Implementing patient safety in laparoscopic surgery: quality assessment and process analysis

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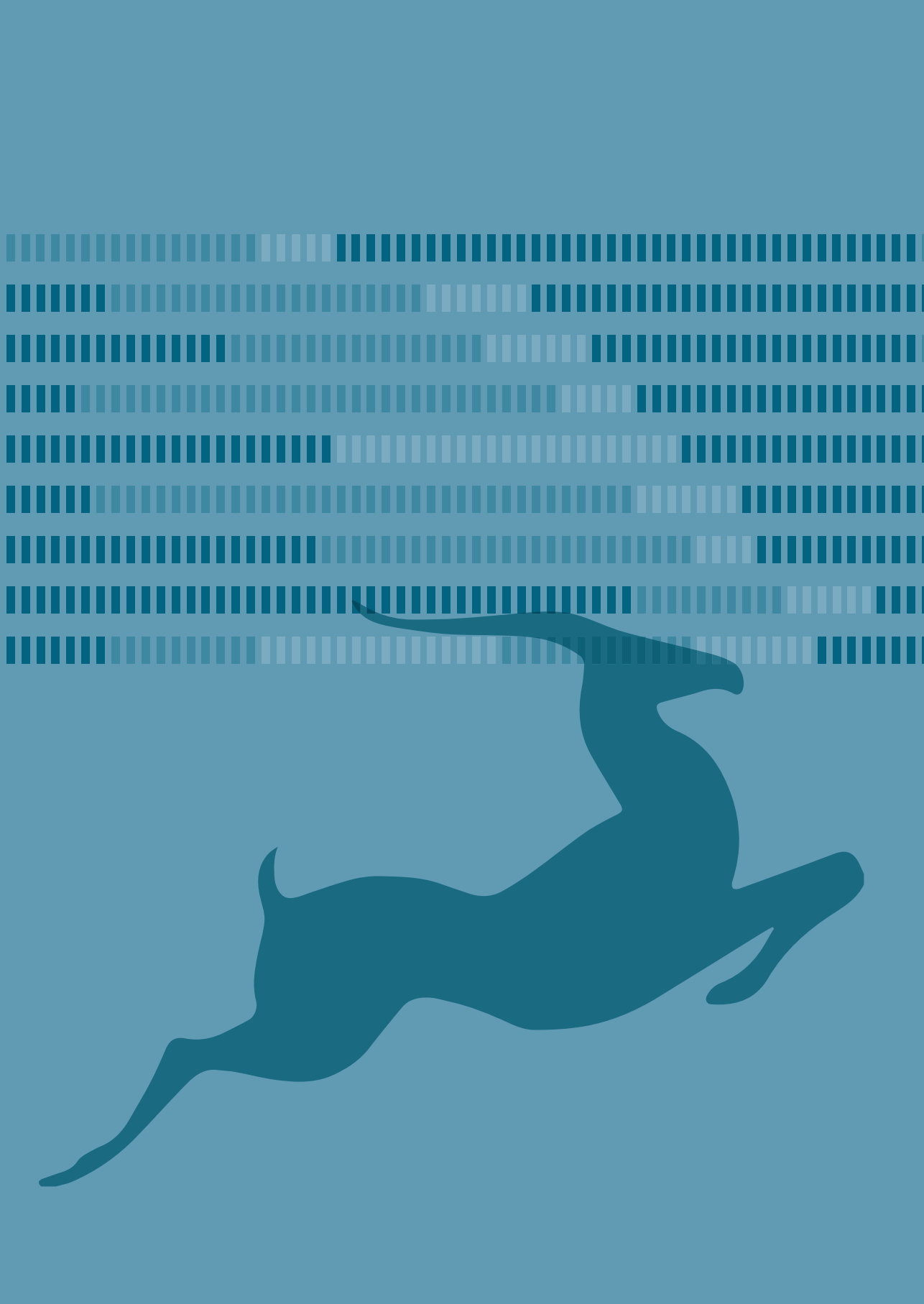

Chapter 9

General discussion

In the era of rapidly evolving surgical techniques and technology, the patient, hospital, health insurance companies and the government demand transparency in surgical outcomes and desire the highest degree of patient safety. Quality indicators are used to measure quality and ensure that patients receive the highest level of care. In this thesis, several process and outcome indicators are described that are clinically relevant in minimally invasive surgery (MIS). Furthermore, a new tool that evaluates the introduction of new interventions (i.e. both techniques and technologies) in MIS is validated. Finally, a technical solution is introduced to support clinicians during the operative process, thereby increasing both efficiency and patient safety.

