Minimum volume standards for quality assurance in day surgery

Fundamentals and Systematic Review

Ludwig Boltzmann Institut
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List of abbreviations

AA..... Association of Anaesthetists
ACL..... anterior cruciate ligament
AE..... adverse event
ASC ..... ambulatory surgical centre
BADS ..... British Association for Day Surgery
BCTQ..... Boston Carpal Tunnel Syndrome Questionnaire
BMASGK..... Austrian Ministry for Labour, Social Affairs, Health, and Consumer Protection
BoE..... body of evidence
B-ZV..... Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene
CCO ..... Cancer Care Ontario
CI..... confidence interval
COI..... conflict of interests
CRD ..... Center for Reviews and Dissemination
CTR..... carpal tunnel release
CTS ..... carpal tunnel syndrome
DARE..... Database of Abstracts of Reviews of Effects
DKG..... Deutsche Krankenhausgesellschaft
DVT..... deep vein thrombosis
EBM ..... Einheitlicher Bewertungsmaßstab
ED ..... emergency department
G-BA..... Federal Joint Comitee
GKV..... Gesetzliche Krankenversicherung-Spitzenverband
GÖG GmbH..... Gesundheit Österreich GmbH
GQG ..... Gesundheitsqualitätsgesetz
G-ZG ..... Gesundheits-Zielsteuerungsgesetz
HA..... hip arthroscopy
HOPD ..... hospital outpatient department
HSM..... highly specialised medicine
HTA ..... health technology assessment
IAAS..... International Association for Ambulatory Surgery
IOL..... intraocular cataract lenses
IQWiG..... Institut für Qualität und Wirtschaftlichkeit im Gesundheits-system (Institute for Quality and Efficiency in Health Care)
IGZ .....Inspectie voor de Gezondheidszorg ((Dutch Healthcare Inspectorate)
ISPOR.....International Society for Pharmacoeconomics and Outcomes Research
IVHSM .....Inter-cantonal agreement for highly specialized medicine)
KBV .....Kassenärztliche Bundesvereinigung
KH .....Krankenhaus
KV.....Kassenärztliche Vereinigung (regional Association of Social Health Insurance Physicians)
LCA .....Ligamentum cruciatum anterius
LOS.....length of stay
MEB.....Mengen-Ergebnis-Beziehung
Men.....Meniscectomy
MI .....myocardial infarction
MM .....Mindestmengen
Mos .....months
MRI.....magnetic resonance imaging
MVSs .....minimum volume standards
NA.....not available
NEI .....National Eye Institute
NHA .....National Health Service (England)
NHS-EED .....NHS Economic Evaluation Database
NIAMS .....National Institute for Arthritis and Musculoskeletal and Skin Diseases
NICE .....National Institute for Health and Care Excellence
NIH.....National Institutes of Health (USA)
NVvH.....Nederlandse Vereniging voor Heelkunde (Dutch Assoc. of Surgeons)
NSAIDs .....nonsteroidal anti-inflammatory drugs
OP .....Operation
ÖGARI.....Österreichische Gesellschaft für Anästhesiologie Reanimation und Intensivmedizin
ÖSG .....Österreichischer Strukturplan Gesundheit (Austrian structural plan health)

PCR ..... Post Cataract Endophthalmitis
PCR ..... posterior capsule rupture
QS ..... Qualitätssicherung/ Qualitätsstandard
PDT ..... photodynamic therapy
PE ..... pulmonary embolism
PREM ..... patient-reported experience measures
PRIKRAF ..... Privatkrankenanstalten-finanzeriungsfonds (Private hospital financing fund)
PRISMA ..... Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROM ..... patient-reported outcome measures
Pts ..... patients
PTK ..... phototherapeutic keratectomy
RARR ..... risk-adjsuted relative risk
RLN ..... recurrent laryngeal nerve
RM ..... Rotatorenmanschette
RR ..... relative risk
QS ..... quality standards
SAE ..... serious adverse events
SONOS ..... Stichting Oncologische Samenwerking (Dutch foundation for oncologic cooperation)
SDS ..... same day surgery
SDT ..... same-day thyroidectomy
TE ..... total endophthalmitis
THA ..... total hip arthroplasty
TT ..... Thyroidectomy
VAS ..... visual analogue scale
VL ..... vitreous loss
VOR ..... volume-outcome relationship
ZS-G ..... Zielsteuerungsvertrag-Gesundheit

Executive Summary

Background

MVSs thresholds as a quality assurance mechanism

The challenge of providing comprehensive health care of high quality that is available to all is shared by universal coverage health care systems of today [1]. One of the quality assurance mechanisms is minimum volume standards (MVSs). While the majority of research observes a positive association in terms of statistical correlation between volume and outcome and infers a causal inverse link between the two, data on specific MVS thresholds are scarce. Up to recently, they have been all primarily concerned with complex and high-risk surgeries mainly conducted in the inpatient setting.

gradual shift from inpatient setting to day surgery

Currently in Austria, inpatient services including day surgeries are gradually shifting to the ambulatory setting and so MVSs in the ambulatory surgical setting may constitute a supplement to commonly applied and currently developed quality standards. Analysing the role of MVSs in day surgery is the aim of this report.

Methods

aim: investigate if MVSs bring about better outcomes in day surgery, EUnetHTA Core Model® used

The present systematic review aimed to investigate whether minimum volume standards in comparison to no minimum volume standards in the day surgery setting lead to better efficacy and safety outcomes. Assessment elements from the EUnetHTA Core Model® for screening technologies 3.0 were customised so that they could be used for the purposes of this assessment.

systematic search in five databases, articles in English and German, total 595 hits

The systematic literature search was conducted in the following five databases (Medline via Ovid, Embase, The Cochrane Library, CRD (DARE, NHS-EED, HTA), and Livivo). The search was limited to years 2000 to 2019 and to articles published in English or German. After deduplication, overall 538 citations were found via systematic search and additional 57 via hand search – resulting in the total of 595 hits.

search for the MVSs chapter in 3 databases plus hand search

The exploratory literature search for the section on minimum volume standards was carried out in Google, Google Scholar, and PubMed. Then, a hand search in websites of governmental and public bodies, expert societies, and other health care stakeholders was carried out.

Day surgery setting

international definitions of day surgery

The International Association for Ambulatory Surgery defines *day surgery* as a practice where patients are admitted, operated on, and discharged during the time frame of one working day (six to eight hours), with no overnight stay [2]. The EU observatory as well as the British Association for Day Surgery further add that "true" day surgery includes planned non-emergency surgical procedures on carefully-selected and prepared patients that are intended to be treated in the day surgery setting [3, 4].

Austrian definition of day surgery and the challenge of the Austrian fragmented health care system

The present definition from the Austrian Target-Based Governance (Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene – B-ZV) states that day surgery refers to the hospital care for patients who receive an intervention from the catalogue of daily reimbursed interventions (according to the Austrian DRG System – LKF model) and are admitted and discharged on the same day [5]. However, because the Austrian health care system is complex and fragmented, day surgery is regulated differently depending on the setting and the corresponding legal authority responsible for the premises where it takes place.

Minimum volume standards

Understanding the volume-outcome relationship

practice makes perfect as the intuitive approach where quantity leads to quality

On the one hand, *practice makes perfect* seems the most intuitive approach explaining the volume-outcome relationship (VOR). The purported hypothesis presumes that physicians, non-physician staff, or hospitals improve their (surgical) capabilities and outcomes with increasing volume of patients through a learning effect [6]. The expected causality here is clear: quantity affects quality.

selective referral as a competing approach that assumes that quality draws quantity (inverse causality)

On the other hand, another approach explaining the link between volume and outcome is called *selective referral*. This purported hypothesis assumes that high-quality service providers are more likely to accumulate a large proportion of overall conducted services because patients are more likely to seek these providers in the first place [7]. Hence, volume depends on outcome or the provider's (initial) quality. Both hypotheses seem to be valid in the empirical literature [8].

Description of MVSs and current use

MVSs in place as a quality assurance measure

Besides further quality standards, stakeholders in the health care sector have promoted the implementation of a (regulatory) MVSs framework. The goal of MVSs is to assure that surgeons or hospitals that comply with the minimum volume of surgeries provide a certain level of quality [9]. A possible consequence of not complying with these minimum requirements – but mostly rarely enforced – is that surgeries are not reimbursed anymore [10].

MVSs in place internationally for inpatient services, MVSs in place for day surgery only in Germany

Various countries have already implemented MVSs in hospitals for selected complex and high-risk surgeries for quality and safety reasons. Among the countries that provide a MVSs framework in the inpatient setting are Germany, Canada, the Netherlands, Switzerland and Austria [10]. According to the identified literature, the hand and exploratory search, no country, except for Germany seems to have specific threshold values for day or ambulatory surgery in force [11, 12].

no universal methods on establishing MVSs, regression models used – yet with challenges

The literature on the VOR, however, provides no universally solid method to specify administrative MVS thresholds [13, 14]. Generally, modelling approaches on the basis of regression models seem to be most appropriate, but the choice of the appropriate model depends on the specific problem and the available data [15, 16]. Most of the studies implementing regression models neglect methodical issues associated with the calculation of thresholds that consequently affect the reliability of the thresholds as discussed above [13, 17].

MVSs claim to improve quality aspects via structural quality that purports to increase quality of outcome

MVSs claim to improve economic aspects via production efficiency and cost reduction

In terms of the mechanism of action, MVSs claim to improve both quality aspects as well as economic aspects. In the context of the Donabedian model, MVSs target the structural quality and are seen as an intermediate step to increase quality of outcome [18]. It is expected that implementation of MVSs improves the level of training and the abilities of the surgical personnel as well as the management abilities of care units. However, patient-related factors and process related factors such as overall preoperative preparation, anaesthetic management, postoperative recovery and discharge, or follow-up are other factors not influenced by MVSs that are equally relevant for successful and high-quality day surgeries [19, 20]. In terms of economic aspects, MVSs are, in theory, expected to increase production efficiency through a learning effect and reduce costs via economies of scale.

Results

Available evidence

For the assessment of clinical effectiveness, eight studies met the inclusion criteria and reported seven different interventions. The interventions at stake in the current assessment were not predefine, but were selected based upon the systematic literature search. The indications are thyroid surgery (thyroidectomy), cataract surgery, primary hip arthroscopy, open carpal tunnel release, rotator cuff repair, anterior cruciate ligament reconstruction, and meniscectomy. One of the studies had a control group [21], however, none of the studies was done prospectively – all the studies were retrospective. While two studies were single centre analyses [21, 22], the remaining six studies were analyses of health care databases [23-28]. Seven studies were conducted in the US [21-26, 28] and the eighth study was conducted in the Netherlands [27]. Information about study sponsors was not disclosed in five studies [21-23, 25, 26], two studies were funded by the National Institutes of Health/National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIH/NIAMS) [27, 28], and one study was funded by the National Eye Institute (NEI) [24].

8 studies included in the analysis, 7 different interventions

all studies were retrospective

7 studies conducted in the US, one in the Netherlands

3 studies sponsored

All the studies gathered data on the outpatient setting and while four studies analysed the VOR from the perspective of surgeons [22, 24, 27, 28], one analysed it from the hospital perspective [23], and three from the perspectives of both surgeons as well as hospitals [21, 25, 26]. Follow-up time was not reported in five studies [21, 22, 24-26], it was ten years in [28], six months in [27], and 30 days in [23]. In terms of patient population, **primary hip arthroscopy** included 7,836 patients [28], **carpal tunnel release** included 1,345 patients [27], **rotator cuff repair** included 9,973 patients [25], **anterior cruciate ligament (ACL) reconstruction** included 45,262 patients [23, 26], **meniscectomy** included 123,012 patients [26], **thyroidectomy** included 109 outpatient patients [21], and **cataract surgery** included 2,289,307 patients [22]. Surgeon as well as hospital volume was categorised into low, medium, and high (very high in one study [28]) and the thresholds differed with interventions.

VOR analysed from surgeon/hospital perspectives, follow-up not reported in 5 studies

large patient sample included in all the studies – except for thyroidectomy

Clinical effectiveness

Concerning **thyroidectomy**, there was no VOR observed, but it was suggested that **thyroidectomy** is safe also in low volume centers as in the only low volume center, no cases of readmission occurred [21].

no VOR observed in thyroidectomy

Concerning **cataract surgery**, the number of cases per surgeon was inversely correlated with the adverse event of posterior capsule rupture (PCR) where PCR and vitreous loss rate were 3.75% for low volume and 0.29% for very high volume surgeons [22]. The difference in relative risk for endophtalmitis was 4-fold between low and very high volume surgeons [24].

VOR observed in cataract surgery

Concerning **hip arthroscopy**, the survival rates for very high volume surgeons were 11.1-24.9% higher than for low volume and the hazard ratio for reoperation (with reference value of low volume) was 0.17 for very high volume surgeons [28].

VOR observed in hip arthroscopy

Concerning **open carpal tunnel release**, BCTQ score did not vary with volume at all while the difference on the VAS scale was 1 point (out of 100) between low and high volume surgeons (18 vs. 19 points) [27]. Such difference is below the threshold of the minimal clinically important difference [29].

no VOR observed in open carpal tunnel release

Concerning **rotator cuff repair**, patients of low volume surgeons were 2.8 time more likely to have non-routine disposition at discharge, while low volume hospitals were 2.1 times more likely to discharge patients with non-routine

VOR observed in rotator cuff repair

dispositions. Surgeon-related mean operating time was 10 minutes shorter and hospital-related mean operating time was 6 minutes shorter for high volume compared to low volume surgeons/hospitals. The length of stay (LOS) was 2.3 times longer for low volume surgeons and 0.5 times for low volume hospitals compared to high volume surgeons/hospitals [25].

