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EDITORIAL

Six Sigma in surgery: how to create a safer culture in the operating theatre using innovative technology

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Summary

Safe delivery of patient care in the operating theatre is complex and co-dependent of many individual, organisational, and environmental factors, including patient, task and technology, individual, and human factors. The Six Sigma approach aims to implement a data-driven strategy to reduce variability and consequently improve safety. Analytical data platforms such as a Black Box ought to be embraced to support process optimisation and ultimately create a higher level of Six Sigma safety performance of the operating theatre team.

Keywords: black box; operating room; quality improvement; safety culture; Six Sigma; team training

The operating theatre is a high-performance and high-stress environment, and an environment where a culture of blame and shame is still prevalent.[1] This, despite the fact that errors are rarely the result of individual failure, but are the consequence of an uninterrupted chain of multiple and multifactorial events. Safe delivery of surgical care is complex and co-dependent of many organisational and environmental factors, including patient, task and technology, individual and team factors.[1] Human factors are known to have a major impact on surgical outcome.[1]

Multiple strategies aim at improving surgical safety and can therefore be categorised into two routes; technological/managerial/engineering related or non-technical/human factors related.[2] The first involves the higher levels in an organisation and the latter is at the workers' level, including job satisfaction, motivation, and attitudes, all influencing safety behaviour. Both routes, however, impact the same outcomes and influence or even complement each other. Safety culture combines the technical, social, and scientific dimensions of safety management, which encompasses all ideas, beliefs, and habits that affect how safety is managed at different organisational levels.[1,2] Organisations with a positive safety culture are characterised by communications founded on mutual trust, shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.[1] Safety culture is hence a very broad and inclusive high-order construct, founded on the individual attitudes and values of everyone involved.[1,2] This editorial highlights the importance of improving safety culture and discusses an innovative strategy to reach a higher safety level in the operating theatre.

Six Sigma safety level

Before the COVID-19 pandemic, more than 100 000 flights a day were safely executed. The risk of an airplane being involved in a fatal accident is one in 16 million flights. Key to this success has been the implementation of a *system approach*,

in which 'errors' are addressed without blame, yet proactively, to diminish the consequences before they escalate into serious adverse events.[3] Causes are searched for within the system rather than blaming one individual. As a result, safety improvement gaps within the system and their consequences can be identified and resolved.[4] Using this approach, aviation was able to reach the *Six Sigma* level of system performance.[3] The term 'Six Sigma' comes from statistics, specifically from the field of statistical quality control, which evaluates process capability. The concept of Six Sigma was originally developed by Motorola engineers in the 1980s, to provide greater resolution in measuring and decreasing defects in every product, service, and transactional process. It helped to optimise operational processes, by reducing process output variation.[5] In statistical terms, Six Sigma refers to 3.4 defects per million opportunities (i.e. nearly perfect). The formula represents the variation about the process average (mean), hence the expectation that the first six standard deviations (sigma) of production variability fall within acceptable failure limits.[5,6]

The fundamental objective of the Six Sigma methodology is the implementation of a structured data-driven strategy, focusing on reduction of variation and process improvement.[6,7] A balance between error prevention, detection, handling, and learning is crucial. The operating theatre remains an environment that often lacks comprehensive data capture, robust monitoring strategies, and process evaluation, causing a knowledge gap on perioperative process optimisation.[8] Currently, most quality and safety improvement approaches in healthcare focus on retrospective data and *post hoc* error analysis to identify poor quality, resulting in recall bias, low compliance, and a lack of detail. Objective multisource data monitoring systems are needed.

The Six Sigma framework includes five steps: define, measure, analyse, improve, and control (DMAIC).[6] In healthcare, organisations need first to recognise that human error cannot be completely avoided. Instead, events that may lead to errors ought to be spotted early, analysed, and reduced. Using a *system approach*, procedures are standardised so that, for example, specific protocols (e.g. use of name stickers or the WHO Surgical Safety checklist) help minimise the chance of human error occurring.[9,10] It is important, as well, that operating theatre teams using this approach are often able to overcome unexpected events and deviations, achieving good outcomes. This is termed *system resilience*, meaning that the team is able to adapt successfully before, during, or after safety threats occur, despite conditions that could lead to failure.[11,12] The positive consequences of increased transparency about errors ought to be highlighted, such as long-term learning, improving team performance, and innovation, known as *error management*.