Towards quality indicators for MIS that are clinically relevant

Many different outcomes and processes are currently used as quality indicators. Based on these indicators, hospitals are ranked, health insurance and government policies are made, and patients' preferences are determined. However, for most of the indicators that are used to 'measure' quality, the scientific basis or at least the clinical relevance is often lacking.

In general, and in particular to the LH, the minimal requirements for a quality indicator include (Table 9.1): relevance, evidence, feasibility (i.e. data easily available and reliable), controllability (i.e. can future outcomes be controlled?), and correction for case-mix [1]. Besides the mandatory registration of adverse events, other quality indicators that are suggested to be useful in MIS are conversion to laparotomy, hospital volume and the ratio between the minimally invasive and the conventional approach(es). Recently, the QUSUM was developed and tested as a dynamic quality assessment tool for measuring individual surgical outcomes for laparoscopic hysterectomy (LH) [2].

Table 9.1 Minimal requirements for quality indicators – particularly to the LH – per domain (adapted from Driessen et al. [1])

	Relevance	Evidence	Feasibility	Controllability	Case-mix
Structure indicator					
Volume	±	+	+	±	–
Process indicator					
Type of hysterectomy	±	+	+	+	–
Outcome indicator					
Conversion	+	+	±	±	±
Complications	+	+	±	–	–
QUSUM	+	+	±	+	+

+ present, ± partly present, – not present

In **Chapter 3**, the relevance, evidence and controllability of conversion rate as a means of evaluation in LH are described. Besides the predictors for conversion (BMI, uterus weight and surgical experience), we identified the presence of an intrinsic factor influencing the risk of conversion, which we referred to as the surgical skills factor. Virtually independent from patient and performer characteristics (i.e. experience), this factor therefore represents surgical skills including the functionality of the operating team. The presence of such a factor is confirmed by others who have stated that surgical skills seem to have a more important role than surgical experience [3]. Similarly, it has been argued that using structure and process indicators, which incorporate individual skills, may be a valuable additional means of evaluation than the conventional focus on outcome measurements alone [4-6]. For example, the implementation of mandatory and regularly scenario trainings of real-life complications (major bleedings, disfunctioning devices, etc.) will better prepare the entire surgical team to adequately manage these emergency situations laparoscopically. If we compare proficiency in surgery with driving a car, we can use the following metaphor: It is not only the possession of a driver's license (i.e., completed a learning curve) and how many times he/she has driven a car before that determines the outcome of the drive, but also the skills of the driver and the functionality of the car influence the outcome of each ride. Therefore, we should be aware of the presence of such an intrinsic surgical skills factor influencing the risk of conversion.

However, before conversion rate can be widely used as a quality indicator in MIS, it is important that a uniform and multidisciplinary applicable definition is available. Therefore, we performed a Delphi study in **Chapter 2**. The study was conducted among a representative group of laparoscopically experienced general surgeons, gynecologists, and urologists in the Netherlands. After two Delphi rounds, one definition received a very high rate of agreement (90 %), was preferred by most respondents, and was considered applicable in its current form. In order to facilitate a more detailed analysis of the reason for and outcome of the conversion, we introduced a differentiation between a *strategic* and a *reactive* conversion in the definition. This subdivision is important since reactive conversion is associated with a higher risk of postoperative adverse events and prolonged hospital stay [7, 8]. In addition, while strategic conversions mainly are the result of suboptimal indication and also low surgical volume [9], an insufficiently trained surgeon and operating team might be the cause of either a strategic or reactive conversion.

