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English Title: Patient Safety Issues in Office-based Surgery and Anaesthesia in Switzerland: A Qualitative Study

German Title: Aspekte der Patientensicherheit von chirurgischen Eingriffen und Anästhesie in der Arztpraxis in der Schweiz: eine qualitative Studie

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Abstract

Objectives: To identify the spectrum of patient safety issues in office-based surgery and anaesthesia in Switzerland.

Methods: Purposive sample of 23 experts in surgery and anaesthesia and quality and regulation in Switzerland. Data were collected via individual qualitative interviews using a researcher-developed semi-structured interview guide between March 2016 and September 2016. Interviews were transcribed and analysed using conventional content analysis. Issues were categorised under the headings “structure”, “process”, and “outcome”.

Results: Experts identified two key overarching patient safety and regulatory issues in relation to office-based surgery and anaesthesia in Switzerland. First, experts repeatedly raised the current lack of data and transparency of the setting. It is unknown how many surgeons are operating in offices, how many and what types of operations are being done, and outcomes. Secondly, experts also noted the limited oversight and regulation of the setting. While some standards exists, most experts felt that more minimal safety standards regarding what requirements need to be met to do office-based surgery and what can and cannot be done in the office-based setting are needed, but advocated a self-regulatory approach.

Conclusion: There is currently a lack of empirical data regarding the quantity and quality office-based surgery and anaesthesia in Switzerland. Further research is needed to address these research gaps and inform health policy in relation to patient safety in office-based surgery and anaesthesia in Switzerland.

Key words: Office Surgery; Patient Safety; Switzerland

Zusammenfassung

Ziel: Identifikation des Spektrums von Aspekten der Patientensicherheit in der Chirurgie und Anästhesie in der Arztpraxis in der Schweiz

Methoden: Zwischen März und September 2016 wurden 23 qualitative semi-strukturierte Interviews mit Experten aus den Bereichen Chirurgie, Anästhesie, sowie Qualität und Regulation in der Schweiz geführt. Die Interviews wurden transkribiert und mittels konventioneller Inhaltsanalyse analysiert. Die Aspekte der Patientensicherheit wurden unter den Überschriften "Struktur", "Prozess" und "Ergebnis" kategorisiert.

Ergebnisse: Experten identifizierten zwei wichtige überspannend Patientensicherheits- und Regulierungsthemen in Bezug auf der Chirurgie und Anästhesie in der Arztpraxis in der Schweiz. Erstens wurde der aktuelle Mangel an Daten und Transparenz berichtet. So ist etwa nicht bekannt, wie viele Chirurgen in Praxis-OPs arbeiten, wie viele und welche Arten von Operationen durchgeführt werden, und welche Ergebnisse erzielt werden. Zweitens stellten Experten auch die begrenzte Aufsicht und Regulierung fest. Obwohl es bereits einige Standards gibt, glaubten die meisten Experten, dass die derzeitige Situation nicht ausreichend sei und dass mehr Grenzen erforderlich seien. Experten befürworten einen selbstregulierenden Regulierungsansatz.

Schlussfolgerung: Derzeit gibt es einen Mangel an empirischen Daten zur Quantität und Qualität der Chirurgie und Anästhesie in der Arztpraxis in der Schweiz. Weitere Forschungsarbeiten sind erforderlich, um diese Lücken zu schließen und die Gesundheitspolitik in Bezug auf die Patientensicherheit in der ambulanten Chirurgie und Anästhesie in der Schweiz zu informieren.

Schlüsselwörter: der Chirurgie und Anästhesie in der Arztpraxis ; Patientensicherheit; Schweiz

1. **Introduction**

With ageing populations and increasing rates of chronic diseases leading to a growing demand for healthcare, outpatient care is seen as a promising alternative to inpatient care [1]. One of the clearest examples of this move towards outpatient care has been the growth of outpatient surgery and anaesthesia. Outpatient surgery, however, has increasingly moved out of hospitals and ambulatory surgery centres and into physician's offices. Office-based surgery and anaesthesia has seen remarkable growth internationally in recent decades, particularly in the United States [2-4]. While it was initially seen to be best suited for a young healthy patient population, office-based surgical procedures have become increasingly complex (and as a result longer in duration) and conducted on older patients with more comorbidities [2,5]. A number of factors have been identified as being behind this growth of office-based surgery, including economic advantages, increased patient and surgeon convenience and satisfaction, consistent staffing, efficiency, patient privacy, increased autonomy of practice, decreased risk of infection, and an ageing population and increased demand for cosmetic surgery [2-4,6].

Leading patient safety advocates, however, have raised concerns that the growth of office-based surgery "has not been widely accompanied by adherence to the safety standards present in hospital settings or ambulatory surgical facilities" [7]. These concerns have been heightened by reports of tragic mishaps that have allegedly occurred due to a lack of resources that are usually available in a hospital or ambulatory surgical centres, or due to patients being discharged too early into the unmonitored home setting [2-5,7]. Nevertheless, there remains a general lack of regulation and oversight in this setting in many countries, which has given office-based surgery "a reputation for being the 'Wild West' of healthcare" [5].