VOR observed in ACL reconstruction

Concerning **anterior cruciate ligament (ACL) reconstruction**, the odds ratio for hospital based acute care within 30 days (with reference of low volume hospitals) was 0.47 for high volume hospitals [23]. Low volume surgeons were 4.5 times more likely and low volume hospital 3.33 times more likely to have non-routinely discharged patients compared to high volume surgeons [26]. Furthermore, low volume surgeons had a 27 minutes longer and low volume hospitals 21 minutes longer mean operating time than high volume surgeons/hospitals [26].

VOR observed in meniscectomy

Concerning **meniscectomy**, low volume surgeons were 2.8 times and low volume hospitals were 8 times more likely to have non-routinely disposed patients at discharge than high volume surgeons/hospitals [26]. In terms of mean operating time, both low volume surgeons and low volume hospitals had a longer mean operating time by 19 minutes compared to high volume surgeons/hospitals [26].

Safety

no VOR data on safety

The only safety related data reported were without its relationship to surgeon/hospital volume. In the **hip arthroscopy** study, 0.2% of patients experienced procedural complication at 30 days post intervention [28]. In the **carpal tunnel release** study, 1.6% of patients experienced procedural complications [27], and in the **thyroidectomy** study [21], 19 of the 160 patients experienced complications.

Discussion

ISPOR checklist for quality assessment used

all studies included were of very low quality

The quality assessment of individual studies was done using the ISPOR Task Force Checklist for Quality Assessment of Retrospective Database Studies [30]. Concerning effectiveness and safety of MVSs, the quality of the evidence base is very low. The main reasons are the retrospective design of all the studies [21-28], the lack of justification for its use [21, 22, 25-27], or the lack of a priori data analysis plan [21-28]. Further reasons include unclear eligibility criteria [21-23, 27, 28], lack of justification for the statistical models used [21-23, 25-28], lack of interpretation of the statistical findings in terms of their clinical or economical evidence [22, 23, 25-28], and limited recognition of the generalisability of the retrospective study design [21, 22, 25-27].

gaps in evidence – no prospective controlled data found, partly applicable conclusions due to similar setting to inpatient and high number of patients included

generalisability questionable

Due to these gaps in evidence, the relevance of the current evidence base to relative effectiveness assessment of MVSs is questionable. Retrospective database analyses do not fulfil the evidence-based medicine standards as they are prone to a spectrum of biases. For that reason, their conclusions are applicable only in part. In their favour plays the relatively robust body of evidence from the inpatient setting, relatively high number of patients included in the day surgery studies, and studies supporting no significant difference in outcomes between the settings [3]. Against it plays the poor internal and external validity of the present evidence base and the critical considerations related to MVSs in general. Generalisability of the data is put in question because all the studies (except for [27]) were conducted in the USA where the definition of day surgery and outpatient surgery may vary [20].

When conducting volume-outcome analysis, one has to be cautious not to fall in a mono-causal or reverse causality trap when establishing links between two or more variables. An observed correlation does not necessarily indicate causation. Against this backdrop, it is important to synthesise the various approaches to emphasise the complexity of the VOR and its derived policies. The two approaches – *practice makes perfect* and *selective-referral* – imply significantly different policy choices [8]. While the *practice makes perfect* hypothesis gives reasonable arguments to implement a (regulatory) framework in the form of MVSs, the *selective referral* approach would indirectly appeal to healthcare research to understand why phenomena such as centralisation of services in form of volume accumulation of a few hospitals came up in the first place.

VOR can be plausibly explained via *practice makes perfect* as well as *selective referral* hypotheses, hence caution required when applying MVSs

In terms of limitations of the present systematic review, we only found VOR data on eight interventions, which, however, is not a representative sample of all the interventions eligible for day surgery. Furthermore, the following studies on arthroscopy, meniscal repair, and colonoscopy [31-33] were excluded from the analysis even though they met the inclusion criteria. The reason was that they were found in an additional search in the end stage of the report when including them was no longer feasible. Additional reason for not including them was their assumed low marginal utility as quality of all studies was low due to their retrospectives study design.

SR limitations include: small sample of studies and excluded evidence that was potentially relevant

Conclusion

The need for a shift of surgical interventions from the inpatient setting to the day surgery setting is advocated in the international literature. Because the VOR does have some standing in the inpatient setting, the role of MVSs applied to the day surgery setting was scrutinised in this report. Besides the theory of MVSs, we aimed to provide the data on international variations and current use of MVSs with a particular focus on the German context. There is no consensus behind the theory of MVSs, and also the results from our systematic review cannot offer any clear-cut MVS thresholds. This present report, however, provides some evidence in favour of VOR, even though it based on low quality retrospective data-analyses. The low quality of the retrospective evidence found does not establish the clear presence of the VOR nor any clear MVSs. Two out of eight studies did not suggest a VOR at all. For these reasons, we argue that the application of MVSs should be well thought out. Moreover, because establishing the VOR and henceforth the MVSs is possible, quality prospective controlled evidence for the day surgery setting is required. Also, other quality assurance standards such as standards focusing on process and outcome quality should be taken into account.

theory on MVSs and day surgery provided

MVSs set in the international context – particular focus on Germany

some evidence in favour of VOR in day surgery, no data on clear MVSs thresholds

other quality assurance criteria to be considered

Zusammenfassung

Hintergrund

Mindestmengen als eine Qualitätssicherungsmaßnahme

Der Herausforderung, eine umfassende und qualitativ hochwertige Gesundheitsversorgung anzubieten, die in gleicher Weise für alle zugänglich ist, müssen sich die heutigen flächendeckenden Gesundheitssysteme gleichermaßen stellen [1]. Eine mögliche Maßnahme zur Qualitätssicherung stellen dabei Mindestmengen (MM) dar. Während der Großteil der Forschung einen positiven Zusammenhang in Form von statistischer Korrelation zwischen Leistungsmenge und Ergebnis beobachten kann und einen kausalen inversen Zusammenhang zwischen beiden ableitet, ist die Verfügbarkeit von Daten über spezifische und evidenzbasierte MM-Schwellenwerte gering. Bislang lag der Fokus der Forschung im Kontext von MM auf komplexen und risikoreichen Operationen, die überwiegend im stationären Bereich durchgeführt werden.

schrittweise Verlagerung von stationären Leistungen einschließlich der Tageschirurgie in den ambulanten Bereich

In Österreich ist derzeit eine schrittweise Verlagerung von stationären Leistungen einschließlich der Tageschirurgie in den ambulanten Bereich, zu beobachten. MM im ambulanten Bereich für tageschirurgische Eingriffe können möglicherweise eine Ergänzung zu den allgemein angewandten und aktuell entwickelten Qualitätsstandards darstellen. Der vorliegende Bericht hat das Ziel einer kritischen Analyse von MM in der Tageschirurgie.

Methoden

Ziel: Untersuchung, ob MM zu besseren Ergebnissen in der Tageschirurgie führen mit Hilfe des EUnetHTA-Core Model®

Die vorliegende systematische Übersichtsarbeit zielte darauf ab, zu untersuchen, ob MM im Vergleich zu keinen MM in der Tageschirurgie zu besseren Ergebnissen hinsichtlich der Wirksamkeit und Sicherheit führen. Im Zuge der Analyse wurden Bewertungselemente aus dem EUnetHTA-Core Model® für Screening-Technologien 3.0 dahingehend adaptiert, dass sie für die Zwecke dieser Bewertung verwendet werden können.

systematische Suche in 5 Datenbanken, Artikel auf Englisch und Deutsch, insgesamt 595 Treffer

Die systematische Literaturrecherche wurde in folgenden fünf Datenbanken durchgeführt: Medline via Ovid, Embase, The Cochrane Library, CRD (DARE, NHS-EED, HTA) und Livivo. Der Untersuchungszeitraum wurde auf die Jahre 2000 bis 2019 und auf Artikel in englischer oder deutscher Sprache beschränkt. Nach der Deduplizierung wurden insgesamt 538 Zitate über die systematische Suche und weitere 57 über die manuelle Suche gefunden – insgesamt 595 Treffer.

Suche für den Abschnitt über MM in 3 Datenbanken plus Handsuche

Die explorative Literaturrecherche für die Abschnitte über die MM und über die Mengen-Ergebnis-Beziehung (MEB) wurde in Google, Google Scholar und PubMed durchgeführt. Anschließend wurde eine Handsuche auf Webseiten von behördlichen, staatlichen und öffentlichen Einrichtungen, Fachgesellschaften und anderen Interessengruppen und AkteurInnen im Gesundheitswesen durchgeführt – mit Beschränkung auf Informationen auf Deutsch und Englisch.

Tageschirurgie (ambulantes Operieren)

internationale Definitionen der Tageschirurgie

Die internationale Vereinigung für ambulantes Operieren (International Association of Ambulatory Surgery – IAAS) definiert Tageschirurgie als eine Praxis, in der PatientInnen innerhalb eines Werktages (sechs bis acht Stunden) ohne Übernachtung aufgenommen, operiert und entlassen werden [2]. Das EU-Observatory sowie die British Association for Day Surgery (BADS)

fügen hinzu, dass die „echte“ Tageschirurgie geplante chirurgische Eingriffe an sorgfältig ausgewählten und vorbereiteten PatientInnen umfasst – d. h. keine Notfälle [3, 4].

Österreichische Definition der Tageschirurgie und das fragmentierte österreichische Gesundheitssystems

Die Definition von Tageschirurgie (Tagesklinik) im aktuellen Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene (B-ZV) besagt, dass sich die Tageschirurgie (Tagesklinik) auf PatientenInnen im Krankenhauskontext bezieht, die eine Intervention gemäß dem österreichischen DRG-System bzw. LKF-Modell erhalten, am selben Tag aufgenommen und entlassen werden [5]. Aufgrund der Komplexität und Fragmentierung des österreichischen Gesundheitssystems sind tageschirurgische Leistungen inklusive ambulanter Operationen, je nach Setting und je nachdem wie die rechtlichen Befugnisse bzw. Zuständigkeiten sind, unterschiedlich geregelt.

Gründe für eine Verlagerung von chirurgischen Leistungen sind vielfältig

mögliche Zielvorstellungen

Die Gründe für eine Verlagerung von stationären operativen Leistungen in den tageschirurgischen bzw. ambulanten Bereich sind vielfältig und können organisatorische, ethische, wirtschaftliche und medizinische Gründe umfassen. Mögliche Zielvorstellungen sind ebenfalls vielfältig. Beispielsweise wird durch eine Verschiebung versucht, Versorgungspfade zu verbessern bei gleichzeitiger Gewährleistung der Verteilungsgerechtigkeit und der Sicherstellung eines wirtschaftlichen Umgangs mit Ressourcen. Tageschirurgische Leistungen ermöglichen es den PatientInnen, ihre Umgebung für die Genesung selbst zu wählen. Zusätzlich ist die Tageschirurgie möglicherweise mit kürzeren Wartezeiten und einem möglichen geringeren Ausfallsrisiko seitens der PatientInnen verbunden [20]. Des Weiteren wird beansprucht, dass die Rate der im Krankenhaus erworbenen Infektionen (nosokomiale Infektionen) und venösen Thromboembolien reduziert werden kann [20]. Darüber hinaus scheint ein Übergang zur Tageschirurgie zu einer potentiellen Win-Win-Situation für alle Beteiligten zu führen [20]. Der Wegfall von Übernachtungs- und Wochenendaufenthalten kann sowohl für die PatientInnen als auch für das Behandlungsteam von Vorteil sein, da es über diese Zeiträume nicht am Behandlungsort bleiben muss.

Mindestmengen

Die Mengen-Ergebnis-Beziehung

***Übung machten den Meister* als intuitiver Erklärungsansatz: Quantität führt zu Qualität**

Auf der einen Seite scheint die Erklärung Übung macht den Meister (Practice makes perfect) der intuitivste Ansatz zu sein, um einen Zusammenhang zwischen Leistungsmengen und Ergebnis, kurz Mengen-Ergebnis-Beziehung (MEB), zu erklären. Bei der Hypothese wird davon ausgegangen, dass durch eine zunehmende Leistungsmenge und damit assoziierten Lerneffekten ÄrztInnen, nichtärztliches Personal oder Krankenhäuser ihre (chirurgischen) Fähigkeiten und Ergebnisse verbessern [6]. Der erwartete Wirkungsmechanismus (Kausalität) bei dieser Hypothese liegt auf der Hand: Quantität beeinflusst Qualität.

***Selektive Überweisung* als konkurrierender Erklärungsansatz: Qualität „lockt“ Quantität (umgekehrte Kausalität)**

Auf der anderen Seite gibt es einen weiteren Erklärungsansatz, der den Zusammenhang zwischen Leistungsvolumen und Ergebnis herstellt: selektive Überweisung bzw. Selective referral. Diese Hypothese geht davon aus, dass qualitativ hochwertige Leistungserbringer eine höhere Leistungsmenge bzw. Fallzahl akkumulieren, da die PatientInnen eher qualitativ hochwertige Leistungserbringer aufsuchen [7]. Die erbrachte Leistungsmenge bzw. die Fallzahl hängt also vom Ergebnis oder der (Erst-)Qualität des Leistungsanbieters ab. Beide Hypothesen scheinen in der empirischen Literatur gültig zu sein [8].

