Universiteit
Leiden
The Netherlands

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

Blikkendaal, M.D.

Citation
Blikkendaal, M. D. (2018, May 23). *Implementing patient safety in laparoscopic surgery: quality assessment and process analysis*. Retrieved from https://hdl.handle.net/1887/62352

Version:	Not Applicable (or Unknown)
License:	Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden
Downloaded from:	https://hdl.handle.net/1887/62352

Note: To cite this publication please use the final published version (if applicable).

Cover Page

Universiteit Leiden

The handle http://hdl.handle.net/1887/62352 holds various files of this Leiden University dissertation.

Author: Blikkendaal, M.D.
Title: Implementing patient safety in laparoscopic surgery: quality assessment and process analysis
Issue Date: 2018-05-23

Chapter 1

General introduction

Due to the wide availability of therapeutic treatment options, nowadays it is not just the availability of care, but mainly the outcome of the care that has become important. To put it more strongly, it is particularly the prevention of suboptimal or undesired outcomes of care that has come to the fore [1]. This trend was first noted by the well-known report of the Institute of Medicine: To Err is Human [2]. At that time the world was first startled by the fact that in the USA alone annually between 44,000 and 98,000 patients die as a result of medical errors. Thus the term '*patient safety*', which is defined as reducing the risk of unnecessary harm associated with healthcare to an acceptable minimum, was born [3].

Quality is obtained by ensuring safety. Safety is ensured by guaranteeing in advance the frameworks in which care is provided. By measuring these processes and outcomes, the quality is determined afterwards [4]. With regard to the introduction of new surgical techniques and technologies (hereinafter referred to as '*new interventions*') it is conventionally recognized that efficacy and safety (i.e. major short-term safety issues) are assessed by means of Randomized Controlled Trials (RCT). To demonstrate long-term safety, cohort studies are the gold standard. The major disadvantage of RCTs is that they are not suitable for detecting complications with a low incidence. In addition, large numbers are required for both study designs, which means that in daily clinical practice such studies can be difficult to perform, for example, when there are rapid successive developments [5]. The question is: how can the quality of care be determined in such a situation?

In order to make quality comprehensible and transparent, quality indicators have been created [6]. Three different types of quality indicators can be distinguished: structure, process and outcome indicators [7]. Structure indicators assess the setting in which care takes place (e.g. the adequacy of facilities and equipment; the qualifications of medical staff). Process indicators examine the process of care itself (e.g. technical competence in the performance of surgical procedures; adherence to guidelines). Finally, outcome indicators (e.g. mortality, return to work) are the most frequently used by doctors as an indicator of the quality of healthcare. A major disadvantage of outcome indicators is that outcomes are influenced by many factors other than medical care itself. Using process indicators eliminates this problem as they focus on applying what is now known to be 'good' medical care. Although the estimates of quality that one obtains are less fixed/definite than those derived from the measurement of outcomes, they may be more relevant to the question at hand: whether medicine is properly practiced [7]. However, scientifically well-founded quality indicators are scarce.

Concerns with respect to potentially preventable damage are recognized in the field of minimally invasive surgery (MIS), especially in advanced laparoscopic procedures. These concerns are mainly due to two factors. The first factor is the use of advanced technology

in this surgical technique. This results in a high number of errors that are attributable to equipment [8, 9]. Secondly, MIS is already very safe in general. The introduction of a new intervention can thus potentially yield only marginal benefits, but unexpectedly could also entail new risks with possibly much greater consequences [10]. An example is the occurrence of capacitive coupling between an insulated electrode and a surrounding metal sleeve that has been suggested as the cause of unintended injury during laparoscopy [11, 12]. This pitfall was also emphasized in a report published by the Dutch Health Care Inspectorate (IGZ) in 2007 [13]. One of the suggested measures that had to be taken to prevent laparoscopic surgery from being unnecessarily risky was to guarantee patient safety by developing a quality-control system. Ideally, such a system should be based on clinically relevant indicators for quality.

