Abstract

Over the last twenty years, there has been increased attention to improving all aspects of patient safety and, in particular, the important role of checklists and human factors. This article gives a condensed overview of selected aspects of patient safety and aims to raise the awareness of the reader and encourage further study of referenced literature, with the goal of increased knowledge and use of proven safety methods. The CME questions should help indicate where there is still potential for improvement in patient safety, namely in the field of non-technical skills.
Introduction

The important role of human factors in patient safety has been extensively studied in the last twenty years. From this focus, many useful tools, such as surgical checklists and techniques of Crew Resource Management (CRM), have been introduced into surgical practice. There is scientific evidence that these tools contribute greatly to patient safety, if used properly. The purpose of this article is to give a condensed overview of selected aspects of patient safety as well as to provide a better understanding of the significant role of human factors in improving patient safety. The reader is encouraged to use proven patient safety methods while considering the human factors. The extensive reference list provides additional resources for further reading on this critical subject.

Preventable Adverse Effects

Following the publication of To Err Is Human: Building a Safer Health System, by the Institute of Medicine (IOM) in the year 2000, awareness for the need to prevent human error grew among the medical community. It also became evident that human errors were the main cause of preventable adverse events in surgery. Preventable adverse effects refers to harm from medical care rather than an underlying disease that occurred due to error or failure to apply an accepted strategy for prevention. Acknowledging that «Systems that rely on error-free performance are doomed to fail», a lack of appropriate measures for the sake of patient safety was established. While much effort has always been made to train surgeons and operating room staff in their knowledge and technical skills, the aspects of non-technical skills, namely team work, leadership, situational awareness, decision making, task management, and communication, have long been neglected.

Checklists

Surgical checklists have been increasingly used since 2009, especially after the publication of the first global survey on the use of a surgical checklist by Haynes made it clear that this tool, adopted from the aviation industry, would have an increasing impact on patient safety.

Much of the present literature proves that the introduction of checklists has had a positive impact for safety. But there have also been critical reports on their effect. Careful analysis of these reports shows that the lack of positive impact was due to the expectation of immediate measurable results following the introduction of the safety checklist, when
in reality, the process represents a gradual, step-by-step improvement plan. Furthermore, success can only be achieved if the leadership pays close attention to the quality of the checklist and the performance of the teams that use them. Furthermore, it is well documented that “safety checklists are beneficial for OR teamwork and communication and this may be one mechanism through which patient outcomes are improved”.13

It is important to note that the World Health Organization (WHO), when it introduced its surgical checklist in 2009, indicated that ‘This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged’.14 And the Implementation Manual for checklists emphasizes the necessity of modifying the checklist in order to promote a culture of safety.15 This indicates that the WHO checklist should only be used as an example or guideline and that a checklist has to be adapted to the specific needs of its users. Or, as Harden says, “While powerful, checklists are not ‘one size fits all’ and must be customized to local practices, which is especially true in a plastic surgeon’s office.” 16 Furthermore, different surgical specialties, like plastic surgery, will have different needs, and a checklist will only be well accepted by the surgeons and staff if it is designed by a plastic surgery team.17 While the support of hospital leadership is essential for the success of any safety measure, a top-down enforcement will only create a false feeling of safety. Acceptance of a checklist comes from participation of the users in the design.

The WHO checklist is essentially a perioperative checklist. Efforts to expand the checklist concept to a “practice checklist” covering the patient’s course from initial consultation all the way through postoperative care, have been proven to contribute to better safety.18,19

With the introduction of surgical checklists, especially after 2009, much importance has been given to filling out a specific form with checkmarks and signatures. This may be useful to monitor the compliance of the users, but documentation and administrative control must not be the purpose of a checklist as this is contrary to all safety-relevant efforts. Aviation has proven that reading though a checklist without a pen is just as useful. Attempts to run checklists without check-marking items on a paper with a pen should be encouraged as long as they fit the needs and culture of a team.20