Mindestmengen und derzeitige Anwendung

MM als Qualitätssicherungsmaßnahme

Neben weiteren Qualitätsstandards fordern und fördern AkteurInnen im Gesundheitswesen die Umsetzung eines (regulatorischen) MM-Rahmens. Erklärtes Ziel von MM ist es sicherzustellen, dass ChirurgInnen oder Krankenhäuser, die die MM an chirurgischen Eingriffen erfüllen, ein gewisses (besseres) Qualitätsniveau erreichen [9]. Eine mögliche Konsequenz bei Nichteinhaltung dieser Mindestanforderungen – jedoch meist selten durchgesetzt – ist, dass die spezifischen Operationen nicht mehr erstattet werden [10]

International: MM für stationäre Leistungen, MM für tageschirurgische nur in Deutschland vorhanden

Verschiedene Länder haben bereits MM für ausgewählte komplexe und risikoreiche Operationen im Krankenhauskontext aus Qualitäts- und Sicherheitsgründen implementiert. Zu den Ländern, die einen MM-Rahmen im stationären Bereich anbieten, gehören Deutschland, Kanada, die Niederlande, die Schweiz und Österreich [10]. Auf Basis der identifizierten Literatur, der Handsuche und explorativen Suche scheint kein Land, außer Deutschland, spezifische Schwellenwerte für tageschirurgische Leistungen bzw. ambulante Operationen in Kraft zu haben [11, 12].

keine universellen Methoden zur Festlegung von MM, Regressionsmodelle werden herangezogen – jedoch mit Herausforderungen

Die Literatur zur MEB bietet jedoch keine universelle solide Methode zur Festlegung administrativer MM [13, 14]. Im Allgemeinen erscheinen Modellierungsansätze auf der Grundlage von Regressionsmodellen am besten geeignet zu sein. Allerdings hängt die Wahl des geeigneten Modells vom spezifischen Problem und der verfügbaren Datenlage ab [15, 16]. Die meisten der Studien, die Regressionsmodelle verwenden, vernachlässigen methodische Fragen im Zusammenhang mit der Berechnung von Schwellenwerten. Diese Limitationen wirken sich auf die Zuverlässigkeit der Schwellenwerte aus [13, 17].

nur ein qualitativ hochwertiger Evidenzkörper sollte für eine Festlegung administrativer MM herangezogen werden

Grundsätzlich sollte nur ein qualitativ hochwertiger Evidenzkörper (prospektive und kontrollierte Studien), der einen robusten Zusammenhang zwischen Leistungsvolumen und Ergebnis bzw. Endpunkt herstellt, herangezogen werden, um administrative MM als Qualitätsstandard zu implementieren. Unter einem robusten Zusammenhang von Leistungsvolumen und Ergebnis wird ein Zusammenhang verstanden, der eine hohe klinische Relevanz aufweist, der plausibel, logisch, auf der Grundlage strenger statistischer Kriterien durch eine Reihe von Studien, die einen konsistenten statistischen Zusammenhang eindeutig belegen, verifiziert wurde. Diese Definition steht im Einklang mit den neun Bradford-Hill-Kriterien, die bei der Herleitung potenzieller kausaler Zusammenhänge herangezogen werden und auch vom National Cancer Policy Board in den USA verwendet werden [7, 34].

MM und die Ergebnisqualität: Einfluss über die strukturelle Qualitätsdimension

MM und ökonomische Aspekte: Produktionseffizienz und Kostensenkung

Zentralisierungseffekte und Exzellenzzentren

Im Hinblick auf den Wirkungsmechanismus haben MM den Anspruch, Ergebnisse hinsichtlich qualitativer als auch wirtschaftlicher Aspekte zu verbessern. Im Kontext des Qualitätsmodells nach Donadebian können MM in die strukturelle Qualitätsdimension eingeordnet werden. MM werden dabei als ein Zwischenschritt zur Steigerung der Ergebnisqualität angesehen [18]. Die erwarteten Effekte von MM umfassen einen höheren Ausbildungsgrad, eine Verbesserung der Fähigkeiten des chirurgischen Personals sowie eine Steigerung der Managementfähigkeiten von Krankenhäusern und Pflegeeinrichtungen. PatientInnen- und prozessbezogene Faktoren – wie die gesamte präoperative Vorbereitung, das Anästhesiemanagement, die postoperative Genesung und die Entlassung bzw. die Nachsorge – sind jedoch weitere Faktoren, die zwar nicht von MM beeinflusst werden, aber für eine erfolgreiche und qualitativ hochwertige Durchführung von tageschirurgischen Leistungen gleichermaßen relevant sind [19, 20]. Die erwarteten ökonomischen Aspekte von MM betreffen die Steigerung der Produktionseffizienz durch einen Lern-

effekt und eine Kostenreduktion durch Skaleneffekte, welches beiderseits zu niedrigeren langfristigen Kosten führen kann und mit Leistungszentralisierungen bzw. mit Bildungen von Exzellenzzentren verbunden ist.

Leistungszentralisierung hat Einfluss auf die Verteilungsgerechtigkeit

Auf einer aggregierten (sozialen) Wohlfahrtsebene kann ein möglicher durch MM induzierter Zentralisierungseffekt chirurgischer Leistungen jedoch nur dann von Nutzen und nachhaltig sein, wenn sich die Ergebnisse für PatientInnen in der gesamten Bevölkerung verbessern bzw. zumindest für niemanden verschlechtern. Ein kritischer Aspekt bei Leistungszentralisierungen aufgrund von MM betrifft eine mögliche Verschlechterung der Versorgungsqualität (Verfügbarkeit bzw. Zuverlässigkeit). Zentralisierungen könnten die Ungleichheiten beim Zugang zu hochwertiger Versorgung, in Form von größeren Entfernungen zur nächsten Versorgungseinrichtung, vergrößern. Dies scheint besonders für vulnerable Gruppen, wie Menschen mit sozioökonomischen Benachteiligungen oder älteren Menschen, wichtig zu sein. Diese Personengruppen erfahren nicht nur in Bezug auf die Entfernung einen eingeschränkten Zugang zur Gesundheitsversorgung. Darüber hinaus könnte die Zentralisierung die eigenständige Wahl der PatientInnen beeinträchtigen, da sie in diesem Fall kaum oder gar keine Wahlmöglichkeiten zwischen verschiedenen Gesundheitseinrichtungen haben.

Organisatorische Aspekte und Implikationen im österreichischen Kontext

Grundprinzipien bei der Umsetzung von Qualitätsstandards sind von zentraler Bedeutung

Die Festlegung von Grundprinzipien zur Stärkung der Umsetzung von Qualitätsnormen ist von zentraler Bedeutung [35, 36]. International gibt es etablierte Programme zur Bestimmung von Qualitätsstandards, wie beispielsweise jene von Health Quality Ontario (HQO) und NICE [36, 37]. In Österreich hat die GÖG GmbH im Auftrag des Bundesministeriums für Arbeit, Soziales, Gesundheit und Konsumentenschutz (BMASGK) kürzlich eine aktualisierte Version ihres methodischen Handbuchs zur Erstellung von Qualitätsstandards auf der Grundlage der genannten Prozessleitfäden von NICE und HQO veröffentlicht [38]. Das Handbuch schlägt ein dreistufiges Verfahren zur Entwicklung von Qualitätsstandards vor: Festlegung der Kernelemente des jeweiligen Standards, Erstellung der Qualitätsstandards sowie politische und organisatorische Umsetzung einer Qualitätsnorm. Nach Abschluss der Qualitätsstandards müssen auch noch einige nachgelagerte Prozesse wie Monitoring berücksichtigt werden.

Regelung der Tageschirurgie in Deutschland – ambulantes Operieren

in Deutschland existiert bereits ein einheitlicher Rahmen inklusive MM für das ambulante Operieren bzw. tageschirurgische Leistungen

In Deutschland kann mittlerweile ein breites Spektrum an chirurgischen Eingriffen ambulant bzw. auf tagesklinischer Basis auch von (Vertrags-)ÄrztInnen im niedergelassenen Bereich durchgeführt werden. Dazu gehören Arthroskopien, Kataraktoperationen, Biopsien und mehr. Darüber hinaus haben sich die gesetzliche Krankenversicherung (GKV), die Deutsche Krankenhausgesellschaft (DKG) und die Kassenärztliche Bundesvereinigung (KBV) vertraglich darauf geeinigt, die ambulante Chirurgie zu stärken und chirurgische Eingriffe im stationären Bereich zu ersetzen. Der so genannte AOP-Vertrag soll einen einheitlichen Rahmen für die Durchführung von ambulanten Operationen und stationsersetzenden Verfahren schaffen. Zusätzlich soll die Zusammenarbeit zwischen dem niedergelassenen Bereich und dem Krankenhaussektor unterstützt werden. Der Vertrag legt darüber hinaus fest, dass eine erfolgreiche Zulassung an Auflagen gebunden ist: So müssen für das Operieren im ambulanten Bereich – für spezifische tageschirurgische Eingriffe - Mindestanforderungen gemäß FachärztInnenstand erfüllt sein. Die chirurgischen Mindestvolumenanforderungen für die Erlaubnis zur Durch-

führung der spezifischen Operation und die Frequenzanforderungen (jährliche Mindestmengen) zur Fortsetzung der spezifischen Operation sind in entsprechenden Qualitätsvereinbarungen neben der Rahmenvereinbarung „Qualitätssicherungsmaßnahmen nach § 135 Abs. 2 SGB V für das ambulante Operieren“ festgelegt. Die drei Parteien (GKV, DKG und KBV) einigten sich auch auf eine entsprechende einheitliche Vergütung für Krankenhäuser und KBV-VertragsärztInnen. Alle für das ambulante Operieren relevanten tageschirurgischen Eingriffe sind im AOP-Katalog aufgeführt. Darüber hinaus gibt es regionale Verträge, die den Spielraum für Krankenkassen und die 17 Kassenärztlichen Vereinigungen erweitern sollen. Dazu gehören differenzierte Gebührensysteme, aber auch zusätzliche Mindestvolumen- und Frequenzanforderungen können Teil dieser Verträge sein.

Ergebnisse der systematischen Übersichtsarbeit

Verfügbare Evidenz

8 Studien wurden in die Analyse einbezogen, 7 verschiedene Interventionen

alle Studien waren retrospektiv

sieben Studien wurden in den USA durchgeführt, eine in den Niederlanden

drei Studien mit Finanzierung/Sponsoring

Zur Beurteilung der klinischen Wirksamkeit im vorliegenden Bericht erfüllten acht Studien mit sieben verschiedenen Interventionen die Einschlusskriterien. Die Interventionen wurden nicht vordefiniert, sondern auf Grundlage der systematischen Literaturrecherche identifiziert. Die Indikationen sind Schilddrüsenoperation (Thyreoidektomie), Kataraktoperation, primäre Hüftarthroskopie, offene Karpaltunnelspaltung, Reparatur der Rotatorenmanschette, Rekonstruktion des vorderen Kreuzbandes (LCA) und Meniskektomie. Eine der Studien beinhaltete eine Kontrollgruppe [21], jedoch wurde keine der Studien prospektiv durchgeführt – alle Studien waren retrospektiv. Während zwei Studien Single-Center-Studien waren [21, 22], handelte es sich bei den restlichen sechs Studien um Analysen mit (administrativen) Daten aus dem Gesundheitswesen [23-28]. Sieben Studien wurden in den USA durchgeführt [21-26, 28] und die achte Studie wurde in den Niederlanden durchgeführt [27]. Informationen über die Finanzierung der Studien wurden in fünf Studien nicht berichtet [21-26, 25, 26], zwei Studien wurden vom National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH/NIAMS) finanziert [27, 28], und eine Studie wurde vom National Eye Institute (NEI) finanziert [24].

MEB wurde aus der Sicht der ChirurgIn/des Krankenhauses analysiert, Follow-up wurde in fünf Studien nicht beschrieben

große Stichprobe in allen Studien - mit Ausnahme der Thyreoidektomie

Alle Studien sammelten Daten für den ambulanten Bereich. Während vier Studien die Mengen-Ergebnis-Beziehung (MEB) aus ChirurgInnensicht analysierten [22, 24, 27, 28], analysierte eine Studie die MEB aus Krankenhaussicht [23]. Drei Studien berücksichtigen sowohl die Leistungsmenge aus ChirurgInnensicht als auch die Leistungsmenge aus Krankenhaussicht [21, 25, 26]. In fünf Studien wurde die Länge des Follow-Ups nicht berichtet [21, 22, 24-26], in einer Studie betrug die Länge des Follow-Ups zehn Jahre [28], sechs Monate in [27] und 30 Tage in [23]. In Bezug auf die PatientInnenpopulation umfasste die primäre Hüftarthroskopie 7.836 PatientInnen [28], die offene Karpaltunnelspaltung 1.345 PatientInnen [27], die Reparatur der Rotatorenmanschette 9.973 PatientInnen [25], die LCA-Rekonstruktion 45.262 Patienten [23, 26], die Meniskusoperation 123.012 PatientInnen [26], die Schilddrüsenenoperation 109 PatientInnen [21] und die Kataraktoperation 2.289.307 PatientInnen [22]. Die Leistungsmenge der ChirurgInnen als auch das Krankenhausvolumen wurden in drei bzw. vier Kategorien eingeteilt (niedrige, mittlere und hohe bzw. in einer Studie sehr hohe Leistungsmenge [28]). Die Schwellenwerte bzw. Intervalle der Kategorien unterschieden sich bei allen Interventionen.