Transparency regarding errors in healthcare is needed, but has proved difficult to achieve.[3,13] Healthcare is complex because of the diversity of professionals, each with their own educational background, attitudes, and standard procedures.[14] Regardless, a shared mental model is essential in high-risk environments such as the operating theatre. A shared mental model indicates that all members of the operating theatre team have a common understanding of the plan for patient management, and of the roles and responsibilities of each individual, ensuring a psychologically supportive and safe environment.[15] One in which every team member feels respected, encouraged, and safe to speak up.[3,4] This appears to be difficult to accomplish, even when teams work together regularly, and therefore requires leadership, communication,

commitment, resources, and awareness from both the entire operating theatre team and the organisation.[1,2,15]
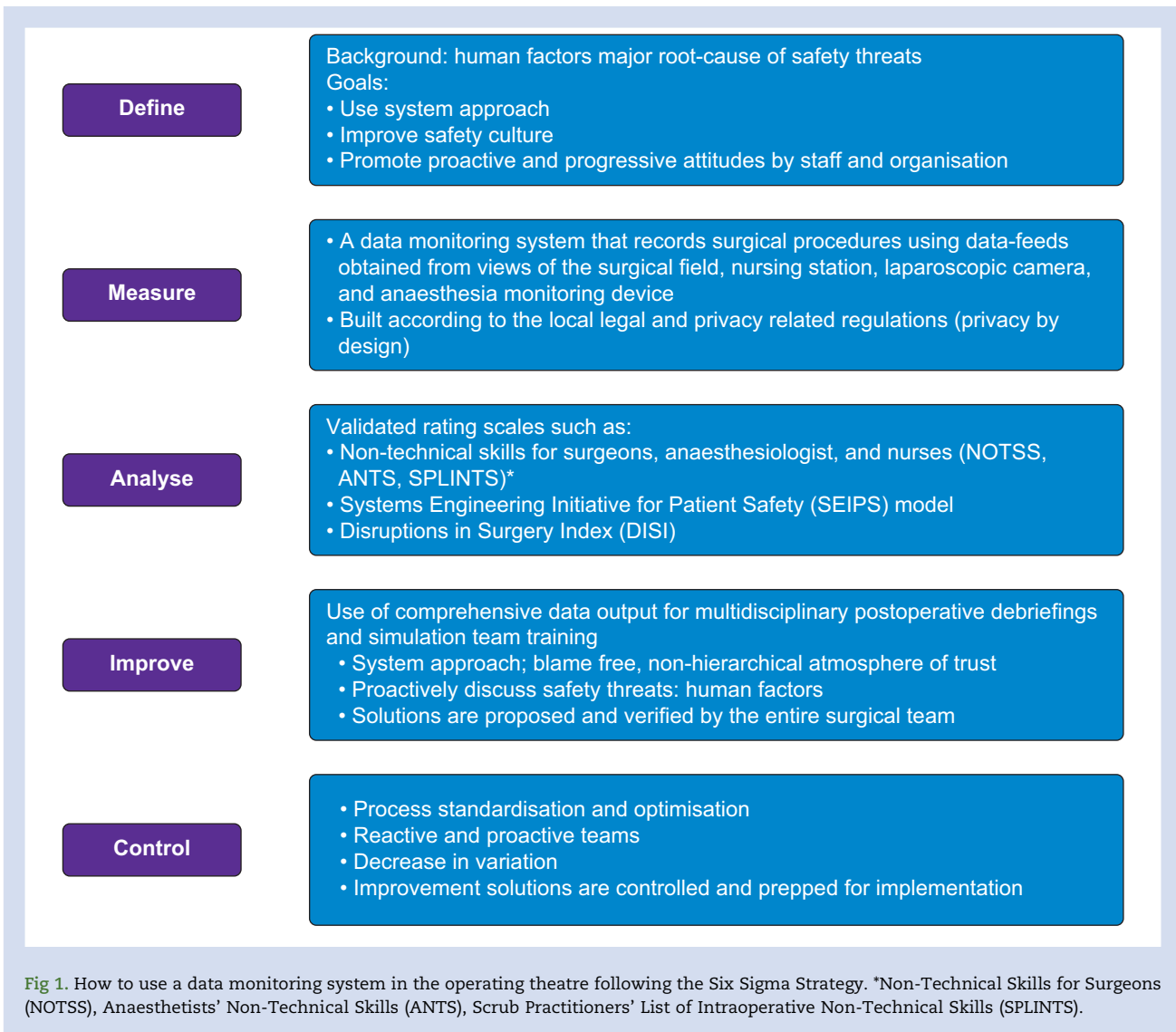
How can we use the Six Sigma approach?