Especially in MIS, new interventions are introduced in rapid succession or even simultaneously into the operating room (OR). To guarantee safety during this process, ideally, this implementation is preceded by performing a Prospective Risk Inventory (PRI) based on the Healthcare Failure Mode and Effect Analysis method (HFMEA) [14]. This approach has been promoted in the guideline 'New interventions into clinical practice' that was developed by the Dutch Order of Medical Specialists (OMS) in 2014 [15]. However, according to this guideline, an analysis of safety and effectiveness should be performed after 6 to 12 months *after* the actual introduction. Therefore safety *during* this first period of the introduction of new interventions is not completely ensured [10, 16]. Inherently, this causes a potential patient safety hazard that should be prevented.

Nevertheless, detection of safety issues during the introduction of new interventions is difficult [5]. One of the current theories about the origin of adverse events is the Swiss cheese model, which has been described by Reason [17]. Only in situations in which a variety of contributing factors combine to breach the many barriers and safeguards (i.e. when all holes are aligned) an adverse event may occur. The crux is therefore to find markers for the near misses and to learn from them so that they can be prevented in the future [18]. Clinicians must therefore actively seek other measuring instruments to continue to guarantee safety even during the introduction of new interventions.

Safety is monitored not only during a surgical procedure but also during the entire perioperative process. Technical solutions that autonomously ensure safety in the OR are being widely implemented. Well known are the systems that provide continuous monitoring of sterility, door movements, air temperature and air quality [19]. More recent developments are systems that report the location and maintenance status of the devices [20]. Both of these technical solutions constantly monitor factors that potentially affect the safety during the procedure and consequently lower the risks of adverse outcomes. However, monitoring of the progress of the surgical procedure is still depending almost completely on manpower.

A system that can automatically monitor the progress of the surgical procedure in real-time can offer many benefits. Due to increased efficiency of the OR schedule, more interventions will be ready during daytime instead of being delayed in after-hours. This is desirable, in particular with respect to the current staffing at all departments during after-hours [21]. Therefore, there are many initiatives worldwide to increase the efficiency of the OR [22]. This is typically attempted by better planning, i.e. better estimation in advance of the planned duration of the procedure [23]. However, the course of surgical procedures seems to be difficult to predict in practice [24]. Perioperative delays are very common in surgical procedures and moreover are hard to anticipate beforehand. Currently, any deviation from the planning must be recognized by the OR team and/or the OR manager. The OR schedule is therefore unreliable and not comprehensible for other participants throughout the process (patient ward, holding/recovery department, OR cleaning services, hospital transport, surgeon of next procedure etc.) [25, 26]. Allowing technical solutions to take over this task can support the clinicians better and more accurately so that they can engage in their primary task: to provide good care. This can potentially further improve the quality and safety of the surgical process [27].

To ensure patient safety during the introduction of new interventions in MIS, both the clinical questions and the technical process should be addressed. Therefore, the main objectives of this thesis are:

- To obtain clinically relevant tools to evaluate quality of minimally invasive surgical procedures, both in general as well as specifically regarding laparoscopic hysterectomy (LH), as the most frequently performed advanced gynecological MIS procedure; and
- To support clinicians to ensure surgical safety by means of process analysis.

Outline of this thesis

Conversion is suggested in the report of the Dutch Healthcare Inspectorate as a potential quality indicator [13]. The main reason for this is that a patient is exposed to the risks of complications specific to both surgical approaches if the laparoscopic procedure is converted to a laparotomy. Moreover, between different hospitals, a wide range of conversion rates are reported for the same procedures. However, these numbers cannot be used for reliable comparison at this time because very different definitions are used for what is referred to as conversion. Furthermore, in literature there is no consensus regarding an unambiguous definition and the same definitions are interpreted differently between different specialties. **Chapter 2** describes a study aimed at achieving multidisciplinary consensus on a generally applicable definition of conversion in laparoscopic surgery by means of the Delphi approach.