Klinische Wirksamkeit

keine MEB für Thyreoidektomie festgestellt

Bei der Schilddrüsenresektion wurde keine MEB beobachtet, aber es wurde darauf hingewiesen, dass eine Schilddrüsenresektion auch in Zentren mit geringem Leistungsvolumen sicher durchgeführt werden kann, da kein Fall von Wiederaufnahme auftrat [21].

MEB für Katarakt-OP beobachtet

Bei der Kataraktoperation war die Leistungsmenge pro ChirurgIn negativ mit dem Auftreten einer Ruptur der hinteren Linsenkapsel (PCR) korreliert. Die Rate einer PCR bzw. Rate eines Glaskörperverlusts bei niedriger Leistungsmenge betrug 3,75% und 0,29% bei hoher Leistungsmenge [22]. Das relative Risiko einer Endophthalmitis war bei ChirurgInnen mit niedriger Leistungsmenge 4-fach höher als bei jenen mit hoher Leistungsmenge [24].

MEB für Hüftarthroskopie festgestellt

Bei der Hüftarthroskopie gestaltete sich die Überlebensrate der PatientInnen von ChirurgenInnen mit sehr hohen Leistungsmengen 11,1-24,9% höher als bei ChirurgInnen mit einer niedrigen Leistungsmenge. Der Risikoquotient (Hazard Ratio) für Reoperationen betrug 0,17 für sehr hohe Leistungsmengen (Referenzwert: niedrige Leistungsmengen) [28].

keine MEB für offene Karpaltunnelspaltung

Bei der offenen Karpaltunnelspaltung hatte die Leistungsmenge keinerlei Einfluss auf den BCTQ-Score. Der Unterschied auf der Visuellen Analogskala (VAS) belief sich auf einen Punkt (von 100) zwischen ChirurgInnen mit niedriger und hoher Leistungsmenge (18 vs. 19 Punkte) [27]. Diese Differenz liegt unter der Schwelle der minimalen klinisch wichtigen Differenz [29].

MEB bei der Reparatur der Rotatorenmanschette festgestellt

Bei der Reparatur der Rotatorenmanschette war die Wahrscheinlichkeit nicht routinemäßiger Dispositionen bei Entlassung für PatientInnen von ChirurgInnen mit niedrigem Leistungsvolumen 2,8-mal höher als von jenen mit hoher Leistungsmenge. Krankenhäuser mit niedrigem Leistungsvolumen entließen 2,1-mal wahrscheinlicher PatientInnen mit einer nicht routinemäßigen Disposition als jene mit hoher Leistungsmenge. Die durchschnittliche Operationszeit war bei ChirurgInnen mit hohen Leistungsmengen im Vergleich zu ChirurgInnen mit einem niedrigen Leistungsvolumen um 10 Minuten kürzer. Krankenhäuser mit hoher Leistungsmenge benötigten hinsichtlich der mittleren Operationszeit 6 Minuten weniger als jene mit niedrigem Volumen. Lost to Follow-Up war bei ChirurgInnen mit niedriger Leistungsmenge 2,3-mal länger und bei Krankenhäusern 0,5-mal länger als bei ChirurgenInnen/ Krankenhäusern mit hoher Leistungsmenge [25].

MEB bei LCA-Rekonstruktion beobachtet

Das Quotenverhältnis (Odds Ratio) zwischen Krankenhäusern mit hoher Leistungsmenge und jenen mit niedriger Leistungsmenge betrug bei der LCA-Rekonstruktion – für eine stationäre Akutversorgung innerhalb von 30 Tagen – 0,47. [23]. Nicht routinemäßig entlassene PatientInnen waren bei ChirurgInnen mit niedrigem Leistungsvolumen 4,5-mal wahrscheinlicher (bei Krankenhäusern mit niedrigem Volumen 3,33-mal wahrscheinlicher) als bei ChirurgInnen/Krankenhäusern mit hoher Leistungsmenge [26]. Darüber hinaus war die durchschnittliche Operationszeit von ChirurgInnen und Krankenhäusern mit niedriger Leistungsmenge um 27 Minuten bzw. 21 Minuten länger als die der ChirurgInnen/Krankenhäuser mit hoher Leistungsmenge [26].

MEB bei Meniskektomie festgestellt

In Bezug auf die Meniskektomie wiesen ChirurgInnen und Krankenhäuser mit niedriger Leistungsmenge eine um 2,8-fach bzw. 8-fach höhere Wahrscheinlichkeit auf, PatientInnen mit einer nicht routinemäßigen Disposition bei der Entlassung zu haben als Chirurgen/Krankenhäuser mit einer hohen Leistungsmenge [26]. In Bezug auf die mittlere Operationszeit hatten sowohl niedervolumige ChirurgInnen als auch niedervolumige Krankenhäuser eine um 19 Minuten längere mittlere Operationszeit als hochvolumige Chirurgen/Krankenhäuser [26].

Sicherheit

keine Daten zur MEB hinsichtlich der Sicherheit

Die berichteten Daten hinsichtlich der Sicherheit wurden nicht mit der Leistungsmenge der ChirurgIn/Krankenhauses in Bezug gesetzt und analysiert. In der Studie zur Hüftarthroskopie erlebten 0,2% der PatientInnen 30 Tage nach der Operation eine verfahrensbezogene Komplikation [28]. In der Studie zur Karpaltunnelspaltung erlitten 1,6% der PatientInnen prozedurbezogene Komplikationen [27] und in der Studie zur Schilddrüsenresektion [21] wiesen 19 der 160 Patienten Komplikationen auf.

Diskussion

Qualitätsbewertung wurde anhand der ISPOR-Checkliste durchgeführt

Die Qualitätsbewertung der einzelnen Studien erfolgte anhand der ISPOR Task Force Checkliste für die Qualitätsbewertung von retrospektiven Datenbank-Studien [30]. Hinsichtlich der Wirksamkeit und Sicherheit von MM ist die Qualität der Evidenzbasis sehr gering. Die Hauptgründe dafür sind das retrospektive Design aller Studien [21-28], die fehlende Rechtfertigung für die Verwendung dieses Studiendesigns [21, 22, 25-27] und der fehlende a priori festgelegte Plan der Datenauswertung [21-28]. Weitere Gründe sind unklare Auswahl- bzw. Zulassungskriterien [21-23, 27, 28], fehlende Rechtfertigung für die verwendeten statistischen Modelle [21-23, 25-28], mangelnde Interpretation der statistischen Ergebnisse in Bezug auf ihre klinische oder ökonomische Evidenz [22, 23, 25-28] und begrenzte Generalisierbarkeit des retrospektiven Studiendesigns [21, 22, 25-27].

alle eingeschlossenen Studien waren von sehr geringer Qualität

Evidenzlücken – keine prospektiv kontrollierten Daten gefunden, teilweise anwendbare Schlussfolgerungen

Aufgrund dieser Evidenzlücken ist die Relevanz der aktuellen Evidenzbasis für die relative Wirksamkeitsbewertung von MM fraglich. Retrospektive Datenbankanalysen erfüllen nicht die Anforderungen der evidenzbasierten Medizin, da sie für ein breites Spektrum an Verzerrungen anfällig sind. Aus diesem Grund sind ihre Schlussfolgerungen nur teilweise anwendbar. Zu ihren Gunsten fallen die relativ robuste Evidenz aus dem stationären Bereich, die relativ hohe Zahl der einbezogenen PatientInnen in den identifizierten und eingeschlossenen Tageschirurgie-Studien und Studien, die keinen signifikanten Unterschied in den Ergebnissen zwischen den Settings belegen, aus [3]. Demgegenüber stehen die schlechte interne und externe Validität der vorliegenden Evidenzbasis und die kritischen Überlegungen zu MM im Allgemeinen. Die Generalisierbarkeit der Daten ist kritisch zu hinterfragen, da alle Studien (mit Ausnahme von [27]) in den USA durchgeführt wurden, wo die Definition von Tages- und ambulanter Chirurgie variieren kann [20].

Generalisierbarkeit ist strittig

MEB kann plausibel durch die *Übung macht den Meister*- als auch durch die *selektive Überweisungs*-Hypothese erklärt werden, daher ist Vorsicht bei der Anwendung von MM geboten.

Bei der Durchführung der Analyse von Mengen-Ergebnis-Beziehungen (MEB) sollte darauf geachtet werden, nicht monokausale Erklärungsansätze anzuwenden oder nicht in die umgekehrte Kausalitätsfalle zu geraten, wenn man Verbindungen zwischen zwei oder mehreren Variablen herstellt. Eine beobachtete Korrelation deutet nicht unbedingt auf einen kausalen Zusammenhang hin – Korrelation ≠ Kausalität. Vor diesem Hintergrund ist es wichtig, die verschiedenen Erklärungsansätze zu berücksichtigen, um die Komplexität der MEB und die daraus abgeleiteten Strategien zur Geltung zu bringen. Die beiden Ansätze – Übung macht den Meister und selektive Überweisung – implizieren deutlich unterschiedliche politische Strategien und Vorgehensweisen [8]. Während die Übung macht den Meister-Hypothese Argumente für die Implementierung eines (regulatorischen) Rahmens in Form von MM liefert, würde die Hypothese der selektiven Überweisung indirekt an die Versorgungsforschung appellieren, zu verstehen, warum Phänomene wie Leistungszentralisierung in Form von Akkumulation von Behandlungsfällen einiger weniger Krankenhäuser überhaupt auftreten.

Im Hinblick auf die Limitationen der vorliegenden systematischen Übersichtsarbeit fanden wir nur MEB-Daten zu acht Interventionen. Dies stellt jedoch keine repräsentative Stichprobe aller für eine tageschirurgischen in Frage kommenden Interventionen dar. Darüber hinaus wurden die folgenden Studien zur Arthroskopie, Meniskusrekonstruktion und Koloskopie [31-33] von der Analyse ausgeschlossen, obwohl sie die Einschlusskriterien erfüllten. Der Grund dafür war, dass sie in einer zusätzlichen Suche in der Endphase des Berichts gefunden wurden, als der Einschluss nicht mehr realisierbar war. Ein weiterer Grund, sie nicht einzubeziehen, war ihr erwarteter geringer Grenznutzen, da die Qualität aller Studien aufgrund ihres retrospektiven Studiendesigns gering war.

Limitationen der systematischen Übersichtsarbeit: kleine Stichprobe von Studien und ausgeschlossene Evidenz, die potenziell relevant sein könnte

Zusammenfassung

Die Notwendigkeit einer Verlagerung von chirurgischen Eingriffen vom stationären in den ambulanten bzw. tageschirurgischen Bereich wird in der internationalen Literatur befürwortet. Da die MEB einen gewissen Stellenwert im stationären Bereich hat, wurde die Rolle von MM bei tageschirurgischen Interventionen in diesem Bericht untersucht. Neben der Theorie der MM wollten wir die Daten über internationale Variationen und die aktuelle Nutzung von MM mit einem besonderen Fokus auf den deutschen Kontext liefern. Die Theorie der MM ist teilweise umstritten und auch die Ergebnisse unserer systematischen Übersichtsarbeit können keine eindeutigen MM-Schwellenwerte bieten. Dieser vorliegende Bericht liefert jedoch einige Belege zu Gunsten von MM, obwohl er auf retrospektiven Datenanalysen mit geringer Qualität basiert. Die geringe Qualität der gefundenen retrospektiven Evidenz belegt weder die klare Präsenz einer MEB noch irgendwelche klaren MM. Zwei von acht Studien gaben keinen Hinweis auf eine MEB. Vor diesem Hintergrund empfehlen wir, dass die Anwendung von MM gut konzipiert und bis zum Ende gedacht werden sollte. Da die Herstellung einer MEB und damit auch eine Herleitung von MM möglich ist, sollten weitere qualitätsgesicherte, prospektiv kontrollierte Studien im tageschirurgischen Setting durchgeführt werden. Zudem sollten bei einer Entscheidung über Qualitätsverbesserungen andere Qualitätssicherungsmaßnahmen – wie Standards, die sich auf die Prozess- und Ergebnisqualität konzentrieren – berücksichtigt werden.

Theorie zu MM und Tageschirurgie aufgezeigt

MM im internationalen Kontext – besonderer Fokus auf Deutschland

einige Hinweise zu Gunsten der MEB in der Tageschirurgie, keine Daten zu klaren MM-Schwellenwerten

Betrachtung weiterer Qualitätssicherungskriterien

1 Background

Mindestmengen (MM) als Qualitätssicherungskriterium in der Tageschirurgie

The challenge of providing comprehensive health care of high quality that is available to all is shared by universal coverage health care systems of today [1]. Focusing on the setting of day surgery, one of the quality assurance mechanisms is minimum volume standards (MVSs). MVSs in day surgery are the topic of this report.

