgeon is constrained, while the assistant by the bedside "dances" with the robot to avoid interacting adversely with the swinging arms, with their motions obscured by the technology. Direct observation of movements (e.g., noticing someone turn to meet a request for a new instrument; a hesitation if that instrument is not the correct or expected one) can no longer be used as a means of implicit communication requiring new communication methods and skills. Furthermore, while staff in laparoscopic surgery may be able to gauge stress from observing a surgeon's postural or facial cues, these are no longer available in robotic surgery. However, the technology may facilitate new strategies for communication (e.g., gestures within the camera view itself).

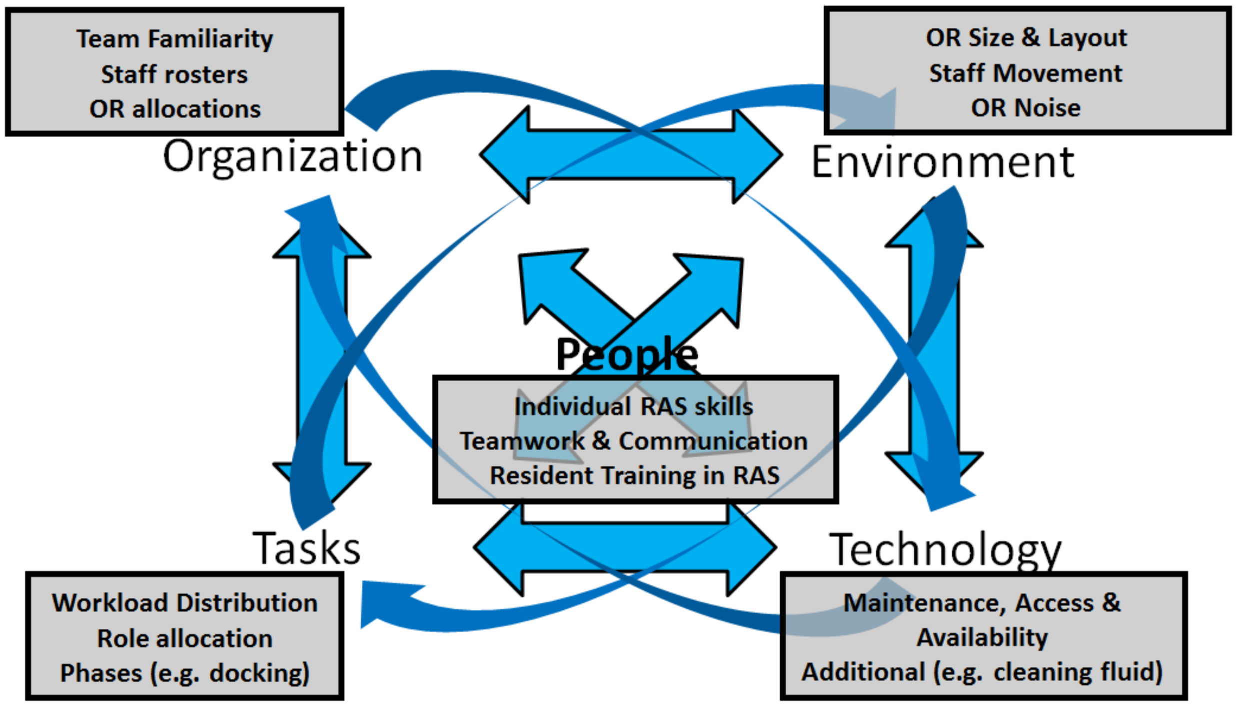

Figure 1: The SEIPS model applied to system-level RAS components

3.0 STUDY SETTINGS AND APPROACHES

Given that the introduction of new technology into surgery can have multi-factorial, emergent, interacting effects on an already complex work environment, RAS research has adopted a number of paradigms and approaches. All the research we summarize here has been conducted in real clinical environments, in partnership with clinicians and clinical organizations, in exploring the challenges in performing “work as done”. The importance of going beyond clinical research (which predominantly focuses on outcomes such as length-of-stay, complications, surgical performance, or pain management) to explore the effects of the technologies on tasks, process, workload, cognition, and teamwork has also required multiple methodological approaches. Self-reports have been used to explore workload in different contexts; direct observation has been employed to study behavior, teamwork and process; and involvement of and interviews with RAS team members, conducted alongside more traditional clinical trials. This has revealed a rich perspective, across different hospitals, and at least three different countries, of how RAS is successfully delivered.