With this clear and concise definition being generally accepted and the influence of patient, procedure, and performer characteristics on conversion being known, a threshold for conversion rate in LH must be set. As demonstrated, > 95% of LH procedures are completed laparoscopically. We therefore suggest a conversion rate of < 5% to act as a future reference standard. In addition, the subdivision between *strategic* and *reactive* conversions enables better identification of conversions that are preventable. If a hospital exceeds these thresholds

(> 5% conversion in general and / or > 30% reactive conversions), we advise to conduct an audit of the converted LH procedures. The questions to be asked would include the following: Were indications properly made? Were the skills of the surgeon and the functionality of the operating team adequate? Thus, additional insight into the indications for conversion is acquired, which will enable further improvement in the outcomes in LH and will prevent unnecessary conversions in future patients.

Just as registration of adverse events is mandatory in every clinic, in order to allow for quality assessment, this registration should also include the number of conversions and their indication. Nevertheless, one has to remain aware that conversion is a phenomenon inherent to laparoscopic surgery, being a calculated risk and a sign of good surgical judgment [10]. Consequently, surgeons should not fear such a measurement and it should especially not deter them from applying the laparoscopic approach. This would deprive patients from the advantages of the minimally invasive approach and obscure the true indication for the abdominal approach. Ideally, on hypothetical grounds, an optimum rate of the laparoscopic approach should be reached, with subsequently low numbers of primary abdominal procedures. In this perspective, with respect to hysterectomy, the ratio of vaginal hysterectomies, abdominal hysterectomies, and LH procedures is another valid and clinically relevant quality indicator that should be evaluated by each clinic [11-14].

As shown in **Chapter 5**, this ratio is especially important in a group of patients inherently at risk because of their BMI ≥ 35 kg/m^2. Although morbidity is obviously the lowest in the minimally invasive approach, the surgeon's preference for the abdominal approach increases with the increase in BMI. Especially because in this group a higher conversion rate is also observed (up to 11%), in such cases the surgical skills and a well-functioning, experienced team are even more important (**Chapter 3**). Since obesity is accountable for a higher incidence of both large uterine size and malignancy [15], especially in the very obese and morbidly obese patients, the laparoscopic approach could be the best alternative to bypass these relative contraindications for the vaginal route. Nonetheless, during laparoscopic surgery in this group of patients special considerations have to be taken into account and it is argued that three-dimensional vision systems could make adequate visualization less difficult [16-18]. Together with increased experience and clustering of LH in high-volume centers, further improvement in the outcomes of hysterectomy in these patients could be achieved [9].

Thus, the analysis of complications is also a process that can ultimately improve outcomes. Especially in case of increased incidence of an adverse event after the introduction of a new intervention, the etiology has to become known. With regard to the LH, the vaginal cuff dehiscence (VCD) is such an adverse event, and the reason for the increased incidence of VCD after LH is internationally still a ground for debate. Since the suturing method used

for closure of the vaginal vault is mentioned as an etiological factor, we performed a study comparing different suturing techniques (**Chapter 4**). Laparoscopic interrupted suturing was associated with the highest incidence of VCD and should therefore – in our opinion – not be the preferred technique for closure of the vaginal cuff. In the absence of statistical superiority of vaginal versus laparoscopic closure with a running suture (e.g. Quill™, V-Loc™ or a regular Vicryl with a suture staple at both ends), the method can be based on the preference and experience of the surgeon. Nevertheless, the incidence of VCD after LH remains higher compared with abdominal or vaginal hysterectomy. Therefore, other steps of the procedure that are unique to LH, such as the amount and type of coagulation used for colpotomy, should be addressed in future research.