In Switzerland, there have been a number of studies concerning various aspects of ambulatory care [8-11], and ambulatory surgery in general [12-14]. For instance, Vuilleumier and

colleagues reported in 2011 that the utilization of a private surgical facility to perform outpatient abdominal surgery was successful, effective, safe, and cost-effective [12], while Gemayel and Christenson found in 2012 that bilateral varicose vein surgery could be safely performed as an outpatient procedure, without increased risk of postoperative complications [13]. However, we are not aware of any previous research specifically concerning office-based surgery and anaesthesia or the issue of patient safety in this setting. The Swiss Patient Safety Foundation is currently conducting a large scale quality improvement program regarding safe surgery in the inpatient setting (progress! Sichere Chirurgie) [15], but has concerns that the same efforts are not being undertaken in the office-based setting, particularly given the apparent diffusion of surgical care in this setting and the lack of regulation. It is currently unclear what the key patient safety issues are in relation to office-based surgery in Switzerland and in what areas research is needed. The aim of this research, therefore, is to identify the spectrum of patient safety issues in office-based surgery in Switzerland.

2. Methods

Study design and data collection did not require approval of an ethical committee in Switzerland referring to Articles 1 and 2 of the Federal Act on Research involving Human Beings (Human Research Act, HRA) [16]. The methods of the study are presented in accordance with the "Consolidated criteria for reporting qualitative research" (COREQ) [17].

2.1. Research team and reflexivity

Interviews were conducted by S.M., a male Post Doc in biomedical ethics, who had previous training and experience in qualitative research [18-19]. S.M. had already had contact with 8 of the 23 experts prior to the study. Otherwise, no relationship was established between S.M. and the other participants prior to the study and participants received limited information about

S.M. There was no hierarchical relationship between SM and the study participants. Y.H. and S.S. have had limited previous experience in qualitative research, while D.S. and B.E. both have longstanding experience with qualitative studies.

2.2. Study design

The theoretical framework employed in this study was conventional content analysis [20]. We primarily selected experts through purposive sampling, in order to ensure sample diversity according to predetermined factors (e.g. field of expertise). Experts who were considered to be knowledgeable about the subject and capable of representing the views of his or her peers were identified through discussions within the research team and wider contacts. Experts were divided into two "subgroups": 1) Experts in surgery and anaesthesia, and 2) Experts in patient safety and regulation. Experts were contacted by email and suitable dates for an interview were found with those willing to participate. A total of 23 experts agreed to participate in the study. The 11 experts in surgery and anaesthesia were all practising surgeons and anaesthesiologists with a known interest in patient safety issues and hold leadership positions in their organisations or professional associations, this included 2 mobile anaesthesiologists, 2 office-based surgeons, and 2 anaesthesiologists and 5 surgeons who work primarily in the in-patient setting. The 12 experts in quality and regulation included representatives of the Swiss Federal Office of Public Health, the Swiss Patient Safety Foundation, the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ), the Swiss Association of Cantonal Officers of Health, the Swiss Conference of the Cantonal Health Directors (GDK/CDS), the Swiss Medical Assoication, the Swiss Patient Protection Foundation (SPO), health insurance companies, liability insurance companies, and a university hospital medical director. Interviews were held between March 2016 and September 2016. Three participants provided their responses in German via email, while all other interviews were conducted in

English via a telephone/Skype video call or in person at a venue of the participants' choosing. Only the participant and the researcher were present during the interview.

A semi-structured interview guide was developed. Experts were asked to respond to three open-ended questions: 1) What are your views about the safety of office-based surgery and anaesthesia in Switzerland? 2) What are your views about the current regulation and oversight of office-based surgery anaesthesia in Switzerland? 3) What research do you think is needed in relation to patient safety in office-based surgery and anaesthesia in Switzerland? Based on the first 2 interviews which did not show any problems, it was decided that no further piloting or adaptation of the interview guide was necessary. No repeat interviews were carried out. Interviews were audio recorded, no field notes were taken. Interviews lasted an average of 33 minutes. After 23 interviews the question about data saturation arose and discussed by the research team. It was concluded that saturation was reached in the content and attitudes expressed by the participants on the main themes and no other major issues were not at least broached. Transcriptions of the interviews were not returned to the participants.

2.3. Analysis and findings

Using the interview transcriptions in their original language (20 English, 3 German), S.M. performed conventional content analysis [20] with the assistance of the qualitative software MAXQDA v11, focusing on themes common across participants as well as those unique to individuals that may offer insight into differences in perspectives and discrepancies in practice. Initial themes discovered in the interviews were labelled using a process of open coding (i.e., no specific preconceived codes were identified or used; rather, codes emerged directly from the data). The other investigators [D.S., Y.H., S.S., B.E.] reviewed the initial analysis to clarify and refine codes, and conversations among the investigators continued until coding differences were resolved and consensus was achieved. Following Donabedian's

model [21-23], issues were categorised under the headings “structure” (concerning the setting in which care is provided), “process” (concerning the way care is provided), and “outcome” (concerning the effects that treatment had on the patient) [22].