Bisantz and her interdisciplinary team, consisting of human factors researchers, communication researchers, and surgeons experienced in RAS, conducted a variety of studies which focused on the interactions among work tasks (Allers et al., 2016), team communication and coordination (Tiferes et al., 2016), and the mediating role of the robotic technology, within a RAS environment (Ahmad et al., 2016). This work was conducted at a major cancer research center. Hallbeck and colleagues explored physical and mental workload trade-off between the console and bedside roles during RAS surgeries to determine if the purported benefits, in terms of postural and physical workload, were borne out in focused studies (Yu et al., 2017). Weigl, Weber and colleagues applied the Surgery Task Load Index (SURG-TLX) to RAS in an University-based Urology Department in Germany. Catchpole and Anger's work, a partnership between human factors and urological surgery expertise, was conducted at Cedars-Sinai hospital in Los Angeles and used the direct observation of flow disruptions to explore communication, coordination (Catchpole et al., 2017), room turnover (Souders et al., 2017), learning curves (Catchpole et al., 2015), and resident training (Jain et al., 2016). Randell and colleagues in the UK explored how RAS is integrated into routine practice (Randell et al., 2014) and its impact on teamwork and decision making (Randell et al., 2016) taking a realist evaluation approach (Pawson et al., 2005). Here literature reviews and interviews are used to generate specific hypotheses that can be subsequently tested empirically through observation, confirming and exploring the challenges associated with communication, trust, and decision making in RAS. This study was undertaken alongside a randomized controlled trial comparing RAS and laparoscopic surgery for curative treatment of rectal cancer and is one of few studies to look at the use of RAS across multiple sites.

4.0 WORKLOAD IN RAS

Robotic techniques have revolutionized many procedures, providing surgeons better tissue access and tool control than open or laparoscopic techniques. However, impact of these novel techniques on the console and assisting surgeons' mental and physical workload is only just starting to be explored. Generally, workload has been considered as "costs incurred by a human operator to achieve a particular level of performance" and evolves from interactions between task demands, circumstances and personal skills, behavior, and perceptions (Noyes and Bruneau, 2007). For physical workload, there are observational methods to analyze body posture (Zhu et al., 2014, 2017) and more recently more objective measures such as Inertial Movement Units (IMUs) (Morrow et al., 2016). Workload can also be measured objectively with EMG, heart rate or using subjective measures, such as the body part discomfort (Kuorinka et al., 1987), NASA-TLX (Hart and Staveland, 1988), and SURG-TLX (Wilson et al., 2011).

In a recent systematic review and meta-analysis comparing surgeon workload in laparoscopy and RAS, overall workload was found to be found to be significantly lower with the robotic technique than laparoscopic technique [Mean difference -5.57 (95% CI -10.75, -0.38)], with heart rate, found to be significantly lower with the robotic technique than laparoscopic technique [Mean difference -11.25 (95% CI -13.74, -8.75)] and musculoskeletal symptoms reported with different nomenclature (e.g., pain, fatigue, discomfort, numbness) and scales which required normalization of the results before reporting the final findings (Abdelrahman et al., 2017). There is a high prevalence of shoulder disorders among surgeons, which not only may lead to sick-leave, but may also impact surgical performance and patient safety, which is why many surgeons may turn to RAS to reduce the physical workload (Plerhoples et al., 2012). However, though RAS console surgeon physical demands may decrease, greater mental resources are demanded for management of the technology, accounting for the mediating role the technology plays between surgeon and patient, the greater need for communication, and the consequent increase in task complexity.