Furthermore, based on the results of a prospective cohort study and after obtaining systematic data on conversion rates, **Chapter 3** hypothesizes the extent to which conversion rate can act as a means of evaluation in an advanced MIS procedure. The LH was chosen as the procedure under research, requiring a wide array of endoscopic instruments and equipment.

A major complication after LH whose causation is sought in the applied technique and/or technology is the vaginal cuff dehiscence (VCD). The risk of VCD after an LH is higher than after vaginal or abdominal hysterectomy [28, 29]. The technology (e.g. type of electrosurgery used for the colpotomy) as well as the technique (type of suture and suturing technique) are thought to affect the risk of VCD. However, very few well-conducted RCTs or cohort studies are available, due to the rapid succession of new techniques and electrosurgical devices that are used. Since the facts have not been elucidated after all these years, a detailed analysis of occurred VCDs may further unravel the etiology of this major complication. **Chapter 4** compares the incidence of vaginal cuff dehiscence after different suturing methods of the vaginal vault after LH.

A group of patients that is a priori at risk for adverse events after surgery are the very obese and morbidly obese (BMI ≥ 35 kg/m^2). Undeniably, the prevalence of these patients has been rapidly increasing in Western countries in the past decades [30, 31]. Obesity can cause a number of gynecological diseases, such as abnormal uterine bleeding and endometrial hyperplasia [32]. As a result, a higher prevalence of enlarged uteri and especially a higher incidence of endometrial carcinoma are observed among these patients [33-35]. Inherently, the number for which hysterectomy is indicated has been rising over time. However, since this group of patients is almost always excluded from RCTs based on their BMI, no conclusive evidence on the preferred route of hysterectomy is available. In **Chapter 5** the outcomes of abdominal, laparoscopic and vaginal hysterectomy in very obese and morbidly obese patients (BMI ≥ 35 kg/m^2) are evaluated by means of a systematic review with cumulative analysis.

Currently, a measurement tool to monitor safety at the time of introduction of new interventions in MIS procedures does not exist. A novel method to evaluate safety is by observing the presence and effect of '*surgical flow disturbances*' during the course of a surgical procedure. These disturbances are defined as stimuli that distract one or more members of the sterile team and could potentially precede a safety issue (i.e. the Swiss cheese model) and are thus a good marker for measuring safety [36, 37]. Up till now, the most widely used method of assessing safety is analysis by a human observer in the OR. However, safety issues are complex and sometimes only noticeable afterwards. In addition, an observer in the OR influences the behavior of the team and/or the course of a procedure (Hawthorne effect) and can hardly identify real-time consequences of previous actions with subsequent effects [27, 38, 39]. Video observation

overcomes these shortcomings and is therefore acknowledged as the ultimate way to analyze the surgical workflow and assess safety in retrospect. Using video observation, in a prospective observational study, we compare a conventional OR with an integrated OR with regard to the incidence and effect of equipment-/instrument-related surgical flow disturbances during an advanced laparoscopic gynecological procedure (i.e. LH) (**Chapter 6**).

However, in daily clinical practice, extensive analysis of the entire procedure is difficult to perform. Firstly, it is time consuming and therefore expensive; at the same time, also privacy issues can be an obstacle. A specific questionnaire filled in by all members of the OR team (surgeon, scrub nurse, anesthetist(-assistant)) could possibly serve as a proxy for the presence of these surgical flow disturbances. Therefore, **Chapter 7** observes whether judgments of the surgical team are a reliable measure of surgical safety. A questionnaire that had to be filled out immediately after surgery was developed to measure surgical safety. Next, the validity of the questionnaire was assessed by comparison with the results from independent video analysis of these procedures.

Finally, **Chapter 8** describes a novel system for automated procedural progress monitoring that will be able to predict the remaining procedure duration. First, it is tested whether adaptation of the planned procedure duration with phase-specific reference data provides a reliable estimation of the actual procedure duration. Subsequently, the requirements for an automated real-time procedural progress monitoring system are described.