Measurement tool for introduction of new interventions in MIS

Innovation of new interventions is still particularly monodisciplinary and commercially driven rather than clinically driven. As stated by the IDEAL recommendations "no surgical innovation should come without evaluation" [19]. Nevertheless, new and expensive interventions are still implemented in surgery without proper evaluation. Good examples are robotic surgery [20-24] and the use of integrated operating rooms dedicated to MIS. With regard to the latter, the manufacturers state that – by their optimized design – these integrated ORs are the solution for safe surgical care by reducing OR clutter and staff workload, increasing comfort and enhancing ergonomics and OR team performance. Importantly, these statements are inherently biased and are only describing potential benefits that are not based on objective research [25-29]. Although it is not clear whether an integrated OR is a useful, cost-effective and safe solution, globally many hospitals have invested or are investing in integrated surgical suites [25, 30]. Therefore, in **Chapter 6** we performed a prospective observational study comparing a conventional versus an integrated OR with respect to equipment-related error rates. We found that the number and the effect of equipment-related surgical flow disturbances is not reduced by performing an advanced laparoscopic procedure in an integrated OR instead of a conventional cart-based OR. As a matter of fact, we observed that, in the integrated OR, intraoperative repositioning of the monitors is a frequent and time-consuming source of disturbance. Apparently, this potential hazard, which comes with the introduction of an integrated OR, is underestimated by the surgical team.

Nevertheless, performing surgery in the integrated OR does not affect outcomes in a negative way and provides some important advantages. Most importantly, for all team members the ergonomics are more favorable, thereby reducing physical complaints and eventually dropout [31]. Furthermore, time savings in the preoperative setup has also been observed [25, 27, 32]. Therefore, performing MIS in an integrated OR could be regarded as an ergonomically

responsible innovation for those who are frequently performing advanced MIS. However, in order to maintain the high level of surgical safety that has been established by laparoscopic surgery, the entire surgical team has to be fully aware that by performing surgery in an integrated OR different potential sources of disruption arise [33].

Therefore, it is important to encourage the surgeon and the entire team to continue to observe themselves critically when implementing new interventions. In any case, this can prevent following procedures from leading to the same safety hazard. To achieve this, we have developed and validated the Surgical Safety Questionnaire (**Chapter 7**). It appears that this short questionnaire filled in by all members of the OR team (surgeon, scrub nurse, anesthetist(-assistant) can demonstrate and in particular can exclude the presence of surgical flow disturbances. Despite the fact that its use takes time, this validated questionnaire potentially prevents future safety hazards. In our opinion, the potential damage that can be avoided is undoubtedly much greater than the short investment in time that is required to fill in the questionnaire thereby demonstrating that the surgical safety is ensured in most cases.

Regarding the application of this questionnaire, in daily clinical practice this would mean that during the introduction of a new intervention the Surgical Safety Questionnaire has to be filled out after each surgical procedure. Involving the complete surgical team with their individual knowledge, experience and opinions will provide the opportunity to constantly evaluate new interventions. Any safety hazards that arise from this can then be analyzed more extensively. If this shows that, for example, additional training, adaptation of the workflow or of the device are necessary, these can be implemented. As a consequence, in an early stage potential safety hazards will be prevented for future patients.

Towards a technical solution to automatically monitor the progress of the operative process

As Sir Cyril Chantler said: “Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous” [34]. To help surgeons and their teams maintain surgical safety, the power of technology is currently insufficiently harnessed in healthcare. This becomes even more clear when it is compared with the way technology is deployed to ensure safety for complex and high-risk processes in, for example, the petrochemical industry [35]. Clinicians know better than anyone where the needs and room for improvement are. With the development of the Digital Operating Room Assistance (DORA) model, we have shown that a cross-pollination between both worlds can contribute to a system that is clinically relevant and achievable with viable technology (**Chapter 8**).

Since the OR is regarded as one of the most expensive departments of the hospital, optimal efficiency also will result in reduced costs. However, improvements in the efficiency are hampered by the fact that the entire perioperative process can be considered a reactive process ("As soon as possible after you ask me, I will do that"). This is in contrast with having the ability to work proactively, which allows the participants to anticipate their work ("I know I should do this in 10 minutes"). This change of the perioperative process from a reactive to a proactive manner, could be achieved by means of a GPS-like system that automatically monitors and tracks the progress of procedures.