Zahlreiche Studien – meist retrospektive – und systematische Übersichtsarbeiten untersuchen den Zusammenhang zwischen Menge und Qualität und finden einen positiven Zusammenhang

Numerous research in the past has investigated the link between the quantity of conducted surgeries and its quality. This strand of research dates back up until the 1970's [39]. One of the first research groups explicitly analysing the volume-outcome relationship (VOR) were Luft et al. in 1979 with their study on the empirical relation between surgical volume and mortality [6]. Since then, many studies – mostly retrospective – have been focusing on a set of interventions or on particular surgical interventions such as coronary-artery bypass grafting, esophagectomy, elective repair of abdominal aortic aneurysm, and cancer surgery [40-43]. Also systematic reviews for the previous mentioned interventions and even systematic reviews of systematic reviews have been conducted to verify the connection between surgical volume and outcome [44-46]. The majority of research observes a positive association in terms of statistical correlation between volume and outcome and infers a causal inverse link between volume and outcome. This means the interpretation that with increasing surgical volume, health-related outcome measures such as mortality or further non-health related outcomes such as hospital readmission improve.

Ergebnisse der Studien und Wunsch nach stetiger Verbesserung des Gesundheitssystems führten zu einer MM-Debatte, um Qualität sicherzustellen

The past findings in the literature and the need for steady improvement of the health care system and its provided services with regard to quality, safety, and efficiency lead to a debate about quantitative minimum requirements as a quality assurance criterion. As a result, governmental bodies such as the Federal Joint Committee (Gemeinsamer Bundesausschuss) and the Federal Association of Social Health Insurance Physician (Kassenärztliche Bundesvereinigung) in Germany, private organisations in the health system such as the Leapfrog Group in the USA, expert societies or single experts have promoted (and still promote) the implementation of MVSs. As a result, MVSs with specific thresholds have been already implemented for elective surgeries in some countries, either in form of a regulative framework or suggested by respective expert societies [10].

Großteil der Studien und MM-Regelungen für komplexe/risikoreiche Operationen im stationären Setting; qualitätssteigernder Effekt von MM in der Tageschirurgie ist weniger klar

The majority of the studies analysing the VOR and already implemented MVS frameworks have a common denominator. They are all primarily concerned with complex and high-risk surgeries mainly conducted in the inpatient setting. The same denominator is also applied not only to the VOR, but also to the specific topic of MVSs. Hence, it seems that the relationship is generally accepted for complex and high-risk procedures and supported in the form of a statistical correlation – although the majority of the studies are lacking methodical rigour. The quality enhancing effect of MVSs, however, especially for day surgery procedures, seems to be less clear.

schrittweise Verlagerung von Leistungen in den ambulanten Sektor macht standardisierte und anwendbare Qualitätsstandards (QS) unerlässlich

MM als ein möglicher QS in Österreich

Also in Austria, inpatient services including day surgeries are gradually shifted to the ambulatory setting. The planned shift specified in the course of the Target-Based Health Governance (Zielsteuerung-Gesundheit), the federal contract on Target-Based Governance (Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene – B-ZS) and the underlying regulations makes it imperative to define comprehensive, standardised, and applicable quality standards across sectors. Especially, the complexity and the fragmentation of the health care system, which includes different legal responsibilities within the ambulatory care setting and the mixed financing structure, pose a challenge that needs to be taken into account when implementing quality standards for day surgery across different sectors. MVSs in the ambulatory surgical setting may constitute a supplement to commonly applied and currently developed quality standards.

Ziel des Berichts: Analyse der Evidenz von MM als Qualitätssicherungskriterium und des Zusammenhangs von Menge und Qualität in der Tageschirurgie bzw. beim ambulanten Operieren (AO)

The aim of this report was to address the question of quality assurance in day surgery, with a particular focus on MVSs. We thus aimed to analyse the day surgery setting, scrutinise the fundamentals of the VOR and MVSs, map the current practice of using MVSs, and provide the evidence on the effectiveness and safety of MVSs in specific day surgery interventions. Thus, in terms of structure of this report, we first set the background of day surgery, analyse the role of MVSs, and present the case of Germany where MVSs in day surgery are in place. Then, we present the data from our systematic review on MVSs in day surgery.

2 Methods

2.1 Research questions

Day surgery setting	
Element ID	**Research question**
A0002	What is day surgery?
A0003	What are the interventions suitable for the day surgery setting?
A0001	What are the particular interventions at stake in the current assessment?
B0008	What kind of special premises are needed for conducting day surgery inteventions?
B0009	What equipment and supplies are needed for conducting day surgery interventions?
A0007	What is the target population for day surgery?
A0023	How many people belong to the target population?
A0006	What are the consequences of implementing day surgery?
A0025	How is day surgery managed according to GL and in practice?

Description of minimum volume standards and current use	
Element ID	**Research question**
B0001	What are minimum volume standards?
B0018	Are thresholds and administrative reference values clearly established?
A0012	What kind of variations in use are there across countries
B0002	What are the claimed benefits and consequences

Organisational aspects and policy implications in the Austrian context	
Element ID	**Research question**
B0012	What kinds of requirements in terms of quality assurance processes are needed for implementation?

Clinical Effectiveness and Safety	
Element ID	**Research question**
D0001	What is the expected beneficial effect of MVSs on mortality?
D0005	How does MVSs affect symptoms and findings of the disease or health condition?
D0006	How does MVSs affect progression (or recurrence) of the disease or health condition?
D0010	How does MVSs modify the need for hospitalisation?
D0013	What is the effect of MVSs on disease-specific quality of life?
D0017	Was the use of MVSs worthwhile?
C0008	Are interventions with required surgeon/hospital MVSs safer than intervention without MVS?
C0005	What are the susceptible patient groups that are more likely to be harmed through the use of MVSs?
B0010	What kind of data/records and/or registry is needed to monitor the application of MVSs?

2.2 PICO question for clinical effectiveness and safety of minimum volume standards

PIKO-Frage

Do minimum volume standards in comparison to no minimum volume standards in the day surgery setting lead to better efficacy and safety outcomes?

2.3 Inclusion criteria

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarised in Table 2-1.

Table 2-1: Inclusion criteria

Population	Patients suitable for day surgery, for example: • according to anesthesia risk classes (ÖGARI), • according to the type of anesthetic options (local, mask), • according to ASA classification or general illness/condition. The appropriate patients are identified in the literature analysis for the specific interventions/indications found. Key words: day surgery, same day surgery, ambulatory surgery, outpatient surgery, day-care hospital, day only, zero-day hospital stays
Intervention	Identified surgical interventions from the international literature in the day surgery setting that implement minimum volume standards.
Control	The same or comparable surgical interventions in the day surgery setting without minimum volume standards implemented.
Outcomes	Depending on the identified indications/interventions, general health-relevant results such as morbidity, mortality, functional outcomes such as functionality in everyday life or at the workplace, quality of life or satisfaction are taken into account. In addition, results are specifically considered for outpatient interventions such as frequency of hospital infections and venous thrombosis embolisms, etc.
Setting	Day surgery/outpatient care/day clinic/zero-day stays/same-day surgery
Study design	No limitation
Publication period	2000-2019
Language	English/German

2.4 Sources

Quellen

Day surgery setting

- Exploratory web-based literature search
- Hand search in the UpToDate, POP, AdHopHTA and CRD databases for Health Technology Assessments
- Background publications identified in database search: see section 2.7

Description of minimum volume standards and current use

- Background publications identified in database search: see section 2.7
- Exploratory web-based literature search in combination with Google, Google Scholar, and PubMed
- Hand search in websites of governmental or public bodies, (surgical) expert societies, non-departmental public bodies, and other stakeholders in various health systems (only sources in German/English language)

2.5 Systematic literature search for clinical effectiveness and safety

systematische Literatursuche in 5 Datenbanken

For the domains clinical effectiveness and safety, the systematic literature search was conducted on the 12th of July 2019 in the following databases:

- Medline via Ovid
- Embase
- The Cochrane Library
- CRD (DARE, NHS-EED, HTA)
- Livivo

The systematic search was limited to the years 2000 to 2019 and to articles published in English or German. After deduplication, overall 538 citations were included. The specific search strategy employed can be found in the Appendix.

insgesamt 595 Publikationen identifiziert

By hand-search, an additional 57 citations were found, resulting in overall 595 hits.

Assessment elements from the EUnetHTA Core Model® for screening technologies 3.0 were customised so that they could be used for the purposes of this assessment.

2.6 Literature search and methods used for the section on minimum volume standards

ergänzende Literatursuche durch eine explorative Suchmethode

Complementary literature search for the contextualisation of the present analysis and in particular for the domain minimum volume standards was carried out using an exploratory search in:

- Google,
- Google Scholar, and
- PubMed

zusätzliche Handsuche auf Webseiten von verschiedenen Körperschaften/ Instanzen in verschiedenen Gesundheitssystemen (Sprache: Deutsch und Englisch)

In addition, a hand search in websites of the following entities was conducted:

- Governmental or public bodies (e.g. NHS, G-BA, KBV, KV, etc.)
- Social health insurance funds/institutions (Allgemeine Ortskrankenkasse in Germany etc.)
- Surgical expert societies (e.g. IAAS, Bundesärztekammer in Deutschland, Bundesverband für ambulantes Operieren e.V. etc.)
- Non-departmental public bodies (e.g. NICE, IQwiG, GÖG GmbH, NIH, etc.) and,
- other stakeholders in various health systems (Deutsche Krankenhausgesellschaft in Germany).

The search was limited to articles published in English or German and was conducted over the period of report writing. The specific search strategy employed with search terms can be found in the Appendix.

2.7 Flow chart of study selection for effectiveness and safety of MVSs

Literaturauswahl

Overall 595 hits were identified. The references were screened by two independent researchers (MS, CS). All cases of disagreement were resolved through discussion. The selection process is displayed in Figure 2-1.

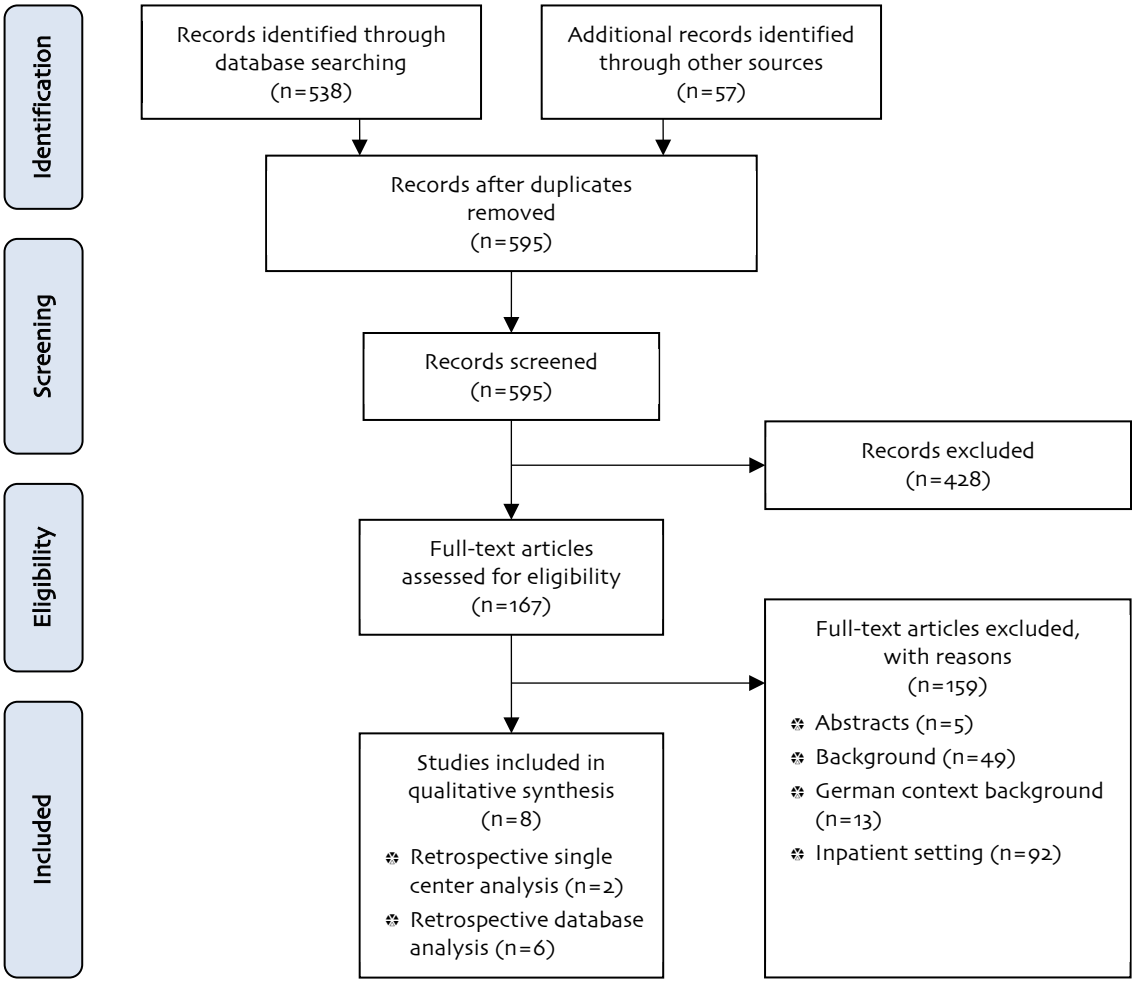

Figure 2-1: Flow chart of study selection (PRISMA Flow Diagram)

2.8 Analysis and Synthesis

systematische Extraktion und Darstellung der Daten in Tabellen für die Domänen Effektivität und Sicherheit

For the systematic literature search on effectiveness and safety, the data retrieved from the selected studies were systematically extracted into data-extraction-tables (see Appendix Table 13-1 and Table 13-2). No further data processing (e.g. indirect comparison) was applied. Two independent researchers (MS, CS) systematically assessed the quality of evidence using the checklist presented in the Appendix (Table 13-3). Due to the retrospective study design, data on each selected outcome category were not synthesised across studies according to Grading of Recommendations Assessment, Development and Evaluation (GRADE).

für die Analyse der MM-Evidenz wurden Elemente des EUnetHTA Core Models® 3.0 herangezogen; mangelnde Evidenz zu MM-Regelung beim AO in anderen Ländern, Fokus auf MM-Regelung beim AO in Deutschland

For the analysis of minimum volume standards, the information retrieved form the identified literature was used in conjunction with adjusted assessment elements from the EUnetHTA Core Model® 3.0 to structure the chapter on MVSs. According to the identified literature, the hand, and exploratory search, no country (except for Germany) seems to have specific threshold values for day or ambulatory surgery in force. Therefore, MVSs in ambulatory care in Germany is discussed in detail in chapter 7. The data for ambulatory surgeries for which minimum quantities and frequency regulations are defined in the German context were extracted and are presented in an extraction table.