In **Chapter 9** the general discussion of the findings is provided and perspectives for future research will be given. **Chapter 10** gives a summary of this thesis.

References

1. Fink AS, Campbell DA, Jr., Mentzer RM, Jr., Henderson WG, Daley J, Bannister J, et al. The National Surgical Quality Improvement Program in non-veterans administration hospitals: initial demonstration of feasibility. *Ann Surg.* 2002;236:344-353
2. Institute of Medicine. To Err Is Human: Building a Safer Health System. The National Academies Press, Washington, DC; 2000
3. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an International Classification for Patient Safety: key concepts and terms. *Int J Qual Health Care.* 2009;21:18-26
4. Eisenberg D, Wren SM. Innovation in safety, and safety in innovation. *JAMA Surg.* 2014;149:7-9
5. Ergina PL, Cook JA, Blazeby JM, Boutron I, Clavien PA, Reeves BC, et al. Challenges in evaluating surgical innovation. *Lancet.* 2009;374:1097-1104
6. Kotter T, Blozik E, Scherer M. Methods for the guideline-based development of quality indicators--a systematic review. *Implement Sci.* 2012;7:21
7. Donabedian A. Evaluating the quality of medical care. *The Milbank Memorial Fund quarterly.* 1966;44: Suppl:166-206
8. Verdaasdonk EG, Stassen LP, van der Elst M, Karsten TM, Dankelman J. Problems with technical equipment during laparoscopic surgery. An observational study. *Surg Endosc.* 2007;21:275-279
9. Weerakkody RA, Cheshire NJ, Riga C, Lear R, Hamady MS, Moorthy K, et al. Surgical technology and operating-room safety failures: a systematic review of quantitative studies. *BMJ Qual Saf.* 2013;22:710-718
10. Barkun JS, Aronson JK, Feldman LS, Maddern GJ, Strasberg SM, Altman DG, et al. Evaluation and stages of surgical innovations. *Lancet.* 2009;374:1089-1096
11. Grosskinsky CM, Ryder RM, Pendergrass HM, Hulka JF. Laparoscopic capacitance: a mystery measured. Experiments in pigs with confirmation in the engineering laboratory. *Am J Obstet Gynecol.* 1993;169:1632-1635
12. Vilos GA, Rajakumar C. Electrosurgical generators and monopolar and bipolar electrosurgery. *J Minim Invasive Gynecol.* 2013;20:279-287
13. Inspectie voor de gezondheidszorg. Risico's minimaal invasieve chirurgie onderschat, kwaliteitssysteem voor laparoscopische operaties ontbreekt. The Hague, The Netherlands; 2007.
14. Linkin DR, Sausman C, Santos L, Lyons C, Fox C, Aumiller L, et al. Applicability of Healthcare Failure Mode and Effects Analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clin Infect Dis.* 2005;41:1014-1019
15. Orde van Medisch Specialisten, Zorginstituut Nederland. Leidraad Nieuwe Interventies in de Klinische Praktijk. 2014.
16. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH. Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Qual Saf Health Care.* 2010;19:e64
17. Reason J. Beyond the organisational accident: the need for "error wisdom" on the frontline. *Qual Saf Health Care.* 2004;13 Suppl 2:ii28-ii33
18. Calland JF, Guerlain S, Adams RB, Tribble CG, Foley E, Chekan EG. A systems approach to surgical safety. *Surg Endosc.* 2002;16:1005-1014

19. Birgand G, Azevedo C, Toupet G, Pissard-Gibollet R, Grandbastien B, Fleury E, et al. Attitudes, risk of infection and behaviours in the operating room (the ARIBO Project): a prospective, cross-sectional study. *BMJ Open*. 2014;4

20. Guedon AC, Wauben LS, Overvelde M, Blok JH, van der Elst M, Dankelman J, et al. Safety status system for operating room devices. *Technol Health Care*. 2014;22:795-803