Implementation of a checklist without team training is not useful.21,22 Of course, the concept of a team is completely different in healthcare, as compared to military or sports, for example. For office-based surgery and small surgery centers where a surgeon is in control of staff and their training, it is possible to achieve a concept of true teams. In many other settings, like in large hospitals, it has been noted that in surgery, teams are actually “teams in name only”, because “union work rules, financial
constraints, and restriction of flexibility have discouraged most hospital administrations from creating and implementing true teams".23 Teams are put together for each operation. They consist of professional individuals who often barely know each other and who sometimes work together for the first time.24 They have not been trained together. This makes team behavior challenging. Nevertheless, it should be considered an imperative of surgical leadership to address these difficulties and find innovative solutions that fit into the operating room workplace and its culture.25

Surgeons’ leadership reflects in the fact that as far as surgical safety checklist performance is concerned, it is better when surgeons lead the checklist process and when all team members are present and paused.26 Checklist completion has proven to be an essential factor for outcomes. While mortality was not significantly reduced, Mayer et al. reported that “complications could be prevented if full completion of the checklist was implemented”.27

Addressing human factors with Crew Resource Management (CRM)

Airlines introduced Crew Resource Management (CRM), the concept of maximizing effectiveness and safety by optimal utilization of all available resources of a team, especially the human factor, about 40 years ago as an important safety measure.28 Although the work of a cockpit crew differs in many ways from that of a surgical team, many mental processes used for ensuring safety of the operations are common: communication, situational awareness, stress management, interpersonal interactions, and teamwork. These processes can be improved by CRM, which typically addresses non-technical skills.

CRM programs require time and money, but they have proven to offer a high return on investment.29 A “CRM crash course“ will not produce long term effects, and it is not enough to think that blindly copying a tool from aviation will improve safety, as we may have tended to believe. The U.S. Department of Health & Human Services’ Agency for Healthcare Research and Quality (AHRQ) concluded in a recent report that we wrongly were hoping to find solutions to medical errors by simply adopting some techniques drawn from aviation and other “safe industries”. On the contrary, “making patients safe will require ongoing efforts to improve practices, training, information technology, and culture. It will need top-down resources and leadership, accompanied by bottom-up wisdom and innovation. It will depend on a strong policy environment that creates appropriate incentives, while avoiding an environment in which providers’ enthusiasm and creativity are sapped by an overly rigid, prescriptive
bureaucracy and set of rules.” In summary, it has to be accepted that safety concepts cannot be borrowed and adopted on a 1:1 scale from aviation, but need to be developed by healthcare specialists for their specific use.

**Speaking up and stopping the line**

Speaking up and encouragement to do so can be considered to be an essential element of Crew Resource Management (CRM). There are numerous clinical examples to illustrate how speaking up can prevent adverse events. However, there are many reasons why nurses, for example, may not speak up to a surgeon if they notice a problem, i.e. fear of being ridiculed for perhaps being incorrect, or the fear of being blamed by a superior for interfering. On the other hand, analysis of problems, major complications, or casualties shows that in a majority of the cases someone along the line saw an issue arise and did not mention it. Encouragement to speaking up and creating a climate allowing all members of a team to speak up without the risk of being punished is therefore a true act of medical leadership. Patient care is the foremost concern of the operating room staff and the surgeon should be aware of each team member's contribution to the positive outcome of an operation. *Stopping the line* is a technique used in the automobile industry in which all employees on the assembly line have the power and responsibility to stop a process whenever they notice a defect or safety issue on the assembly line.

In healthcare, and especially in surgery, all team members must be empowered to *stop the line* if they sense or discover an essential safety breach. Structured language can make it easier to speak up and be assertive when it's needed. Using a "script" of set phrases that the team has agreed upon in advance can make interactions more predictable and less "personal."

While a stop-the-line expression must be clearly understood as such by all members of a team, it is useful that it does not sound too alarming. A typical script to stop the line is “I need clarity”.

**Patient involvement**

Patients are, of course, the ones most motivated to care about their safety. This has been demonstrated by their support to the delivery of safety improvements. Therefore, we must not neglect to include patients in our safety protocols. Especially in plastic surgery, where many
operations are done under local anesthesia, it makes sense to involve the patient in checklists and encourage them to speak up. This will not break down the doctor-patient relationship, but on the contrary, emphasize the partnership.\textsuperscript{38}

**Self-assessment of safety status; fatigue**

All healthcare professionals should consider their own assessment of their ability to perform correctly a personal responsibility. Such an assessment should be done before surgery by every member of the team, including the surgeon. This is also the occasion for speaking up about safety relevant issues. In *Team Strategies & Tools to Enhance Performance & Patients Safety (Team STEPPS)*, AHRQ gives an example of how such an assessment can be conducted.\textsuperscript{39} It must be emphasized that this assessment is a private matter. Obligation to document or report it will be counter-productive. However, in some situations a team member may be comfortable to communicate personal matters to other members of the team, for example, fatigue.