A system based on the DORA model should be developed in close cooperation with engineers and IT specialists. Privacy concerns regarding having a camera and microphone in the OR should be addressed and – at least at the beginning – will demand continuous explanation to all users of the OR [36]. However, the DORA system directly analyzes the video and audio streams using an algorithm that produces a binary output and no observational data have to be stored for the purpose of this system.

Moreover, there is a fear that ICT solutions will completely take over certain processes by making autonomous decisions which the clinician then can no longer affect. Health care is the epitome of a professional area that refuses to be limited to a fixed path. Instead, it is often through small adjustments to the standard that the best care is provided which is tailored to the patient [37]. The best of these two worlds comes together in a principle called "adaptive support" [38]. Hereby, clinical knowledge guides the process, but any bias that it may include is taken away by algorithms. In this way, processes are automated and standardized where possible, and information and flexibility is provided to professionals when needed.

In conclusion, measuring quality and safety during the introduction of new interventions is an important topic, yet also very difficult and often lacking clinical relevance. Clinicians strive to deliver the highest quality of care and patients demand the highest safety of care. With this thesis, regarding the operative process, the set of measurement tools that the clinician has available to achieve this goal is extended and validated from a clinical perspective.

Future perspectives

To take full advantage of the use of the conversion ratio, the Surgical Safety Checklist and the DORA system, further steps need to be taken.

Of course, during the introduction of new surgical interventions, the Randomized Controlled Trial will continue to be the gold standard for evaluating effectiveness. With regard to safety, a Prospective Risk Inventory is performed to prevent any problems *in advance* of its introduction. The current vacuum in the evaluation of safety *during* this introduction can be

covered by using the Surgical Safety Questionnaire. In future studies, it should be considered whether the questionnaire can be further shortened, considering that the answer to just one of the items "*The functioning of devices and instruments was optimal*" already proved to be highly correlated with surgical flow disturbances (as a surrogate measure for surgical safety). Thus, the use in daily clinical practice will be further improved. In addition, future research can also test the validity of our findings with regard to other new interventions and other medical specializations.

For good compliance regarding the use of the questionnaire, it should also be included in the next version of the "Guideline to New Interventions in the Clinical Practice" of the Dutch Order of Medical Specialists [39]. The same applies to the definition of conversion. Although, the current multidisciplinary Dutch guideline "Minimally Invasive Surgery" already advised to use a preliminary distinction between a strategic and reactive conversion, it lacks the nuances of our validated definition [40]. As a result, for example, currently the option of performing of a diagnostic laparoscopy in order to assess the operability still falls in a gray area.

Provided that it becomes obligatory to adopt this definition in laparoscopic surgery, an unambiguous interpretation of conversion will result in a more reliable clinical registration of conversion and scientific evaluation of the feasibility of a surgical procedure. In order to allow conversion rate to act as a quality indicator with respect to other procedures, future studies should be performed to assess the predictors for conversion associated with this procedure and to set a cut-off percentage for reference. In this way, each surgeon or at least each clinic will similarly be able to evaluate their conversions for procedures other than LH and as a consequence will be able to prevent potentially unnecessary conversions for these future patients too. In the long term, with regard to these procedures, conversion rate should be included in the list "Basic Quality Indicators" of the Dutch Healthcare Inspectorate (IGZ) [41]. However, the field must prevent that the demand for registration does not unnecessarily increase. Nevertheless, in daily practice, this is already ensured as conversions are mandatory to be registered and conversion ratio as a quality indicator will have to replace indicators without or with less clinical relevance.

With regard to the increased incidence of VCD after LH, further research on the technique of the colpotomy may provide an answer. For example, the vaginal approach to the colpotomy is proposed to simplify this relatively difficult step within the LH [42]. This way, the colpotomy is performed more efficiently, thereby potentially reducing excessive coagulation to maintain adequate vascularization. Furthermore, we would like to challenge others to publish their data and opinion on this important subject, to enable future scientific analysis of pooled data.