3. Results

Experts identified fourteen broad patient safety and regulatory issues in relation to office-based surgery and anaesthesia in Switzerland (see **Tables 1-3** for example quotes).

3.1. Structural Related Issues

3.1.1. Cantonal Oversight

Experts were not aware of any specific Cantonal regulations concerning office-based surgery. Indeed, representatives of the Swiss Association of Cantonal Officers of Health and the Swiss Conference of the Cantonal Health Directors (GDK/CDS) noted that beyond granting a practice permit (Praxisbewilligung) the Cantonal authorities actually have limited legal competences to regulate the outpatient setting, which is largely left to self-regulation. However, it was reported that clinicians often did not appreciate this and often contacted Cantonal Officers of Health asking for information or guidance which the Officers are not able to provide. This was reflected in the frustrations reported by some mobile anaesthesiologists who reported that the Cantons authorities were “poor partners” and provided insufficient information and oversight. While the requirements to obtain a practice permit are effectively the same in all Cantons, it was also reported that there is significant variation regarding the level of checks and controls carried out by Cantonal Officers of Health following the granting of a permit.

3.1.2. Continuing Medical Education

Both office-based surgeons and mobile anaesthesiologists described difficulties regarding further integration of patient safety in continuing medical education, for example professional courses were reported to prioritise new techniques that would lead to greater profits over patient safety, with some course organisers rejecting the importance of including patient safety at all.

3.1.3. Demarcation of Field

One expert noted that there is no clear definition in Switzerland of what is and what isn´t office-based surgery, describing how an outpatient surgical centre they build up could have been classified either as a hospital facility or an “office”, and yet this classification has important implications for which regulations and level of controls apply.

3.1.4. Financing

The financing of office-based surgery was an issue raised by many experts. In relation to patient safety, it was noted that it was not possible to include this issue in the outpatient tariff system negotiations which resulted in the implementation of a standardised fee schedule for all outpatient procedures known as TARMED (Tarif Médicaux), and as a result health insurance companies are obligated to contract with and to reimburse all physicians in the outpatient setting (Kontrahierungszwang), treating them equally regardless of their quality and safety. It was felt by one expert that as long as there is this obligation to contract and no rewards for transparency regarding quality, there would be little incentive for physicians to be transparent. However, a mobile anaesthesiologist feared that the removal of the obligation to contract would be a severe threat to their work, with health insurances companies reported to be already eager to refuse to pay for office-based anaesthesia, regularly questioning mobile anaesthesia bills and the need for anaesthesia in the office-based setting.

3.1.5. Hygiene / Sterilisation

Limited standards regarding hygiene and sterilisation in the office-based setting were noted and some concerns were raised by some experts about the sterilisation of equipment. However, most experts thought that there was no significant hygiene issues in the office-based setting, and some experts even speculated that the office-based setting could potentially have some advantages over the hospital setting, particularly in terms of infection control, given the types of surgeries and the smaller teams involved. .

3.1.6. Minimal Safety Standards

It was noted by experts that there is currently very limited “minimal safety standards” in Switzerland regarding what requirements need to be met to do office-based surgery and what types of surgery can and cannot be done in the office. While experts noted that some standards exists (for instance, under outpatient tariff system TARMED and guidelines published for the Swiss Society for Anaesthesia and Resuscitation), most experts felt that more minimal safety standards regarding what requirements need to be met to do office-based surgery and what can and cannot be done in the office-based setting are needed. In terms of who should be setting these minimal safety standards, most experts thought that it would be the most appropriate for professional societies to set these.

3.1.7. Outpatient Statistics

The current lack of data concerning outpatient care was repeatedly raised. In the context of office-based surgery, experts noted that this lack of information and transparency meant that it is unknown how many surgeons are operating in offices, and how many and what types of operations are being done. Many experts noted that the Federal Office of Statistics was developing a new outpatient statistics system called “MARS”, which will improve outpatient

statistics. However, experts were unaware of the details of the system and what "MARS" would include.

3.2. Process Related Issues

3.2.1. Collegiality

a. Working in isolation – A number of experts raised concerns about surgeons working alone in the office-based setting given the lack of feedback and support from colleagues that is typically available in hospitals.

b. Team dynamics – Some experts expressed fears that the dependency of mobile anaesthesiologists on surgeons to be hired may inhibit them speak up about concerns about patient care. However, mobile anaesthesiologists reported the relationship with the surgeon and level of cooperation was in fact much better in the office-based setting compared to the hospital and that they set clear expectations regarding patient safety.

3.2.2. Histology

One expert raised concerns regarding a lack of systematic processes to ensure that biopsies in the office-based setting are analysed following clear rules.