3 Day surgery setting

3.1 Overview of the day surgery setting

3.1.1 Austrian context

aufgrund der Fragmentierung des österreichischen Gesundheitssystems können tageschirurgische Leistungen in unterschiedliche Zuständigkeitsbereiche fallen

In Austria, the health care system is complex and fragmented. Responsibilities are divided between the federal government and the federal states (Länder). In addition, tasks are delegated to self-governing bodies such as the social insurance and professional associations of health care providers. Due to the fragmentation, day surgery is regulated differently depending on the setting and the corresponding legal authority responsible for the premises where it takes place. It can take place in the hospital setting (intramural) in the form of a 0-day admission (0-Tagesaufenthalt) or day care (tagesklinische Versorgung), whereby under the latter regulation, only those types of surgeries are reimbursed that are listed in the ambulatory Austrian DRG-System (LKF ambulant). In addition, it can take place in the extramural setting (niedergelassener Bereich) on a (contracted) private practice basis or in outpatient clinics (selbstständige Ambulatorien) [47, 48]. Both sectors are characterised by different regulations and responsibilities for reimbursement. Hospital-based day surgeries are reimbursed according to the DRG-based hospital financing system (Leistungsorientierte Krankenanstaltenfinanzierung), whereas day surgeries in extramural care (niedergelassener Bereich) are reimbursed according to tariffs that result from negotiations between the self-governing bodies of social insurance funds and providers represented by the chamber of physicians [47].

in Zukunft sollen in Österreich vermehrt chirurgische Leistungen im ambulanten Bereich (spitalsambulant und extramural) bzw. auf tageschirurgischer Basis erbracht werden

In the context of the target-based Health Governance (Zielsteuerung-Gesundheit), the underlying regulations, and the federal contract on Target-Based Governance (Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene – B-ZV), one central objective is to relieve the burden on the fully inpatient sector in acute hospitals (stationärer Sektor) by shifting services to the day care (tagesklinische Versorgung im Krankenhaus) or outpatient sector (extramural). Hence, day surgeries in hospital day clinics, the private sector, and independent outpatient clinics are expected to be on the rise [49-51]. Because of the different responsibilities, no clear cut definition on day surgery across settings is available for Austria compared to other health systems.

3.1.2 General definition

unterschiedliche Definitionen von Tageschirurgie/AO: IAAS-Definition ähnlich jener im intramuralen Bereich im Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene

The International Association for Ambulatory Surgery (IAAS) defines *day surgery* as a practice where patients are admitted, operated on, and discharged during the time frame of one working day (six to eight hours), with no overnight stay [2]. The current definition from B-ZV conveys a similar meaning as the IAAS definition, however, it does not explicitly mention the length of a working day and it mentions the hospital setting. It states that day surgery refers to the hospital care for patients who receive an intervention from the catalogue of daily reimbursed interventions (according to the Austrian DRG System – LKF model) and are admitted and discharged on the same day [5].

BADS- und EU-Observatory-Definition haben eine erweiterte Definition; US-Definition beinhaltet auch chirurgische Leistungen mit einer Aufenthaltsdauer von bis zu 23 Stunden

The EU observatory as well as the British Association for Day Surgery (BADS) further add that "true" day surgery includes planned non-emergency surgical procedures on carefully-selected and prepared patients that are intended to be treated in the day surgery setting [3, 4]. Because some procedures may require longer recovery/observation, in order to keep them as day surgeries, they have to be performed in the morning sessions [4]. The US ambulatory care setting shares the definition of IAAS [52], yet at times, the US' use of the term day surgery includes 23 hours stay surgery, which in the EU is seen as an inpatient surgery with a one day length of stay (LOS).

versch. Definitionen von Tageschirurgie/AO

Alternative terms conveying the same meaning in different contexts are *same day surgery*, *ambulatory surgery*, *outpatient surgery*, *day-care hospital*, *day only*, or *zero day hospital stay*. For a complete list of terms used throughout the assessment, please see Table 3-1.

Table 3-1: Internationally agreed terminology, abbreviations and definitions as proposed by the IAAS [3]

Terminology	Synonyms and definitions
Day surgery	Ambulatory surgery, same-day surgery, day only
Day surgery center	Ambulatory surgery center, day-surgery unit, ambulatory surgery unit, day clinic. A center or facility designed for the optimum management of an ambulatory surgery patient.
Extended recovery	23 hours, overnight stay, single night. Treatments requiring an overnight stay before discharge.
Short stay	Treatments requiring 24–72 hours in hospital before discharge.
Outpatient	A patient treated at a hospital who is not admitted for a stay of 24 hours or more.
Inpatient	A patient admitted into a hospital, public or private, for a stay of 24 hours or more.
Office based surgery/ office procedure	An operation or procedure carried out in a medical practitioner's professional premises, which provide an appropriately-designed, equipped service room(s) for its safe performance.
Day surgery procedure	An operation or procedure which is not outpatient- or office-based, where the patient is discharged on the same working day.

3.1.3 Reasons of implementing day surgery

organisatorische, ökonomische, ethische und medizinische Gründe für Leistungsverschiebungen

Reasons for the shift from inpatient surgery to the day surgery context are manifold: organisational, ethical, economic, and medical. The aim is to improve the pathway of care, while alleviating the distributive justice mechanism and thus saving economic resources that can be allocated elsewhere. Day surgeries allow patients to choose their own surrounding to convalesce and they are associated with shorter waiting times and lower risks of surgery cancellation [20]. Also, day surgeries claim to reduce the rates of hospital-acquired infection and venous thromboembolism [20].

tageschirurgische Leistungen als eine mögliche Win-Win-Situation für PatientInnen, ZahlerInnen und LeistungserbringerInnen

Furthermore, the consequences of shifting to day surgery seem to be a win-win situation for all parties involved [20]. Omitting overnight and weekend stays can be a benefit both for the patient as well as for the medical team that does not have to stay at work over those times. This, in turn, saves the resources to the payers, potentially making the surgical interventions less expensive overall. In a report published by the NHS in the United Kingdom in 1989, costs of day surgery were estimated to be significantly lower compared to in-patient treatment [53]. In 2015, the Kings Fund verified the initial estimates stating that increases in day surgery over the period from 1998 to 2013 have generated savings of around £ 2 billion (€ 2.32 billion) [54].

From a scientific perspective, however, further surgery specific economic evaluations are necessary for a more concrete assessment of the economic dimension of day surgery as the 2012 report from LBI-HTA did not identify any meaningful cost comparisons for 11 procedures between day surgery and inpatient surgery setting [53].

weitere interventionsspezifische Studien notwendig für eine konkrete Beurteilung der ökonom. Dimension

Further patient-relevant consequences of day surgery are increase of control over patients' own time and health. Being called to come right before the intervention and then being followed by a telephone call after the intervention allows the patients to be more in charge [20]. Day surgery also potentially reduces the stigma that is associated with hospital admission as the patients return home within one working day.

erhöhte Kontrolle der Freizeit/Gesundheit durch die PatientIn, mehr Eigenverantwortung

3.2 Interventions and target population of the current assessment

3.2.1 Interventions in general

The past 30 years have seen a shift from inpatient pathways to day surgeries that are performed by both public as well as private entities that, thanks to advances in anesthesia and surgical techniques [20], treat an increasing number of patients without the need of hospital admission.

Fortschritte in Anästhesie- und Operationstechniken führten in den letzten 30 Jahren zu einer Zunahme an tageschirurgischen Leistungen

The list of interventions suitable for day surgery varies from one country to another and, along with the technological developments, it is still expanding. In 1990 in the UK, a list of 32 procedures was included in the "basket" of interventions suitable for day surgery. In 2006, the British Association for Day Surgery directory of procedures published its 4th edition with 200 procedures across all surgical specialties [20]. In 2019, the 6th edition of the BADS Directory of Procedures includes more than 300 procedures [4]. The NHS Institute for Innovation and Improvement even advocates the eventual shift of all elective surgery to the day surgery context [20]. For a detailed historical development of day surgery, see the LBI-HTA report on "Tageschirurgie" from 2012 [55].

Liste der durchführbaren tageschirurgischen Leistungen variiert von Land zu Land

As for January 2019, the Austrian model of reimbursed ambulatory medical services (Leistungskatalog BMASGK 2019 – Codierung ambulant) contained 341 surgical interventions across all specialties [56].

Leistungskatalog BMASGK 2019 – Codierung ambulant enthält 341 Operationen

3.2.2 Interventions and target population at stake in the current assessment

Interventionen im vorliegenden Bericht wurden durch die systematische Suche identifiziert

The interventions at stake in the current assessment were selected based upon the systematic literature search. All those interventions that reported information of the volume-outcome relationship in the day surgery setting were included.

This list of interventions is the following:

7 Interventionen: Schilddrüsen-Operation (OP), Katarakt-OP, primäre Hüftarthroskopie, offene Karpaltunnel-OP, OP der Rotatorenmanschette (RM), Rekonstruktion des vorderen Kreuzbandes (LCA) und Meniskektomie

- thyroid surgery (thyroidectomy),
- cataract surgery,
- primary hip arthroscopy,
- open carpal tunnel release,
- rotator cuff repair,
- anterior cruciate ligament reconstruction, and
- meniscectomy.

In addition, the target population and the volume of the target population will be addressed in the course of analysing each specific indication.

Thyroid surgery (thyroidectomy)

Schilddrüsen-OP: (Teil)Entfernung der Schilddrüse wird heutzutage bei ausgewählten PatientInnen im Rahmen eines tageschirurg. Eingriffs durchgeführt; häufige Gründe für Monitoring über Nacht: Schmerzmanagement, Hypokalzämie, Hämatombildung; Thyreoidektomie ist die häufigste Schilddrüsen-OP und betrifft verschiedene gutartige wie bösartige Erkrankungen

Thyroidectomy is the removal of part or all of the thyroid gland. While thyroid surgery used to be reserved for cases of goiter with mortality rate of 40% or higher in the past, today, thyroid surgery has evolved into a common procedure performed on selected patients also in the day surgery setting [21]. Most frequent reasons why patients may be admitted for overnight observation are pain management, hypocalcemia, or hematoma formation monitoring [57].

Thyroidectomy is the most frequently used thyroid surgery [58] and it targets a number of benign as well as malignant conditions including [57]:

- thyroid nodules,
- hyperthyroidism,
- obstructive or substernal goiter,
- differentiated (papillary or follicular) thyroid cancer,
- medullary thyroid cancer,
- anaplastic thyroid cancer,
- primary thyroid lymphoma (surgery for obtaining tissue biopsy), and
- metastases to the thyroid.

Thyreoidektomie ist v. a. für Risikogruppen von Belang

Thyroid nodules are solid or fluid-filled lumps that form within the thyroid. The great majority of thyroid nodules are not serious and do not cause symptoms [59] and so thyroidectomy is a procedure of choice for those patients with thyroid nodules, who have an increased chance of the nodules being cancerous [60].

Basedowkrankheit meist als Ursache für eine Hyperthyreose

Hyperthyroidism is, for the most part, caused by Graves disease – caused by autoantibodies to the thyrotropin receptor [61]. Other causes of hyperthyroidism include toxic multinodular goiter, toxic single adenoma, and thyroiditis [61]. For most instances of hyperthyroidism, thyroidectomy is the treatment of choice [61].

Goiter refers to abnormal growth of the thyroid gland. In the cases of obstructive or substernal goiter, thyroidectomy may be in place due to compressive symptoms, potential airway compromise, and the possibility of an association with thyroid malignancy [62].

OP indiziert bei Drucksymptomen, Atemwegsbeschwerden (durch Struma)

Thyroid cancer is the most common endocrine malignancy [63] and the most common indication for thyroidectomy [58]. Reasons for its increase in incidence is unclear, yet one explanation is overdiagnosis caused by the widespread use of radiology tests detecting small non-palpable thyroid cancers [63]. The incidence of thyroid cancer in Austria between years 2014 to 2016 was 837 new cases annually [64]. It was two to three fold more common in females than males [64], which is aligned with the international statistics [63]. Even though the peak incidence of thyroid cancer diagnosis is 45 to 49 years in women and 65 to 69 years in men, it nonetheless affects young people – accounting for approximately 10% of malignancies diagnosed in persons aged 15 to 29 years [63].