RAS may introduce a range of new mental workload challenges, for example, in the need to control multiple arms, with multiple instruments; and the increased demands of being physically separated from the team. This spatial separation may also introduce new demands for surgeon's mental capabilities particular with respect to maintain awareness on the overall situation in the OR and surgical decision making. Thus, Weber, Weigl, and colleagues (Weber et al., Under Submission) conducted a study that investigated the perceived mental workload reports of the OR team members during 43 RAS-procedures (40 radical prostatectomies and 3 partial nephrectomies). At the end of each observation, all OR team members were asked to fill out short questionnaire to evaluate their perceived mental workload. A total of 234 workload assessments were received (100/42.7% from nursing; 87/32.2% from surgeons and surgical assistants; 47/20.1% from anesthesiologists).

All three professions evaluated the perioperative demands during RAS differently. Significant differences between the professions for two of the three SURG-TLX mental workload dimensions were obtained. Mental demands and distraction were rated significantly higher among anesthetists compared to surgeons, whereas surgeons gave significantly higher ratings for perceived productivity and quality of work during the procedure compared to nurses and anesthetists. We also noted that anesthetists may experience new or particularly high intraoperative workload demands due to changes in the management of anesthesia. In particular, due to high angle patient positioning during the robotic operation, attention and adaptation to blood pressures is necessary. These perceptual differences have been found in previous OR-based investigations, showing different perceptions among professions about the extent and value of interactions in the OR (Sexton et al., 2006; Sexton et al., 2000).

In order to test whether physical workload was being transferred from the surgeon to the surgical assistant by the bedside, a study was performed of physical workload for console and assisting surgeons during RAS using objective and subjective physical measurements. Ten Swedish surgeons with 3 to 25 years (median 12) of surgical experience performed 15 robotic prostatectomy cases. For the purpose of postural load quantification, they wore IMUs to track neck, shoulder, and torso postures. The muscular activity was obtained by surface electromyography (EMG) bilaterally from the upper trapezius muscle, and normalized to the individual maximum. Assisting surgeons by the bed-side worked in demanding neck postures for 58% of the procedure compared to 24% for the console surgeon ($p<0.01$). Surgeons at the console were primarily in static postures; there were 2-5 times more movements in the assisting role than at the console ($p<0.01$). The 10th percentile of static muscle activity level at the console was higher on both sides, significantly so for the right trapezius (Yu et al., 2017). The static level was high in comparison to other occupations. In conclusion, the neck postures were more flexed and demanding for assistants at the bedside. However, the console may constrain postures more than expected, leading to static loads that have been associated with musculoskeletal symptoms for the neck-shoulder region.

While it appears that some aspects of mental workload and physical stressors for some team members are reduced, they may increase for others. Thus, while more definitive studies are awaited, we observe a repetition of the familiar observation that purported benefits are not necessarily supported by detailed human factors and ergonomics investigations.

5.0 WORKFLOW DISRUPTIONS IN RAS

Workflow disruptions impact efficiency, safety, and quality of care, and can signal deeper problems within the system of work. The Flow Disruptions observational methodology counts and classifies the events that disrupt the natural progression of a case (Parker et al., 2010). In most surgeries these 'hiccups' occur approximately every 5 to 15 minutes, and are usually an indication of mismatches between the required process, and the resources (human, environmental, organizational, etc.). They have been shown to correlate with surgical errors (Wiegmann et al., 2007), care duration (Shao et al., 2015), and can concatenate to threaten the safety of the patient (Catchpole et al., 2006; de Leval et al., 2000). Similar approaches label essentially the same types of observations as "Non Routine Events" (Schraagen et al., 2010; Weinger et al., 2003), minor and major problems (Catchpole et al., 2007; de Leval et al., 2000) or glitches (Morgan et al., 2013).

Direct observation of flow disruptions in 89 RAS cases (Catchpole et al., 2015; Catchpole et al., 2017), found a mean of 9.62 flow disruptions per hour, predominantly caused by coordination, communication, equipment, and training problems. Operative duration and flow disruption rate varied with surgeon experience, training cases, and surgical specialty. The highest rate of flow disruptions was found during the docking period, followed by the main surgical intervention. The fewest flow disruptions were found once the surgeon had completed their work on the RAS console. During some parts of the operation, disruption rates were also sensitive to the robot model and patient characteristics. Team familiarity was not evaluated in these studies and may have contributed to variability in disruptions, though a relatively small pool of specialist staff were involved.