3.2.3. Preoperative Evaluations

a. Receiving sufficient information about patients – Mobile anaesthesiologists described difficulties in receiving sufficient information about patients in order to conduct proper pre-operative evaluations, with one estimating that they did not received sufficient information before the surgery regarding approximately 10% of patients.

b. Informed Consent – Some experts also raised concerns regarding the quality of the informed consent process and whether sufficient information was being provided to patients and enough time for them to consider it and make a decision:

3.2.4. Resource Planning

The importance of having sufficient resources available in office-based surgery to manage complications was noted. Mobile anaesthesiologists in particular stressed the importance of careful planning and having backups to deal with intraoperative complications and any failures of personnel (e.g. epileptic fit) or equipment (e.g. monitor failing). However, some experts were concerned that resources were often intentionally limited by mobile anaesthesia teams to maximise profits. A lack of postoperative resources in terms of monitoring patients and manging complications was also noted, particularly when patients go home after the operation.

3.2.5. Standardised Safety Procedures

a. Checklists – Concerns were raised by experts that there is a lack of standardized safety procedures in preparing and checking operations in the office-based setting. However, there was wide variation of views regarding the importance of using checklists or time outs in the office-based setting.

b. Critical Incident Reporting – The currently limited number of critical incident reporting systems in the outpatient setting were seen as concerning by experts and that the establishment of such systems would be helpful.

3.2.5. Undeclared work

Experts reported two different situations in which care provided in the office-based setting but went undeclared to authorities. First, both surgeons and mobile anaesthesiologists reported that they knew of colleagues doing undisclosed work in the office-based setting, primarily to assist a friend and earn “pocket money”, and estimated that between 50-80 patients a year would be operated in this manner in the office-based setting. Secondly, experts also reported

that there are clinicians from neighboring countries coming into Switzerland to do office-based surgery in areas close to the boarder but that there was little oversight of this and it was not known how many cross boarder clinicians there are, how often they operated or what quality they provided. Although one expert noted that under the bi-lateral rules, EU physicians can practice for 90 days in Switzerland without a license and that approximately 200 physicians have practiced on this basis in Switzerland during the last years. As a result of these two situations, experts thought that there are a number of operations, particularly in the field of plastic surgery as the health insurance companies are often not involved, being done in the office-base setting that are never reported and would not be easily identifiable.

3.3. Outcome Related Issues

3.3.1. Outcomes

There were contrasting views expressed by experts regarding office-based surgery and anaesthesia outcomes. Many thought that complications were low due to the type of surgery being done and the type of patients being operated on. Liability insurance representatives also reported that they had received no significant number of claims involving office-based surgery. However, other experts thought the issue of complications in the office-based setting was more of an issue, pointing to known cases of complications in Switzerland and internationally. However, it was acknowledged that as quality indicators or outcome data are not being systematically collected in the outpatient setting in Switzerland makes it difficult to know if there is really a problem.

4. Discussion

This study was conducted as it was unclear what the key patient safety issues are in relation to office-based surgery and anaesthesia in Switzerland and in what areas further research is needed. As far as we are aware, this is the first study to examine the issue of patient safety in

office-based surgery and anaesthesia in Switzerland and one of first qualitative studies done on this issue internationally. Experts identified two key overarching issues in relation to office-based surgery and anaesthesia in Switzerland. Firstly, experts repeatedly raised the current lack of data and transparency of the setting. Second, experts also noted the limited regulation and oversight of the setting.

The availability of health service data has been a long standing issue in Switzerland. While there have been significant improvements in the availability of data in the inpatient setting since the late 1990s, information about the provision of health services in the ambulatory setting remains limited [24]. The Federal Council of Switzerland identified the introduction of a statistical health information system in ambulatory care as one of ten priority measures in its "Health 2020" [25]. While the Federal Office for Statistics has been conducting a project to develop statistics on outpatient healthcare known as "MARS" (Modules Ambulatoires des Relevés sur la Santé), which was implemented on 15 November 2016 [26], it does not appear that this will address many of the research gaps identified in this project. There is currently a lack of data concerning not only the quantity of office-based surgery and anaesthesia (e.g. how many surgeons are operating in offices and how many and what types of operations are being done etc.) but also the quality of these operations. While there were contrasting views expressed by experts about outcomes in this setting, there was agreement that the current lack of outcome data makes it difficult to know if there is really a problem.

While there are randomised controlled trials (RCTs) and meta-analyses examining outcomes of procedures done in the ambulatory setting [27-28], there is a lack of RCTs that specifically examine office-based surgery and anaesthesia [2]. There have been, however, a number of observational studies (retrospective and prospective) comparing the morbidity and mortality of surgical procedures in the hospital, ambulatory surgical centre and office-based settings

[29-37]. Further studies (such as the one we have started) are urgently needed because the evidence is not clear. There are studies that seem to indicate increased mortality in office based surgery as compared to ambulatory surgery centres [29], although other studies have not shown such differences between these two settings [30-31,33-34,36-37]. In addition, most of these studies are from outside Switzerland and differences between health care systems and their organisation can have a major effect on quality of care.

As experts noted in the interviews, a special risk of "how" office-based operations are done is the issue of postoperative monitoring of patients. There is a growing knowledge on the "failure to rescue" (the failure to recognize and appropriately respond to early signs of a clinically important deterioration, such as death or permanent disability) phenomenon in the inpatient setting [38-49]. The failure to rescue may also be a particular problem in the outpatient setting and data is currently lacking, although there have been reports internationally of tragic mishaps (including deaths) in office-based surgery and anaesthesia due to patients being discharged too early into the unmonitored home setting [2-5,7].