Schilddrüsenkrebs ist die häufigste Indikation für eine Schilddrüsen-OP

in Österreich: 837 Neuerkrankungen pro Jahr zwischen 2014 und 2016

However, the most prevalent type of thyroid cancer, papillary carcinoma, is a peculiar case. The proliferation rate of papillary microcarcinoma was negatively correlated with age and surgery to remove it did not contribute to reduced mortality from thyroid cancer [65]. This finding suggests the existence of truly malignant self-limiting cancer that does not always progress to the lethal stage [65]. The majority of lethal thyroid cancers appear suddenly after middle age [65].

Sonderfall Papillarkarzinom: Evidenz weist auf die Existenz eines bösartigen, selbst-limitierenden Krebses hin, der nicht immer in die tödliche Phase fortschreitet

Cataract surgery (phacoemulsification)

Cataract surgery is a procedure to remove the lens of the eye and, in most cases, replace it with an artificial lens. It is usually performed in the day surgery setting under local anesthesia supplied by block, or by local infusion [66].

Katarakt-OP: Ersatz der Augenlinse durch eine Kunstlinse

Cataract surgery is a treatment for the condition of cataract, which is an opacity of the lens of the eye that may cause blurred or distorted vision, glare problems, or, in very advanced cases, blindness [66]. Cataracts may be seen as normal parts of ageing, however, excessive exposure to sunlight, poor nutrition, metabolic insults, trauma, and medications such as cortisone may speed their development [66]. Because cataracts are an important cause of blindness, they carry a high burden of disease. The proportion of blindness due to cataract ranges from 12.7% in North America to 42% in Southeast Asia [66]. In 2016 in Austria, there were 110,125 cataract surgeries conducted in both inpatient and day surgery centers [67]. At the backdrop of the paucity of preventive approaches and nonsurgical therapy, surgery is the treatment of choice [66].

Katarakt-OP wird in der Regel tageschirurgisch unter Lokalanästhesie durchgeführt und dient der Behandlung des Grauen Stars; in Österreich (2016): 110.125 Katarakt-OPs im stationären und tagesklinischen Setting

The two surgical techniques that are most commonly used for cataract extraction are phacoemulsification and standard extracapsular cataract extraction [66]:

2 häufig verwendete Verfahrenstechniken:

- Phacoemulsification, also called small incision surgery, is the most common cataract removal technique in high-resource countries. It is performed through a small incision (one to three millimeters) that requires one suture at most. A probe containing a needle that vibrates with ultrasonic energy is used to fragment the hard central part of the lens. The softer cortex is then aspirated and the lens capsule is left behind. A foldable plastic or silicone lens is then put in place instead. In advanced cataracts when the lens nucleus is very hard, phacoemulsification may not be feasible.

Phakoemulsifikation benötigt nur einen kleinen Schnitt, ist jedoch bei weit entwickeltem Katarakt eventuell nicht möglich

bei der extrakapsulären Kataraktextraktion wird in der Regel der Linsenkern in einem Stück entfernt

- Standard extracapsular cataract extraction typically involves removal of the lens nucleus in one piece. The lens cortex is aspirated from the eye and the lens capsule is left behind to support an intraocular lens. A rigid plastic lens is inserted through the same incision and placed on or in the capsule behind the iris.

Katarakt-OP ist generell ein risikoarmes Verfahren, wird jedoch meist bei Risikogruppen durchgeführt

Cataract surgery is a low risk procedure, however, because it is typically performed in older adults with multiple comorbidities, its risk may be increased [66]. The most frequent complications include: toxic anterior segment syndrome, clinically apparent cystoid macular edema, retinal detachment, and the risk of macular degeneration [66].

Hip arthroscopy

Hüftarthroskopie ist ein minimal-invasives chirurgisches Verfahren zur Diagnose und Behandlung und wird häufig in der Tageschirurgie durchgeführt

Hip arthroscopy is a minimally invasive surgical procedure used for diagnosis as well as treatment and it is commonly performed in the day surgery setting [68]. Requiring only two to three incisions, it allows doctors to view the hip joint without having to use the traditional open techniques. Conditions, for which hip arthroscopy is used are the following [69]:

Anwendung der Hüftarthroskopie bei labralen Läsionen, akuten Gelenkschäden, Gelenkknorpelläsionen, Dysplasie, Hüftinstabilität, Osteonekrosen, Sepsis des Hüftgelenks etc.

- removal of symptomatic loose bodies,
- labral lesions,
- femoral acetabular impingement,
- acute articular injury,
- microfracture of select grade IV articular cartilage lesions,
- traumatic rupture of the ligamentum teres,
- dysplasia,
- hip instability,
- arthroscopic synovectomy of the hip,
- debridement,
- adhesive capsulitis of the hip,
- osteonecrosis,
- end-stage avascular necrosis, and
- hip joint sepsis.

Hauptursachen für Hüftbeschwerden: Alterung, Sportverletzungen, Fettleibigkeit, Knochen- und Gelenkserkrankungen

The primary causes of hip conditions that lead to hip arthroscopy are ageing, sports injuries, obesity, and bone and joint disorders like rheumatoid arthritis or hemochromatosis [70]. Despite improvements in equipment and training, arthroscopy remains to be a challenging procedure with revision surgery rates of anywhere from 6.3% to 16.9% [28]. Complications associated with hip arthroscopy include traction-related nerve injuries, fluid extravasation, infection, osteonecrosis, and heterotopic ossification [71].

in Österreich: 271,1 Hüftendoprothesen pro 100.000 Einwohner (2015), Platz 3 im OECD-Vergleich (nach Schweiz und Deutschland)

Hip arthroplasty, or total hip replacement, is the surgical intervention of choice in cases when hip arthroscopy does not bring the desired effect [72]. Hip arthroplasty refers to the procedure where the damaged bone and cartilage are removed and replaced with prosthetic components [72]. In 2015, there were 271.1 hip arthroplasties per 100,000 population in Austria, making it the third country among OECD with the most frequent use of hip arthroplasty (after Switzerland and Germany) [73].

Open carpal tunnel release

Karpaltunnel-OP/ Dekompressionschirurgie ist eine Behandlung des Karpaltunnelsyndroms (KTS) und wird häufig tageschirurgisch durchgeführt

Carpal tunnel release surgery (or decompression surgery) is a surgical treatment of the carpal tunnel syndrome (CTS) that is commonly performed in the day surgery setting. CTS is a condition that occurs when one or more major nerves on the hand are squeezed or compressed as they travel through the wrist and so release surgery is recommended for most patients with severe CTS [74]. Those patients who lack evidence of significant axonal loss or denervation can be treated initially with nonsurgical measures such as nocturnal wrist splinting in the neutral position or a glucocorticoid injection [74].

PatientInnenen mit KTS erleben häufig Schmerzen, Parästhesien und Schwächen in der medianen Nervenverteilung

CTS refers to the complex of symptoms and signs brought on by compression of the median nerve as it travels through the carpal tunnel. Patients commonly experience pain, paresthesia, and weakness in the median nerve distribution. CTS is the most frequent compressive focal mononeuropathy seen in clinical practice [74]. Carpal tunnel release is hence the most frequently performed surgical procedure of the hand and wrist with estimates of 400,000 to 600,000 carpal tunnel releases performed annually in the United States [27]. The estimated prevalence of CTS in the general population is one to five percent. CTS is more frequent in women, with a female-to-male ratio of approximately three to one [75]. Risk factors for CTS include obesity, female gender, coexisting conditions (such as diabetes, pregnancy, rheumatoid arthritis, hypothyroidism, connective tissue diseases, preexisting median mononeuropathy), genetic predisposition, and aromatase inhibitor use [75]. The role of repetitive hand/wrist use and workplace factors in the development of CTS is controversial [75].

Karpaltunnel-OP ist der am häufigsten durchgeführte chirurgische Eingriff an Hand und Handgelenk

OP kann offen oder endoskopisch durchgeführt werden

Carpal tunnel release surgery can be done either as an open surgery – performed through a standard incision or a limited incision, or as an endoscopic surgery – performed through a single or double portal [76]. Most frequent complications include the incomplete release of the transverse carpal ligament and the development of complex regional pain syndrome [76]. Majority of complications in relation to carpal tunnel release are, however, related to the surgery itself, with the rate of only one to two percent of long term complications when performed by experienced surgeons [76].

die meisten Komplikationen sind mit der OP selbst verbunden

Rotator cuff repair

tageschirurgische OP der RM findet Anwendung bei Tendinopathie und entzündeter oder gereizter Schultersehne

Rotator cuff repair is a surgical treatment of rotator cuff disorders (rotator cuff tendinitis/tendinopathy – inflamed or irritated shoulder tendons) that is commonly treated in the day surgery setting [25]. It is a line of treatment that is recommended to patients after less invasive treatments fail (rest, nonsteroidal anti-inflammatory drugs (NSAIDs), adjunct therapies such as electrical stimulation/therapeutic ultrasound/laser, physical therapy, glucocorticoids, or topical glyceryl trinitrate therapy) [77]. In situations of acute, full thickness traumatic tear of an otherwise normal rotator cuff in a healthy individual, rotator cuff repair is recommended within six weeks of injury [78].

Prävalenz von Anomalien nimmt mit zunehmenden Alter zu und ist abhängig von der Beschäftigungsart (erhöhte Morbidität bei manueller Arbeit)

The prevalence of rotator cuff abnormalities increases with age and occupation type. Its prevalence in patients aged 20 years or younger is 9.7% as opposed to 62% in patients aged 80 years and older [79]. Furthermore, in working populations, the incidence of shoulder-related symptoms may be as high as 14-18% [77]. Rotator cuff disorders are a significant source of morbidity among manual laborers and those whose work involves a great deal of repetitive motion [77].

weitere Risikofaktoren: anatomische Prädispositionen, erhöhter BMI, Diabetes und Hyperlipoproteinämie

Hence, repetitive overhead activity, whether in sport or work, is a major risk factor for rotator cuff tendinopathy. Other risk factors include anatomic variants that predispose to rotator cuff impingement, scapular instability or dyskinesis, older age, increased BMI, diabetes, and hyperlipidemia [77]. Any of the rotator cuff tendons may be involved, but the supraspinatus tendon is most frequently injured [77].

muskuloskelettaler Ultraschall gilt als Goldstandard für die Erstuntersuchung von Sehnenerkrankungen

Concerning clinical examination, routine plain radiographs of the shoulder do not reveal signs of rotator cuff tendinopathy and are generally not indicated in patients suspected of such injuries. Musculoskeletal ultrasound is considered the gold standard for the initial evaluation of tendon disorders with additional ultrasound or magnetic resonance imaging (MRI) as the following diagnostic steps [77].

geeignete Eingriff ist abhängig von der Konstitution der PatientIn sowie von der Lage und Art der Pathologie der RM

3 grundlegende Eingriffe: Debridement, Akromioplastik mit Debridement und Wiederherstellung der RM

The appropriate surgical intervention varies with the patient's age, comorbidities, level of activity, and the location and type of rotator cuff pathology. Three basic surgical interventions exist: debridement, acromioplasty with debridement, and rotator cuff repair [77]. Rotator cuff repair can be performed either arthroscopically or in open (alternatively “mini-open”) surgery [78]. All three techniques aim at providing a secure repair of the rotator cuff tendon over a large tendon-bone contact area at the original cuff attachment site on the humerus [78]. Arthroscopic repair is the current procedure of choice for its benefits of limited invasiveness and the ability to see the entire joint including the rotator cuff [78]. Complication rates increase with the age of the target population and they include rerupture, deltoid detachment, infections, axillary nerve injury, glenohumeral joint stiffness, and postoperative pain [78]. Postoperative rehabilitation protocols depend upon the extent of the injury and repair.

Anterior cruciate ligament reconstruction and meniscectomy

Rekonstruktion des LCA wird sowohl stationär als auch tageschirurgisch häufig durchgeführt

Anterior cruciate ligament (ACL) reconstruction is a surgical treatment of ACL injuries (tears of sprains in the ACL in the knee) that is commonly treated in both inpatient as well as day surgery settings. ACL injuries are common in professional athletes and in the general population. Swedish estimates of soft tissue injuries suggest the incidence of 766 and 676 per 100,000 population for males and females respectively [80].

akutes Management: Ruhe, Eis auf das Knie, Kompression und Anhebung der betroffenen unteren Extremität

die wichtigsten diagnostischen Instrumente sind die MRT und die Kniearthroskopie

Acute management consists in rest, putting ice on the knee, compression of the injured knee, and elevation of the affected lower extremity [81]. NSAIDs provide effective short-term pain relief, but the appropriate treatment depends upon the extent of injury, patient characteristics and activities, and available resources [81]. By and large, the patient population that tends to undergo ACL reconstruction are those who participate in high-demand sports or occupations, or those who experience significant knee instability [81]. There are debates with respect to timing of the intervention as well as with respect to the type of graft to be used (autograft or allograft) [82]. The main diagnostic instruments used are MRI and knee arthroscopy [81]. While short-term complications include infection and deficits to knee motion and strength, long-term complications include secondary ACL injury to either the involved or contralateral knee [83].