Allers (Allers et al., 2016) also looked at events and activities which cause a pause in the surgical procedure, as indicated by a lack of motion of surgical instruments (seen on the console video). These events can be understood in terms of the cognitive triad, and include technology related pauses (e.g., cleaning the camera, changing instruments); those related to system agents (e.g., pauses to allow surgical training, to switch between surgeons at the console, or to clarify communication) and others related to the surgical work itself (e.g., handling specimens). Importantly, even pauses not directly involving the mediating artifacts may still be related to the presence of the mediating technology – for instance, time to switch from supervising to trainee surgeons at the console.

Studies are also suggesting that surgeon experience plays a significant role in the frequency of flow disruptions (FD) over a period that extends well beyond the usual technical, procedural, or psychomotor learning. Catchpole et al. (Catchpole et al., 2015) found that surgeons who had conducted more than 700 RAS cases encountered only about 60% of the disruptions encountered by surgeons with less than 250 cases (13 FD/hr vs 8 FD/hr). Since it is extremely unlikely that this difference is due to the procedural knowledge or psychomotor skills of the surgeons, it seems reasonable to attribute this to the ability of the surgeon to communicate and marshal his or her team to anticipate and avoid potential problems. In other words, this is a reflection of the knowledge, amongst more experienced surgeons, that a successful, smooth RAS requires considerations and skills beyond the traditional surgical knowledge. A second study (Jain et al., 2016) explored thirty-two RAS operations, specifically focusing on the effects of resident training. They found that each disruption added on average 2.4 minutes to a case's total operative duration, with the number significantly increased by resident involvement. About one quarter of the training-related FDs were procedure-specific instructions, while one third were related to instrument and robotic instruction. However, pauses to teach residents do not appear to create significant intraoperative delays.

These findings suggest that within robotic surgery equipment, training, communication and coordination disruptions predominate. Though disruption rates have not been directly compared, other types of surgery have similar coordination and communication challenges, but do not tend to experience the equipment and training issues to the same degree. It stands to reason that a technologically more complex procedure would experience more technology-related problems; while the need to acquire specific robotic skills, coupled with reduced opportunities for learning (in comparison to the high volumes of laparoscopic or open surgeries) may lead to greater teaching load, resulting in more frequent training-related disruptions. The evidence suggests that experienced surgeons in particular can anticipate and reduce these disruptions by supporting the whole team. In the next section we explore studies that have specifically focused on teamwork and communication in RAS and thus explain the causes of these disruptions.

6.0 COMMUNICATION AND TEAMWORK IN RAS

RAS fundamentally changes the physical relationship between team members, and their roles, skills and interactions. One consistent observation across different surgical specialties demonstrates that communication and coordination problems are relatively frequent (Catchpole et al., 2008; Catchpole et al., 2010; Greenberg et al., 2007; Lingard et al., 2004; Lingard et al., 2002). However, the nature of those disruptions – and, conversely, the nature of successful teamwork – varies vastly across different specialties. For example, on-pump cardiac surgery requires constant interactive communications between surgeon, anesthesiologist, and perfusionist (Catchpole, 2011), while laparoscopic cholecystectomy requires particular interactions between surgeon and assistant regarding the use and position of the camera. In robotic surgery, the surgeon is no longer at the operating table, so cannot see precisely what is happening at the operating table, nor can the team always hear. Consequently, further study of the communication flow disruptions in robotic surgery suggest that nearly 60% are attributed to repeat communications – either because the message was not heard, or because there was no acknowledgement (‘read back’) from the receiver of having heard (Catchpole et al., 2017). Without the visual feedback of a shared operating space that a message has been received, RAS places extra requirements on verbal communication and confirmation, which is already traditionally weak in surgery.

Tiferes et al. (Tiferes et al., 2016) examined communication among the surgeon and two bedside assistants (the surgical assistant, and the scrub nurse). Sender, receiver, duration, and topic of communication were identified. Additionally, the mode of communication – verbal or non-verbal – was analyzed. Non-verbal communication was prevalent not only between the two bedside assistants, who could see one another’s movements (e.g., the surgical assistant could see the scrub nurse reaching for a requested tool) but also between the assistants and the surgeon, who were not in visual proximity to one another. Instead, the study documented that the mediating technology – the RAS system itself - was being used as a communication tool. Team members could gesture with the tools, seen via the internal camera view which was displayed not only at the RAS console, but at several other locations in the OR as well. For example, the surgeon could use the camera view (centering/zooming) to indicate the area they needed irrigation.