The general lack of regulation in office-based surgery and anaesthesia has also been an issue of concern in other countries [5], where there have been a number of efforts to address this issue. For instance, the first significant regulation of this setting in the United States was in Florida in 2000 after the Florida Board of Medicine became concerned about an increase of deaths in surgical offices performing cosmetic procedures [5]. Nearly 30 states in the U.S. now have some degree of oversight [2], which covers such things as "equipment requirements, facility specifications, emergency procedure policies and training, limitations on the duration of procedures, limitations on the amount of liposuction performed, provider qualifications, and facility accreditation or licensing requirements" [3].

In Switzerland, it appears that regulation concerning office-based surgery and anaesthesia is limited. Relevant laws and regulations includes general civil and criminal law, general professional duties under article 40 of in the Medical Professions Law (Medizinalberufegesetz), the “qualitative Dignitäten” in the outpatient tariff system TARMED – based on article 43(1)(d) of the Health Insurance Law (Krankenversicherungsgesetz - KVG), and the Swiss Society of Anaesthesiology and Resuscitation’s (SGAR/SSAR) Standards and Recommendations for Ambulatory Anaesthesia in Practice (OBA = Office Based Anaesthesia) 2003. Experts identified a clear need for relevant professional societies in Switzerland to develop further minimal safety standards. Furthermore, it was also reported that there is significant variation regarding the level of checks and controls carried out by Cantonal Officers of Health following the granting of a permit, but there is currently no overview of this.

However, it is interesting to see once again a “technology” being diffused in an uncontrolled manner and it takes a long time, in comparison to the diffusion process itself, to set up any quality control measures. In other industries, one would expect to have these minimal safety standards in place before and then observe the technology being spread (e.g. in food production or the pharmaceutical industry). At this stage, when office-based surgery and anaesthesia is already widely diffused, the basic question that needs further discussion is: Do those providing office-based surgery and anaesthesia have to proof it is safe, or do regulatory bodies have to introduce standards after the widespread diffusion?

4.1. Limitations

This was a qualitative study that did not aim at collecting statistically representative data. Although we have no proof that experts have correctly described the reality in all circumstances, there is no particular reason to doubt that their perceptions describe a

significant part of the reality in Switzerland. Indeed, the fact that we interviewed experts who have experience with office-based surgery and anaesthesia or who hold key positions in the Swiss health care system regarding regulation and safety makes it likely that we have captured at least some part of the reality viewed from different sides. A bias might exist towards the reporting of socially desirable attitudes. Given a number of our results are critical of current practice, we believe that such a bias is unlikely to be of significant size.

4.2. Conclusion

There is currently a lack of empirical data regarding the quantity and quality office-based surgery and anaesthesia in Switzerland and the current regulation and oversight in this setting. Further research is needed to address these research gaps. With surgery increasingly moving into the outpatient setting it is important to identify potential safety concerns and possible procedures that may assist safe and cost-effective care in this setting, but which do not cause undue burdens.

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References

1. Kroneman MW, Westert GP, Groenewegen PP, Delnoij DMJ. International variations in availability and diffusion of alternatives to in-patient care in Europe: the case of day surgery. Ambulatory Surgery. 2001; 9: 147–154.
2. Shapiro FE, Punwani N, Rosenberg NM, Valedon A, Twersky R, Urman RD. Office-Based Anesthesia: Safety and Outcomes. Anesth Analg. 2014; 119: 276–85.
3. Bogan V. Anesthesia and Safety Considerations for Office based Cosmetic Surgery Practice. AANA Journal. 2012; 80: 299-305.
4. Kurrek MM, Twersky RS. Office-based anesthesia. Can J Anesth. 2010; 57: 256–272.
5. Urman RD, Punwani N, Shapiro FE. Patient safety and office-based anesthesia. Curr Opin Anesthesiol. 2012; 25: 648–653.
6. Coyle TT, Helfrick JF, Gonzalez ML, Andresen RV, Perrott DH. Office-Based Ambulatory Anesthesia: Factors That Influence Patient Satisfaction or Dissatisfaction With Deep Sedation/ General Anesthesia. J Oral Maxillofac Surg. 2005; 63: 163-172.
7. Kaushal R, Upadhyayula S, Gaba DM, Leape LL. The Wild West: Patient Safety in Office-Based Anesthesia. AHRQ Web M&M. 2006. http://webmm.ahrq.gov/perspective.aspx?perspectiveID=25#ref1 [Accessed 26 September 2016]
8. Eggli Y, Desquins B, Seker E, Halfon P. Comparing potentially avoidable hospitalization rates related to ambulatory care sensitive conditions in Switzerland: the need to refine the definition of health conditions and to adjust for population health status. BMC Health Serv Res. 2014; 14: 25.
9. Busato A, Matter P, Ku B, Goodman D. Geographic variation in the cost of ambulatory care in Switzerland. Journal of Health Services Research & Policy. 2012; 17: 18-23.
10. Eggli Y, Halfon P, Chikhi M, Bandi T. Ambulatory healthcare information system: a