Fatigue as a safety issue is well recognized and dealt with in aviation.\textsuperscript{40} In medicine, it is often neglected and most probably underreported, possibly due to a culture where surgeons feel weak if they admit fatigue. Fatigue must not necessarily prevent someone from working in a surgical team, but it may be something to communicate to other team members. A culture where someone is allowed (but not forced) to say “I slept only three hours last night because my baby was sick” will create better team performance.

**Pre-operative marking and safety**

It is uncontested that pre-operative marking helps to avoid operations of the wrong patient or the wrong side. However, it has other positive effects for patient safety, namely the fact that it lets the patient participate in the safety measures about his/her surgery and shows the efforts being made. Thus, it is a perfect occasion for patient involvement. A standardized way of marking will help to avoid misunderstandings. Masud et al. recommended the use of an arrow to mark the correct side.\textsuperscript{41} This will avoid wrong interpretations. Indeed, an arrow leaves no doubt which side has to be operated, whereas a cross could be interpreted as a NO. (Fig. 1, Fig. 2)
The positive impact of pre-operative marking should not draw attention away from other safety considerations, namely hygiene. Rooney et al. tested the use of the same marking pen for a series of patients and found no risk for sterility. But the discussion about the safety of this method is controversial, and other authors do report potential problems. Water-based pens especially carry a potential danger of cross-infection. Furthermore, marking pens make microlesions to the skin, which could become contaminated with hospital germs. Therefore, our recommendation for surgical marking is to use the same criteria as for hand hygiene. Single-use marking pens should thus be recommended for surgical marking.

**Human factors in long operations**

Plastic surgery often implies long operation times and human factors have a particular significance.

It has been shown that the risk of retained surgical items – a *never event*! - is higher in longer operations. In plastic surgery, where long operations are common, it has been demonstrated that surgery duration is an independent predictor of complications, with a significantly increased risk above 3 hours. Long surgeries have several other impacts that can influence patient safety due to human factors. These include a greater number of handovers, pointing to the usefulness of structuring handovers. Fatigue becomes increasingly relevant with prolonged operations and must be dealt with. Planning micropauses during such surgeries may be a way to prevent fatigue and associated loss of accuracy. Basic human needs such as eating, drinking, and eliminating become increasingly important with longer operating times and may influence patient safety.

**Smartphone use and other distractions**

Originally, the risks described for patient safety with regard to cell phones have been those of unperceived contamination close to the patient. With the increased use of personal smartphones, a new dimension of human factors has entered the operating room. While there is no evidence so far to show that regulating smartphone use in the OR improves patient safety, it seems to be common sense that the distraction caused by their use, especially if used for texting or writing emails, keeps staff from fulfilling other tasks, like observation of the surgery. Other human-caused distractions have an influence on patient safety, too. An observational study by Wheelock et al. showed that the most prevalent
distractions for surgeons were those initiated by external staff, followed by case-irrelevant conversations. Case-irrelevant conversations were associated with poorer team performance. Irrelevant conversations initiated by surgeons were associated with lower teamwork in surgeons. In contrast, Weigl et al. found that case-irrelevant communications may be beneficial for reducing mental fatigue and stress in routine cases, while procedural interruptions may contribute to surgeons' mental focus deteriorating. 

Conclusions

This review of specific topics of patient safety shows there is much potential for improvement in this area. The significance of human factors and non-technical skills for the safety of patients in all of healthcare, and especially in surgery, has been demonstrated by many studies. In addition, the introduction of surgical checklists in 2009 has contributed to an increasing consciousness for these and other safety improvement tools. However, further studies are necessary to assess long-term success. It is the hope of the authors that the selected topics covered in this article, along with the CME questions and answers, will help the reader find possible gaps in their own activity and encourage further reading about patient safety in the literature referenced here and elsewhere.
Legends:

Fig. 1: This way of marking the hand to be operated could be interpreted as “Stop, do not operate the left hand!”

Fig. 2: An arrow leaves no doubt which hand is to be operated.
References