Using the approach of realist evaluation, which involves eliciting, testing, and refining stakeholders' theories of how an intervention works, studies by Randell and colleagues first reviewed studies of RAS to identify stakeholders' theories concerning how RAS impacted teamwork and decision making (Randell et al., 2016). These theories were refined through interviews with operating room personnel across nine hospitals and then tested across four hospitals, collecting data using a range of methods including unstructured direct observation, video recording, questionnaires, and semi-structured interviews (Randell et al., 2014).

Randell et al.'s theory that communication would be worse in robotic surgery due to the distance between the surgeon and the rest of the team was confirmed in interviews with operating room teams. They reported experiencing problems in hearing the surgeon, despite the microphone and speakers provided on the robot console, especially when the speakers were not working (which was reported a number of times), or if the surgeon did not speak clearly. It was also sometimes unclear who the surgeon was speaking to. These problems were compounded by the absence of non-verbal communication such as gestures and gaze, due to the surgeon's position within the console. This led to a repetition of instructions by the surgeon and requests from the team for the surgeon to repeat the instructions, negatively impacting coordination. Teams perceived that this could potentially have a negative impact on operation duration.

However, when discussing with surgeons how they managed these challenges, a new theory arose: the physical separation means that more explicit communication is needed, resulting in improved communication and coordination compared to a laparoscopic operation. In observing the operations it was found that the requests from the surgeon were generally much longer in robotic operations than in the laparoscopic operations and that the surgeon seemed to do more to secure the attention of the team, such as using the name of the person the request was being directed to. Alerting the team seemed particularly important after a period of silence from the surgeon given that without explicit alerting, the team responses to the surgeon's request appeared less reliable. More explicit communication by other members of the team was also observed. In comparison to laparoscopic surgery, responses to the surgeon's requests are normally non-vocal and all team members can see what each other are doing. In robot-assisted surgery, it was necessary to distinguish between requests that are visible on the surgeon's screen and requests that had a significant component that is off-screen and invisible to the surgeon. For the requests where the response is invisible to the surgeon, a verbal acknowledgement was needed, as otherwise the surgeon cannot tell if the request is being actioned. This verbal acknowledgement was often expected by surgeons and could cause frustration if not provided. For more detail, the reader is referred to Randell et al.'s studies (Randell et al, 2014; Randell et al., 2016).

These findings suggest that, for effective teamwork, operating room personnel should provide oral responses to the surgeon's requests, while the surgeon should alert the team's attention before issuing a request and encourage the team to communicate their actions. New forms of verbal and non-verbal communication may also support successful team communication. As has been observed in a range of other industrial applications, increasing technology and automation places new demands on teams and their ability to communicate (Helmreich and Merritt, 1998).

7.0 ENVIRONMENTAL AND ORGANIZATIONAL CONSIDERATIONS IN RAS

RAS also has implications for operating room size and layout (figure 2). An RAS configuration consists of the surgical robot itself, connected to one or two surgical consoles, and a laparoscopic stack. Each unit is sizeable, requiring power cables, with additional communication cables on the floor. Since initial incisions need to be made without the robot, which is then moved into place and docked, additional space is required to allow this to take place, free from the power and communication chords, and avoiding unwanted interaction with overhead lighting, the operating table, the patent, and the usual anesthesia equipment, scrub-tech space, and supplies. Thus, size of the operating room, door location, power socket placement, and the arrangement of all the other equipment in the operating room will influence the ability of the team to perform the key components of RAS, adding another layer of complexity to successful technological integration. Usage is also influential, with some operating rooms RAS-only, others with RAS on some days only, and yet others where RAS and more traditional surgeries will be performed in the same room on the same day.