21. Rodrigues S, ter Kuile M, Dankelman J, Jansen F. Patient safety risk factors in minimally invasive surgery: a validation study. *Gynecol Surg*. 2012;9:265-270

22. Cardoen B, Demeulemeester E, Beliën J. Operating room planning and scheduling: A literature review. *Eur J Oper Res*. 2010;201:921-932

23. van Veen-Berkx E, Elkhuizen SG, van Logten S, Buhre WF, Kalkman CJ, Gooszen HG, et al. Enhancement opportunities in operating room utilization; with a statistical appendix. *J Surg Res*. 2015;194:43-51 e41-42

24. Roque DR, Robison K, Raker CA, Wharton GG, Frishman GN. The accuracy of surgeons' provided estimates for the duration of hysterectomies: a pilot study. *J Minim Invasive Gynecol*. 2015;22:57-65

25. van Essen JT, Hurink JL, Hartholt W, van den Akker BJ. Decision support system for the operating room rescheduling problem. *Health Care Manag Sci*. 2012;15:355-372

26. Bhatia B, Oates T, Xiao Y, Hu P. Real-time identification of operating room state from video. Proceedings of the 19th national conference on Innovative applications of artificial intelligence - Volume 2, AAAI Press, Vancouver, British Columbia, Canada; pp 1761-1766; 2007.

27. Hu YY, Arriaga AF, Roth EM, Peyre SE, Corso KA, Swanson RS, et al. Protecting patients from an unsafe system: the etiology and recovery of intraoperative deviations in care. *Ann Surg*. 2012;256:203-210

28. Agdi M, Al-Ghafri W, Antolin R, Arrington J, O'Kelley K, Thomson AJ, et al. Vaginal vault dehiscence after hysterectomy. *J Minim Invasive Gynecol*. 2009;16:313-317

29. Hur HC, Donnellan N, Mansuria S, Barber RE, Guido R, Lee T. Vaginal cuff dehiscence after different modes of hysterectomy. *Obstet Gynecol*. 2011;118:794-801

30. Berghofer A, Pischon T, Reinhold T, Apovian CM, Sharma AM, Willich SN. Obesity prevalence from a European perspective: a systematic review. *BMC Public Health*. 2008;8:200

31. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA*. 2012;307:491-497

32. Modesitt SC, van Nagell JRJ. The impact of obesity on the incidence and treatment of gynecologic cancers: a review. *Obstet Gynecol Surv*. 2005;60:683-692

33. Dandolu V, Singh R, Lidicker J, Harmanli O. BMI and uterine size: is there any relationship? *Int J Gynecol Pathol*. 2010;29:568-571

34. Evans T, Sany O, Pearmain P, Ganesan R, Blann A, Sundar S. Differential trends in the rising incidence of endometrial cancer by type: data from a UK population-based registry from 1994 to 2006. *Br J Cancer*. 2011;104:1505-1510

35. Fader AN, Arriba LN, Frasure HE, von Gruenigen VE. Endometrial cancer and obesity: epidemiology, biomarkers, prevention and survivorship. *Gynecol Oncol*. 2009;114:121-127

36. Parker SE, Laviana AA, Wadhera RK, Wiegmann DA, Sundt TM, III. Development and evaluation of an observational tool for assessing surgical flow disruptions and their impact on surgical performance. *World J Surg*. 2010;34:353-361

37. Pluyter JR, Buzink SN, Rutkowski AF, Jakimowicz JJ. Do absorption and realistic distraction influence performance of component task surgical procedure? *Surg Endosc*. 2010;24:902-907

38. Guerlain S, Adams RB, Turrentine FB, Shin T, Guo H, Collins SR, et al. Assessing team performance in the operating room: development and use of a "black-box" recorder and other tools for the intraoperative environment. *J Am Coll Surg.* 2005;200:29-37

39. Persoon MC, Broos HJ, Witjes JA, Hendrikx AJ, Scherpbier AJ. The effect of distractions in the operating room during endourological procedures. *Surg Endosc.* 2011;25:437-443