Measurement and understanding the team's current performance, where the team can improve, and the ability to learn, are essential components of ensuring safe patient care.[16] Six Sigma performance might be achieved by creating a continuously monitored operating theatre, capturing natural behaviour and standard operative processes, in order to define both the technical (i.e. technology, managerial, or engineering) and non-technical (i.e. human) factors possibly affecting safety. Comprehensive data capture systems such as an Operating Room Black Box are therefore becoming more widely implemented in high-risk environments such as the operating theatre, trauma bays, and in simulation training centres to measure, analyse, and train teams.[17] These devices collect complex real-time quality data obtained from views of the surgical field, nursing station, laparoscopic camera, and anaesthesia monitoring devices using privacy-by-design principles.[10] Visual data analytics based on big data may facilitate perioperative outcomes research, quality improvement efforts, and real-time clinical decision-making.[16,18]

Video recordings of the entire operating theatre allow an unbiased and de-identified evaluation of patient anatomy, the operating theatre team, and perioperative activities.[7,17] Artificial intelligence (AI) and machine learning are used to facilitate efficient analysis of the multisource big data achieved from the operating environment based on validated rating scales.[19,20] The Operating Room Black Box system our research group uses, creates a video-assisted outcome report that provides comprehensive, detailed, and objective feedback including annotated video segments of interest while protecting user privacy (i.e. faces are blurred, voices are altered).[10,21] A report such as this can be used to apply the Six Sigma strategy (DMAIC) to improve perioperative team performance and processes, for example by team debriefing, coaching, and simulation training.[8,11,17,21]

The Black Box to improve safety culture

Implementation of a platform such as an Operating Room Black Box is an important tool to facilitate transparency, carefully balancing legal restrictions whilst respecting patient interests.[17] Use of such a system may be very valuable in creating a sustainable culture managing error responsibly.[4,7,13]

Use of a data monitoring system such as the Operating Room Black Box in the operating theatre following the Six Sigma approach is summarised in Figure 1. All healthcare professionals working in the operating theatre should be involved to *define* what the purpose of a safety improvement initiative really is; 'what is in it for them?'. Indeed, healthcare professionals need the chance to develop a more *proactive* and *progressive* attitude towards safety culture and improvement.[22] Changing safety culture in healthcare can only be achieved by those working in it. They need and deserve the tools to do so. Proactive and progressive healthcare organisations prioritise safety, actively invest in safety improvement initiatives, and staff raising safety-related issues are rewarded, not blamed.[22] Changing an established working culture in the operating theatre is perceived as being difficult, and therefore a basis of trust, responsibility, and accountability is essential.[1,9]

Fig 1. How to use a data monitoring system in the operating theatre following the Six Sigma Strategy. *Non-Technical Skills for Surgeons (NOTSS), Anaesthetists' Non-Technical Skills (ANTS), Scrub Practitioners' List of Intraoperative Non-Technical Skills (SPLINTS).

The Operating Room Black Box precisely *measures and analyses* how the team interacts and responds to unexpected events, by collecting and analysing objective multisource data from within the operating theatre, which offers a vast new field of data concerning system factors affecting surgical safety.[6,11] Using multisource big data, relevant safety threats, which are often unforeseen, are now identified whilst focusing on resilience and support. In multidisciplinary debriefings, safety threats are proactively discussed in a blame-free atmosphere of trust, where the conventional hierarchical mode is flattened. Solutions are introduced, and the team verifies that the proposed *improvements* are able to solve the issue at hand. This exchange of data may help foster trust, more responsible attitudes, and enhance risk awareness to increase safety. Next, these teams report more errors, allowing them to talk about errors, in turn increasing timely error detection and correction. These highly performing teams will indeed have a proactive attitude towards error reporting, management, and prevention. Suggested safety improvement solutions by the team are consequently *controlled* and prepared for implementation. In this 'circle of safety', suggested improvements

may be tested in a simulation setting and then applied in the real world. The focus of this last step is process standardisation and optimisation. Indeed, Six Sigma focusses on reducing process variability, yet we ought to accept that healthcare is different from the aviation and car industries, as human variability plays a much bigger role. Resilience results in good outcomes in the presence of adverse conditions by positive adaptability within systems, and to this end human variability is essential.[23] However, by using an objective data monitoring system such as the Operating Room Black Box and following the above-mentioned DMAIC approach, variability in the safety of healthcare can be reduced, which may ultimately result in a higher Six Sigma safety level.[6,11]

Conclusions

While it is laudable that healthcare professionals accept responsibility for their actions, their behaviour resonates with and results from the context, organisation and culture in which they act. In most operating environments, even if the atmosphere is constructive, identifying and acknowledging

error is difficult. More transparency concerning error management and shared belief that engagement leads to safety improvement are of utmost importance. To reduce the incidence of errors in the operating theatre, quality and safety improvement initiatives ought to involve the entire team, promoted and supported by the organisation. The use of innovative analytical platforms such as an Operating Room Black Box should therefore be embraced, as they may support process optimisation and help healthcare organisations reach the level of a progressive, sustainable, and Six Sigma safety culture in the operating theatre.

Authors' contributions

Contributed substantially to the conception and drafting of the article or revising it critically for important intellectual content: all authors
Approved the final version of the manuscript: all authors
Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: all authors

Declarations of interest

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