463 conceptual framework. Health Policy. 2006; 78: 26-38.
464 11. Gilliard N, Eggli Y, Halfon P. A methodology to estimate the potential to move
465 inpatient to one day surgery. BMC Health Serv Res. 2006; 6: 78.
466 12. Vuilleumier H, Coquelin G, Wasserfallen JB, Demartines N. Cost-effective utilization
467 of a private facility to perform outpatient surgery in public hospital waiting list
468 patients. Dig Surg. 2011;28(4):299-303.
469 13. Gemayel G, Christenson JT. Can bilateral varicose vein surgery be performed safely
470 in an ambulatory setting? Eur J Vasc Endovasc Surg. 2012 Jan;43(1):95-9.
471 14. Leimbacher B, Samartzis N, Imesch P, Dedes KJ, Fink D, Canonica C. Inpatient and
472 outpatient loop electrosurgery excision procedure for cervical intraepithelial neoplasia:
473 a retrospective analysis. Arch Gynecol Obstet. 2012 May;285(5):1441-5.
474 15. Patientensicherheit Schweiz. Pilotprogramme Patientensicherheit Schweiz: progress!
475 Sichere Chirurgie http://www.patientensicherheit.ch/de/themen/Pilotprogramme-
476 progress--/progress--Sichere-Chirurgie.html [accessed 12.12.2016]
477 16. Federal Authorities of the Swiss Confederation. Federal Act on Research involving
478 Human Beings. 2011 (cited 18 January 2016). http://www admin ch/opc/en/classified-
479 compilation/20061313/indexhtml; http://www.admin.ch/opc/en/classified-
480 compilation/20061313/index.html
481 17. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research
482 (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health C
483 2007; 19: 349-57.
484 18. McLennan, S., Diebold, M., Rich, L.E. & Elger, B. (2016). Nurses' Perspectives
485 Regarding the Disclosure of Errors to Patients: A Qualitative Study. International
486 Journal of Nursing Studies, 54, 16-22.
487 19. McLennan, S., Shaw, D., Leu, A., & Elger, B. (2015). Professional Liability Insurance
488 and Medical Error Disclosure. Swiss Medical Weekly, 145:w14173.

20. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qualitative Health Res. 2005;15(9):1277–88.
21. Donabedian A. The Seven Pillars of Quality. Arch Pathol Lab Med. 1990;114(Nov):1115-1118.
22. Donabedian A. The Quality of Care: How Can it be Assessed? JAMA. 1988;260(12):1754-1748.
23. Donabedian A. Evaluating the quality of medical care. Milbank Q. 1966;44(No. 3, Pt. 2):166-203.
24. De Pietro C, Camenzind P, Sturny I, Crivelli L, Edwards-Garavoglia S, Spranger A, Wittenbecher F, Quentin W. Switzerland: Health system review. Health Systems in Transition, 2015; 17: 1–288.
25. Bundesamt für Gesundheit. Die gesundheitspolitischen Prioritäten des Bundesrates: Health 2020. Berne: Bundesamt für Gesundheit, 2013.
26. Bundesamt für Statistik. Statistiken der ambulanten Gesundheitsversorgung (MARS). https://www.bfs.admin.ch/bfs/de/home/grundlagen/projekte/statistiken-ambulante-gesundheitsversorgung-mars.html [accessed 12.12.2016]
27. Dirksen CD, Schmitz RF, Hans KM, Nieman FH, Hoogenboom LJ, Go PM. [Ambulatory laparoscopic cholecystectomy is as effective as hospitalization and from a social perspective less expensive: a randomized study].[Article in Dutch] Ned Tijdschr Geneeskd. 2001; 145: 2434-9.
28. Ahmad NZ, Byrnes G, Naqvi SA. A meta-analysis of ambulatory versus inpatient laparoscopic cholecystectomy. Surg Endosc. 2008; 22: 1928-34.
29. Vila H Jr, Soto R, Cantor AB, Mackey D. Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers. Arch Surg 2003;138:991–5.
30. Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and

death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. Arch Surg 2004;139:67–72

31. Coldiron B, Shreve E, Balkrishnan R. Patient injuries from surgical procedures performed in medical offices: three years of Florida data. Dermatol Surg 2004;30:1435–43
32. Bhananker SM, Posner KL, Cheney FW, Caplan RA, Lee LA, Domino KB. Injury and liability associated with monitored anesthesia care: a closed claims analysis. Anesthesiology 2006;104:228–34
33. Coldiron BM, Healy C, Bene NI. Office surgery incidents: what seven years of Florida data show us. Dermatol Surg 2008;34:285–91.
34. Keyes GR, Singer R, Iverson RE, McGuire M, Yates J, Gold A, Reed L, Pollack H, Thompson D. Mortality in outpatient surgery. Plast Reconstr Surg 2008;122:245–50.
35. Starling J 3rd, Thosani MK, Coldiron BM. Determining the safety of office-based surgery: what 10 years of Florida data and 6 years of Alabama data reveal. Dermatol Surg 2012;38:171–7.
36. Failey C, Aburto J, de la Portilla HG, Romero JF, Lapuerta L, Barrera A. Office-based outpatient plastic surgery utilizing total intravenous anesthesia. Aesthet Surg J. 2013 Feb;33(2):270-4.
37. Gupta V, Parikh R, Nguyen L, Afshari A, Shack RB, Grotting JC, Higdon KK. Is Office-Based Surgery Safe? Comparing Outcomes of 183,914 Aesthetic Surgical Procedures Across Different Types of Accredited Facilities. Aesthet Surg J. 2016 [Epub ahead of print]
38. Friedman AM, Ananth CV, Huang Y, D'Alton ME, Wright JD. Hospital delivery volume, severe obstetrical morbidity, and failure to rescue. Am J Obstet Gynecol. 2016;215:795.e1-795.e14.
39. Ghaferi AA, Dimick JB2. Importance of teamwork, communication and culture on