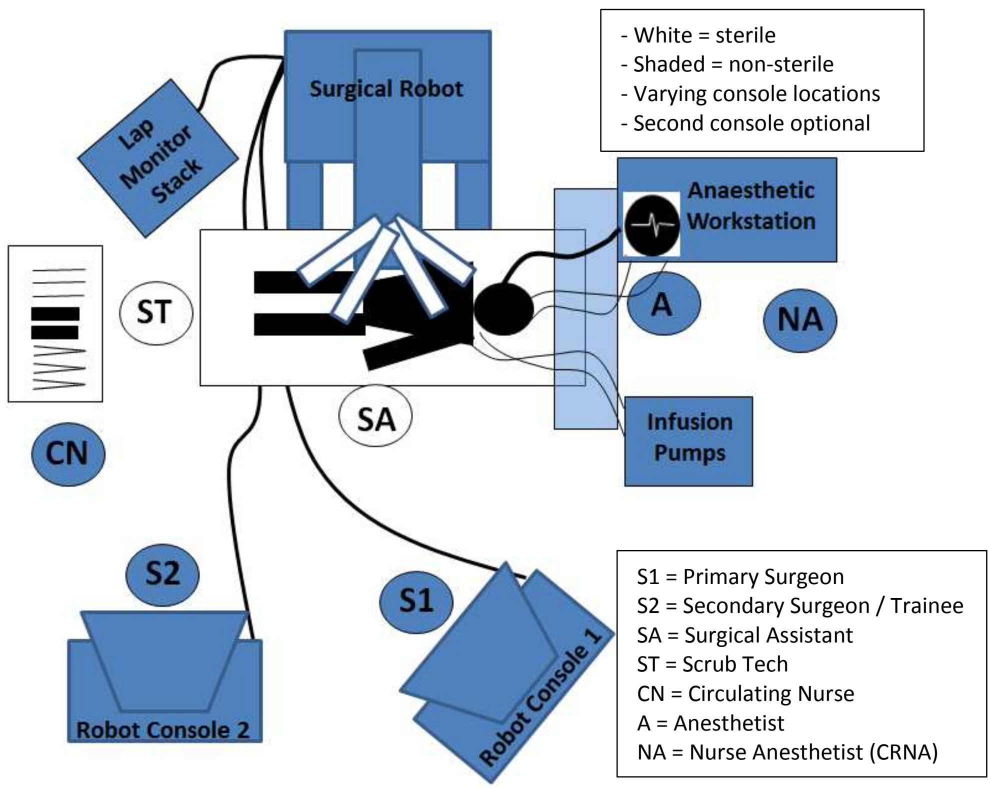

Figure 2: Example Robotic Surgery Room Configuration.

Ahmed et al. (2016) focused their study on the interactions of agents and the work environment in terms of how the layout of the OR facilitates or restricts staff movements. Movements between zones in the OR were documented in terms of staff person, movement time, and reason for movement. Again, although the primary focus was on agent-work environment interaction, the presence of the mediating technology had a strong impact on the results. A large number of movements occurred through a relatively confined area, due in part to the large footprint of RAS technology in the space without any adjustment in OR size or wall configuration. Additionally, there were movements associated with using the RAS in a training setting (e.g., switching surgeons at the console) or accessing non-RAS technology (e.g., the computerized medical record).

Operating room turnover times in RAS can also be highly variable and are often longer than those of more traditional surgery. This can partially be addressed through human-centered interventions such as task cards and improved role definition that can demonstrably reduce room turnover time (Souders et al. 2017), but again this adds to the complexity of integration. This is also reflected in new challenges associated with instrument cleaning and reprocessing. This requires both specific cleaning fluids and processes within the OR to initially clean the instruments. Sterile processing requires further special skills and processes, usually a different ultrasonic cleaning machine, and specific handling, maintenance, lubrication, and storage of the complex instrumentation. Thus, organizationally, a successful RAS program requires the training of OR staff and sterile processing staff, and appropriate shift management to ensure that they are available at the right time. These skills, and appropriate staff levels, need to be developed and managed over time. Such considerations are non-trivial for both safety and performance, and there is little published or grey (non-traditionally distributed) literature that acknowledges this. RAS programs may therefore have hidden complexities, providing unrecognized inefficiencies, and latent safety threats.