The added value of video observation to systematically assess quality and safety of new interventions is becoming more and more recognized [43-45]. Our study shows that it offers

significant benefits for analyzing the surgical procedure in detail. However, full registration of procedures in the OR using cameras is rarely implemented yet. The main reason for this is that constant and complete analysis is expensive and time consuming. Nevertheless, video registration will take a more prominent role in the future because both for training purposes and error analysis it can be of great added value. Several centers do this already and several studies are investigating this [44-48]. In order not to impede further developments and broad application, it is important to better define the privacy and legal status of these data [44]. With regard to the Dutch situation, Blaauw et al. have created a framework for this [49]. However, they argue that according to Dutch law these data should also be available at all times in case of an adverse event. To prevent misinterpretation and to 'protect' the surgical teams, the hospital and the patients, the Academic Medical Center in Amsterdam has put this aside after correspondence with the IGZ and the Dutch Data Protection Authority (Autoriteit Persoonsgegevens) [46]. Further investigation by the Dutch Ministry of Health, Welfare and Sport is currently awaited. On the one hand innovations in video capture technology that automatically enable video data to be made anonymous can contribute to the protection of the privacy of all the participants involved [50]. On the other hand, the possibilities regarding this should be explored to make an agreement, similar to what has been done in the aviation industry, so that in case of a serious adverse event the data are only retrieved for analysis by an independent organization (and thus not the Public Prosecutor) [51].

Nevertheless, currently this type of video recording system is intended only for retrospective evaluation regarding safety assessment and/or (team) training purposes (i.e. a 'Closed' Black Box). Creating a system that focuses on active monitoring, constant support and, if necessary, adjustment of the process (i.e. 'To Open' the Black Box) offers additional opportunities to further exploit its capabilities.

Currently, IT solutions in the health care sector are not yet used to actively support clinicians in their work. This is the case despite the fact that the technology may well be capable of taking over secondary tasks so clinicians can focus more on the primary process (i.e. providing safe healthcare). The DORA system that we presented is a good example of this. The current study is primarily a proof of the principle that the sum of the historical duration of individual phases of the surgical procedure is reliable for predicting the duration of the entire procedure. Based on this, in a follow-up study, a system that is able to detect these phases can be transformed into a system that actually predicts the expected end time of the procedure. In addition, future studies should focus on the reliability, applicability and further expansion of these possibilities.

The increased demand for patient safety is often regarded as a sign of distrust. Essentially, however, providing the best care is an intrinsic driving force of every clinician. From this

perspective, health care should implement a different approach towards safety. This is since focusing on why the desired outcomes of healthcare are achieved in the great majority of the cases, can actually result in more room for educational reflection. This tendency is also the essence of the Safety II framework [37, 52]. As an example, although the practice during the introduction of new interventions may be characterized by frequent minimal hick-ups to near-misses, this does not result in an increase in adverse outcomes. The endorsement of factors because of which the surgical procedure nearly always goes well is a much stronger mechanism to ensure safety than focusing on problems and trying to overcome them in the future with all kinds of tricks. Following the examples of the petrochemical and aviation industries, according to the concept of High Reliability Organization, catastrophes are better avoided in an environment where accidents are normally expected as a result of risk factors and complexity [53-55]. This high level of safety is accomplished by commitment of the entire organization to the prevention of failure, early identification and mitigation of failure, and redesign of processes based on identifiable failures [56]. Thus, with respect to the introduction of new interventions in the OR, for example, more simulation training should be carried out, mandatory both before and during the implementation. This should be done both individually (by the surgeon, resident, scrub nurse, etc.) as well as in teams. This will further improve the skills of the team, will lead to better avoidance of problems or at least ensures that these near-misses are adequately solved by these dedicated OR teams before turning into adverse events. It is precisely here that feedback through video observation is of high added value. In this way, the competencies and capacities of all participants to the operative process will be better ensured. Consequently, this will lead to a further transformation from a reactive safety framework (20th century) to a proactive safety framework (currently) and then finally to a safety framework based on the concept of High Reliability Organization [57].

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