failure-to-rescue in the elderly. Br J Surg. 2016;103:e47-51.

40. Kuo LE, Kaufman E, Hoffman RL, Pascual JL, Martin ND, Kelz RR, Holena DN. Failure-to-rescue after injury is associated with preventability: The results of mortality panel review of failure-to-rescue cases in trauma. Surgery. 2016 Oct 25. [Epub ahead of print]
41. Passot G, Vaudoyer D, Villeneuve L, Wallet F, Beaujard AC, Boschetti G, Rousset P, Bakrin N, Cotte E, Glehen O. A Perioperative Clinical Pathway Can Dramatically Reduce Failure-to-rescue Rates After Cytoreductive Surgery for Peritoneal Carcinomatosis: A Retrospective Study of 666 Consecutive Cytoreductions.
42. Ann Surg. 2016 Apr 11. [Epub ahead of print]
43. Sheetz KH, Dimick JB, Ghaferi AA. Impact of Hospital Characteristics on Failure to Rescue Following Major Surgery. Ann Surg. 2016;263:692-7.
44. Tamirisa NP, Parmar AD, Vargas GM, Mehta HB, Kilbane EM, Hall BL, Pitt HA, Riall TS. Relative Contributions of Complications and Failure to Rescue on Mortality in Older Patients Undergoing Pancreatectomy. Ann Surg. 2016;263:385-91.
45. Tu RH, Lin JX, Zheng CH, Li P Xie JW, Wang JB, Lu J, Chen QY, Cao LL, Lin M, Huang CM. Complications and failure to rescue following laparoscopic or open gastrectomy for gastric cancer: a propensity-matched analysis. Surg Endosc. 2016 Sep 12. [Epub ahead of print]
46. Joseph B, Zangbar B, Khalil M, Kulvatunyou N, Haider AA, O'Keeffe T, Tang A, Vercruysse G, Friese RS, Rhee P. Factors associated with failure-to-rescue in patients undergoing trauma laparotomy. Surgery. 2015;158:393-8.
47. Mulvey CL, Pronovost PJ, Gourin CG. Hospital volume and failure to rescue after head and neck cancer surgery.Otolaryngol Head Neck Surg. 2015;152:783-9.
48. Ferraris VA, Bolanos M, Martin JT, Mahan A, Saha SP. Identification of patients with postoperative complications who are at risk for failure to rescue. JAMA Surg.

2014;149:1103-8.

49. Sheetz KH, Krell RW, Englesbe MJ, Birkmeyer JD, Campbell DA Jr, Ghaferi AA. The importance of the first complication: understanding failure to rescue after emergent surgery in the elderly. J Am Coll Surg. 2014;219:365-70.

572 **Tables**

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574 **Table 1. Structural Related Issues**

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Issue	Example Quote
1. Cantonal Oversight	*"So my daily task often is to tell them, "Yes it's nice that you called me but it's not my legal competence to decide such things"" P23*
2. Continuing Medical Education	*"…Yeah but it is a struggle. I just saw a program of the European course…not one single point on patient safety. So I'm writing to the course directly and…he writes me back, "Oh quality and safety this is what we do every day we don't need to educate this." P13*
3. Demarcation of Field	*"There is no clear distinction between hospital outpatient surgery in Switzerland and office based surgery. I once built up an outpatient centre…and the question was if it would it be recognized as a hospital or as an individual office. It was recognized as the hospital facility but only because we asked for admission by Sanita Swiss insurance with a specific billing number as a hospital. We could have also asked as an office…so there is no clear delimitation. This is quite important for the canton legislation under which regime you are recognized and controlled by the canton authorities." P1*
4. Financing	*"…it has never been a big issue for health insurance because they are not responsible for patient safety so as long as they*

	don't have the power to really punish or reward doctors with good or bad safety, it cannot be an issue for the health insurance. If they have to pay, then they have to pay. They have no way of choosing between good and bad ones and this makes it very difficult for the payer…you have to pay them equally, you cannot distinguish between the one with the good or the bad, safety or quality." P6
5. Hygiene / Sterilisation	*"The second problem is about the sterility. In the normal operating theatre in Switzerland, you have quite tough regulations about the control of the sterilization of equipment. In the office based surgery, there is no such regulation as I know. So the equipment that are used, are not regulated in a very strict manner." P1*
6. Minimal Standards	*"Yeah of the society's perspective of course. What are the minimal requirement for an operative room and also if you are doing anaesthesia what is the minimum requirement also in personal to have an anesthetist, to have also a nurse and doing some standby anaesthesia. …Okay that there are no regulations, there are no rules. And of course if you have to go to court I don't know because it is written nowhere what you have to fulfil or not….certainly on one side our society has a very big interest to have something done, to have something written then that we can show to the Canton or to somebody that are asking do you have some minimal requirements for your office-based surgery?" P17*