8.0 DISCUSSION

The broader systems implications and requirements for RAS, combined with a general dearth of observational studies examining these effects, means that the specific requirements for successful robotic surgery are not well established and may not always be explicitly stated or understood. This review provides human factors and ergonomics perspectives on the challenges and opportunities for improving the integration of surgical robots into the clinical environment from the USA, UK, and Germany. It represents a sizable range of the human factors research currently being conducting on RAS ‘in the wild’.

Increasingly complex surgical automation requires new surgical and technology-related skills, changes in teamwork, improved utilization of available resources, and coordination of all critical elements to minimize risk and maximize performance. The whole team – not just the surgeon – requires robot-specific skills. New approaches to the training of teamwork, communication, and situation awareness skills are also necessary. The required size and layout of the room is altered by the size of the robot, associated control consoles, the new movement paths of staff, and the data and power cables necessary for function. The future design of operating rooms should also allow for improved supplies retrieval, and the design of information systems to more effectively planned or communicated equipment and resource needs. Organizationally, it is necessary to manage the staff shift rosters to ensure team members with sufficient robotic skills are available and those skills are maintained and developed.

In 2016 the FDA’s guidance on regarding the application of Human Factors Engineering to medical device development (FDA, 2016) was updated to require usability testing, focusing on those tasks that pose significant risk to the patients and/or users. Part of the challenge industry faces in conducting this research is simply finding the time in often fast-paced product development environments to investigate how their new creations will impact more than just clinical efficacy. An even bigger part of the challenge facing industry is determining how best to conduct this research. These companies may not always understand the best approach for conducting usability testing of complex systems such as robotic surgical systems. Usability testing that is more representative of real-world use helps to understand how the new technology will impact actual use, before the systems are actually deployed for the first time. While it may be possible to conduct human reliability or task analysis to identify potential threats to safety within limited contexts, studies conducted within the clinical environment appear to be the only way to collect the full diversity of challenges – not least because of differences between work as imagined, documented, or reported, and work as done; and the highly adaptive nature of socio-technical systems.

Through direct observation, pseudo ethnographic, and other associated techniques which explore clinical work "as done" (Blandford et al., 2014; Pennathur et al., 2013), human factors research has demonstrated a wider range of socio-technical systems issues than have previously been reported with RAS. Such studies are critical to maintaining patient safety and enhancing outcomes of robotic assisted surgeries, and have particular implications for technology designs and the training of OR teams performing robot-assisted procedures. The findings indicate a need to improve robotic console ergonomics for both the surgeon and assistant, consider the requirements for ensuring effective communication, and identify specific opportunities to reduce costs, and improve learning curves, teamwork, and socio-technical systems integration. These deeper insights into performance enhancements in robotic technologies identify ways to reduce the expense of RAS while improving the safety and quality of care.

Our work demonstrates the value in working closely with the surgical teams to identify the challenges experienced every day in conducting robotic-assisted procedures. Despite increasing awareness in the healthcare device industry of some aspects of user-centered design, these considerations are not always seen as important in the procurement or implementation of new technologies in healthcare. This contributes to a wider discussion of understanding technologies 'in the wild'; the nature of partnerships among human factors experts, clinicians, administrators, designers and architects; the integration and understanding of surgical technologies; and the implications for future technological development and clinical practice.

9.0 CONCLUSIONS

Human factors related studies have examined tasks, movements, and flow of team members during surgeries as well as documenting communication strategies among the surgical team members. The reported studies demonstrate that the introduction of new technology into a surgical suite poses challenges beyond the clinical skills required to successfully and safely conduct surgery. In particular, workload may be reduced for the surgeon, but increased for other team members. Postural stress, rather than being reduced in RAS may simply be relocated. Workflow disruptions occur at similar rates to other surgeries, but include more equipment and training related issues. Communication, a traditional source of disruption across many surgical types, is fundamentally affected by the relocation of the surgeon away from the operating table, and specific verbal and non-verbal cues required in successful teams suggest benefits in additional co-ordination training. This also requires managing the availability and maintenance of skilled staff specifically for RAS work. The size of the operating room and the cleaning of instruments between surgeries are rarely investigated but also need to be considered. Our studies demonstrate the value of clinically-based human factors engineers working alongside surgical teams, quality improvement experts, administrators, architects, and designers to improve the delivery of RAS.

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