7. Outpatient Statistics	*"Well it's hard topic, to have a general opinion of that, like, from a peers perspective, all we can say is we have a big lack of transparency in that issue. So we don't really know if we have a problem there or not and starting from there, it is hard to have really, an opinion of it." P6*

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578 **Table 2. Process Related Issues**

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Category	Example Quote
8. Collegiality	
8a. Working in isolation	*"… if you are only operating in your own centre, you are quite alone you don't have much feedback or a challenge from, I don't know, your chief residence or whatever. And so this is a potential problem." P13*
8b. Team dynamics	*"For us it's much more comfortable than being in the hospital because basically the relationship with the surgeon is easier because they are sort of happy to see us come. They need us so it's, I think the level of cooperation and the type of interaction we have is much better or much smoother than we have in the hospital where it's basically you are expected to take care of any patient at any time because they ask you to…it's really a relationship, a partnership much more than in a hospitals." P20*
9. Histology	*"The third problem I identified is the problem of systematic or non-systematic histology. I don't think that there are regulations or processes that are implemented in a way that makes sure that any kind of biopsy are analysed following clear rules." P1*
10. Preoperative Evaluations	
10a. Receiving sufficient information about patients	*"That's one thing that remains quite difficult. I would say that at the moment we have a contact with probably 90 percent of our patients before the operation. There is still a 10 percent of patients that will not answer the phone …And there is also percentage of patients who just don't care. They just don't realize that we do need the information to schedule*

	anaesthesia. On the patient safety side that's one thing that remains quite complicated to organize due to working in different places and not having a place where you can have a proper pre-operative consultation." P20
10b. Informed Consent	*"And I think the quality of the inform consensus is of course an issue…when people get informed, how many times they are informed, if they have time to rethink it, you know, and how it is done and if it has the, if it has a quality issue." P12*
11. Resource Planning	*The other thing in patient safety that's very specific about office-based is that when you are in a private practice is you need to think ahead where we don't see for your monitoring. If you have a main monitor and it breaks down during the operation you need a plan B. When you are in a hospital you just go to the next theatre room, pick their back-up monitor and you are laughing. When you are doing office-based anaesthesia you basically bringing all the gear every day to this place…we always work as a team with a fully qualified FMH anesthetics as a doctor and fully qualified nurse. This way should, I mean I'm being probably very paranoid but should the doctor collapse with his first epileptic fit well we've got a nurse that is fully qualified. I mean it has happened." P20* *"Yes, obviously, because we lack of postoperative resources when it comes to management of complications, when it comes to monitoring of the patient. We leave them at home, having no control whether they are covered by people that can care for these patients or not." P19*
12. Standardised Safety	

Procedures	
12a. Checklists	*"…I mean maybe you are a bit quicker but anyway it doesn't take a lot of time and I think it might even be more important because if you are a small team everybody thinks he knows everything and using the checklist you would identify lack of knowledge in certain parts." P21*
12b. Critical Incident Reporting	*"So we have in hospital we have a critical incident reporting system but in outpatient doctor places, you hardly have anything from that point of view, so I think it would be nice to establish something like CIRS for outpatient treatments." P6*
13. Undeclared work	*"Yeah the other trouble is that some colleagues do that as sort of a, they do it once or twice … per month because they are working in a clinic or in a hospital and from time to time they go for a friend that's a dentist or a friend that's a surgeon and then they do anesthetics and they do just as pocket money and they don't declare it to their clinic because they are not supposed to work outside. They've got a contract with the hospital or the clinic that says they are not allowed to work outside. So there is quite a few places where there is probably I don't know, fifty, sixty, eighty patients per year that will never show anywhere because they are done sort of hush hush." P20* *"…forty five plastic surgeons mainly from Italy that do something, somewhere, sometime. Nobody knows in the canton government, who is doing what, how often, at what quality, in which infrastructure. Nobody is able to tell you and probably all this because the hospitals, they don't host these guys, probably it's done in some kind of an office and its surgery."*

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583 **Table 3. Outcome Related Issues**

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Category	Example Quote
14. Rate of complications	*"Well, there have to be. We know the studies from the U.S and the U.K and so there has to be a problem and office based surgery, in particular aesthetic surgery, is a very large market and I am sometimes really concerned about what kind of surgery is done in that setting without any proper anaesthesia staff, without any proper preparation for emergencies and so on… so I am sure we have a problem but I'm also sure we don't know exactly how large it is." P4*

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