Meniskusverletzungen sind häufig, treten isoliert oder mit Seiten-/ Kreuzbandrissen auf

Meniscectomy is a surgical treatment of meniscal injuries that is commonly treated in both inpatient as well as day surgery settings. Meniscal injuries are common and can occur in isolation or in association with collateral or cruciate ligament tears [84]. In the general US population, the incidence rate of meniscal injury was 61 per 100,000 population [85].

Acute management consists in rest, putting ice on the knee, walk with the crutches, and patellar restraining brace [84]. Whether to undergo meniscectomy depends on a variety of factors such as frequency of symptoms, knee function, type of tear, or the likelihood that leaving meniscus unrepaired will lead to further damage of the articular cartilage [84]. Surgical treatment options include partial or total meniscectomy, and repair of the meniscal tear. Open or arthroscopic surgery can be performed always with the aim of retaining as much of the functioning meniscus as possible [84]. The main diagnostic instruments are plain radiographs, ultrasound, and MRI [84]. Intraoperative complications of meniscectomy include neurovascular damages, instrument breakage, and anesthesia complications. The most common postoperative complications include deep vein thrombosis, infection, synovitis, arthrofibrosis, effusion, hemarthrosis, extra-articular edema, postoperative stiffness, and continuous pain [86].

akutes Management: Ruhe, Eis auf das Knie, Gehen mit Krücken und Kniebandage; operative Behandlung: teilweise oder vollständige Meniskektomie, Reparatur des Meniskusrisses; häufige postoperative Komplikationen sind bspw. tiefe Venenthrombose, Infektion, anhaltende Schmerzen

3.3 Current management of day surgery

According to the 2019 guideline from the Association of Anaesthetists (AA) and the BADS, patients eligible for day surgery interventions can be referred from outpatient clinics, emergency departments, or primary care [87]. It is thanks to the advances in surgical and anesthetic techniques that even patients with multiple comorbidities can be treated in the day care setting and hence AA and BADS suggest a paradigm shift towards day surgery – meaning that if inpatient surgery is being considered, it is important to question whether any strategies could be employed to enable the patient to be treated as a day case [87].

AA und BADS empfehlen einen Paradigmenwechsel in Richtung Tageschirurgie

Local agreements between surgeons and the anesthetic department are needed for the appropriate patient selection and three main selection criteria need to be considered when assessing patients' eligibility: social, medical, and surgical [87].

Selektionskriterien für eine geeignete PatientInnenselektion

- Social criteria include the need of a responsible adult to escort the patient home and the presence of a carer for a required number of hours postoperatively in patient's home setting. The amount of time required depends on the invasiveness of the conducted intervention.

soziale Kriterien

- Medical criteria include patients' fitness for the procedure and presence of a chronic disease. Morbidly obese patients or patients with obstructive sleep apnea may be also treated in the day surgery setting, however, appropriate measures need to be taken. Patients with unstable medical conditions in whom surgery is required before the patient's condition can be optimised due to urgency may require inpatient admission.

medizinische Kriterien

- Surgical criteria require that the intervention does not carry a significant risk of serious postoperative complication that would need immediate medical attention. Postoperative symptoms must be controllable and patients should be able to mobilise before discharge. If that is not possible, appropriate venous thromboembolism prophylaxis should be instituted and maintained.

chirurgische Kriterien

generelle präoperative Vorbereitungen wie Aufklärung und Informationsaustausch neben OP-spezifischen Vorbereitungen sind unerlässlich

Specific medical and anesthetic preparation is required for each day surgery intervention individually, yet general pre-operative preparation includes [87]:

- education of patients and carers on day surgery pathways,
- communication of information on planned procedures and postoperative care to help patients make informed decisions – important information should come in writing, and
- identification of medical risk factors, promotion of health and optimisation of patient's condition.

Behandlung einer PatientIn als Tagesfall erfordert eine gut organisierte Tagesklinik

Treating a patient as a day case requires a well-organised day surgery unit that can communicate well with the patient before, during, as well as after the intervention. It is needed because patients should be admitted to the day surgery unit as close as possible to the time of their surgery and followed-up after the surgery once in their own home setting [87]. Patients should be provided with general, as well as procedure-specific, information that should be given to them in advance of admission. Verbal comments should be reinforced with written material [87].

3.3.1 Premises, equipment, and supplies needed for day surgery interventions

britische Richtlinie Tageschirurgie (2019) empfiehlt geschlossene OP-Einheit für die Tageschirurgie, die funktionell und strukturell vom stationären Bereich getrennt ist

Day surgeries can be conducted in hospital outpatient departments, freestanding ambulatory surgery centres, or in office-based surgeries [52]. Also, the same hospital beds used for inpatient surgeries can be used for day surgery procedures. The 2019 UK guideline suggests that day surgery works best when it is provided in a self-contained unit that is functionally and structurally separate from inpatient wards and operating theatres. They suggest that each day surgery unit should have its own reception, consulting rooms, ward, theatres and recovery area, together with administrative facilities [87]. The operating theatre and first-stage recovery areas should be equipped and staffed to the same standards as an inpatient facility, with the exception of the use of trolleys rather than beds [87]. Concerning equipment and supplies, the same is needed for conducting inpatient as well as day surgery interventions, except for the presence of overnight beds.

4 Understanding the volume-outcome relationship

Übung macht den Meister als intuitivste Erklärung der Mengen-Ergebnis-Beziehung (MEB)

Introspectively, *practice makes perfect* seems the most intuitive approach explaining the volume-outcome relationship (VOR). *Practice makes perfect* is a popular proverb used across a wide range of disciplines. The purported *practice makes perfect* hypothesis presumes that physicians, non-physician staff, or hospitals improve their (surgical) capabilities and outcomes with increasing volume of patients through a learning effect. The expected causality here is quite clear: quantity affects quality. This approach is mainly presumed as a working hypothesis to be tested in the literature [8-10, 42, 44, 88, 89] mainly initiated by the paper of Luft et al. [6]. Table 4-1 indicates the presumed direction of causality for the *practice makes perfect* approach: a higher volume leads to a higher level of training and skill set of surgeons or other non-physician care team members. Also the managerial practices of the hospital or care unit are expected to be enhanced by an increasing volume. The expected result are higher-quality outcomes.

Table 4-1: Causal direction in the volume-outcome relationship

Hypothesis (Effect)	Direction of Causality (independent variable → dependent variable)	Decision-maker
Practice makes perfect	Volume → (Provider experience) → Outcome or Quality	Health care planning and medical education
Selective referral	Outcome or (Provider) Quality → Volume	Provider or Patient

Übung macht den Meister ist nicht der einzige Erklärungsansatz der MEB: auch *selektive Überweisung* spielt eine Rolle

However, this quantity-quality relation is not the only approach utilised to link volume and outcome with each other. In the medical context, also the reverse hypothesis of the volume-outcome link – called *selective referral* – has been tested and proposed. The *selective referral* hypothesis assumes that high-quality service providers are more likely to accumulate a large proportion of overall conducted services because patients are more likely to seek these providers in the first place (Table 4-1). In other words, volume depends on outcome or the provider's (initial) quality. Within this hypothesis, provider or patients (simultaneously) decide whether or not to undergo surgery. To fully understand the selection mechanism initiated by the provider or patient, it is essential to define the variable quality or outcome in a twofold nature.

LeistungserbringerIn entscheidet über eine chirurgische Behandlung – ist abhängig von verschiedenen Faktoren

First, patients admitted for surgery are selected according to the service provider' assessment of their need for surgery. Surgeries in different settings can have different priorities and different application procedures, e. g. emergency cases have a higher priority than routine or elective interventions. Therefore, it is the hospitals or surgeons who decide whether or not a surgery is indicated – if possible in coordination with the patient (informed consent). The decision-making depends on expert knowledge, hospital and surgeon specialisation, and level of training or experience [90]. The volume of patients is not necessarily the defining factor. These factors can be summarised under the term provider quality or quality of making the right choice. Further factors influencing the hospitals or surgeons' decision whether or not a patient, de facto, receives a surgery are given by policy makers. These include factors such as regulations, reimbursement schemes, or other incentive mechanisms, yet they are thought to play a minor role [91].

PatientInnen bzw. deren Umstände haben auch wesentlichen Einfluss, ob eine chirurgische Behandlung durchgeführt wird

Second, in most of the non-emergency cases, the choice of surgery site can be made by the patient him- or herself and is even encouraged by health policy in some countries [92]. Proximity is certainly a major factor influencing the choice of the patient, but social and individual factors that determine the accessibility and affordability of health services have also an impact on the decision-making process. These include general preferences, perceived quality, past experience, word-of-mouth recommendations, internet reviews, available information on the service provider, and health literacy of the patient [92-96]. Especially, non-classical (clinical) outcome measures that can be classified in the category patient-reported outcome measures (PROMs) or patient-reported experience measures (PREMs) are of increasing importance [97, 98].

(akkumuliertes) Leistungsvolumen muss nicht die Ursache für die Ergebnisqualität sein, sondern die Ergebnisqualität kann auch die Ursache für das Leistungsvolumen bzw. Fallzahl sein

If it is expected that patients are more likely to seek high-quality providers or high-quality providers have a different referral or public advertising policy, then volume results from patients and providers' preferences. Accumulated volume is then not the cause for quality, but quality is the cause for volume. Therefore, it is possible that different providers with similar quality standards (ceteris paribus) that provided services with high-quality outcome in the first place (regardless of their past volumes) accumulate significantly different volumes [7]. Both hypotheses seem to be valid in the empirical literature [8].

5 Description of minimum volume standards and current use

5.1 General Characteristics

AkteurInnen im Gesundheitswesen fördern und fordern (regulative) MM neben weiteren Qualitätsstandards

On the basis of the previous available studies analysing the VOR, stakeholders in the health care sector have promoted and demanded (and still promote/ demand) the implementation of a (regulatory) MVSs framework besides further quality standards. MVSs should assure that surgeons or hospitals that comply with the minimum volume of surgeries provide a certain level of quality. In most of the cases, annual volumes per surgeon or hospital are considered in MVS frameworks. The definition of annual MVSs corresponds to the notion of minimum volumes as an instrument for ability maintenance guaranteed by the routine for surgeons and hospitals [9].

Konsequenzen von MM-Abweichungen sind davon abhängig, wer diese vorgibt, bspw. unterschiedliche Konsequenzen, ob Fachgesellschaften MM empfehlen oder ob ein rechtlicher Rahmen von MM existiert

A possible consequence of not complying with these minimum requirements in regulatory MVS frameworks – but mostly rarely enforced – is that surgeries are not reimbursed anymore [10]. In other words, if a surgeon or hospital does not perform the specified number of surgeries, the particular surgical intervention may no longer be performed. Certainly, consequences depend on who specifies and defines these minimum standards. There are different consequences when expert societies provide only recommendations or exercise peer pressure compared to a legal basis with the possibility of enforcement of consequences. For example, in the Netherlands, there is no legal basis for MVSs, but MVSs in the inpatient setting are highly respected and valued due to the commitment by the professional associations. Adherence to quality standards is utilised for price negotiations between hospitals and the Dutch health care system. If targets are not met, then it is possible that this service is not reimbursed [10].

MM können auf verschiedenen Ebenen definiert werden

MVSs can be defined on various levels:

- Surgeon/Surgical team
- Hospital department/Hospital

viele MEB-Studien analysieren Leistungsvolumen der ChirurgIn und des Krankenhauses

In most of the studies analysing the VOR, both surgeon and care unit volumes are used as the unit of analysis. But generally, individual surgeon volume is seen as the decisive factor. While surgeon volume seems more important for surgeries with a shorter length of stay and specific intraoperative abilities compared to hospital volume, hospital volume appears more decisive for longer lengths of stay and intensive care [42, 44, 89].

Unterscheidung der verschiedenen Ebenen ist wichtig

The distinction between these various levels is not only important for the sake of ruling out any biases when analysing the VOR with the aim of providing solid evidence for decision-makers. A clear formulation of the unit in consideration is also essential for compliance of MVSs.

5.2 Thresholds and administrative reference values

wissenschaftliche Literatur stellt keine einheitliche Methode für die Spezifizierung von MM bereit

The literature on the VOR provides no universally solid method to specify administrative MVS thresholds [13, 14]. Generally, modelling approaches on the basis of regression models seem to be most appropriate, but the choice of the appropriate model depends on the specific problem and the available data [15, 16]. Most of the studies implementing regression models neglect methodical issues associated with the calculation of thresholds that consequently affect the reliability of the thresholds as discussed above [13, 17].

nur ein qualitativ hochwertiger Evidenzkörper sollte für eine Entscheidung über MM herangezogen werden

Only a high-quality body of evidence (prospective and controlled trials) that established a robust relationship between volume and outcome is recommended to consider when implementing administrative MVSs as a quality standard. A robust relationship can be understood as a number of studies clearly verifying a consistent statistical association between volume and outcome with substantial clinical relevance that is plausible, logical, and was verified on the basis of stringent statistical criteria. This notion is in accordance with the Nine Bradford-Hill criteria[1] that are used when verifying potential causal relationships and is also used by the National Cancer Policy Board in the US [7, 34]. Also in Germany, for MVSs to be in force, it is necessary that scientific studies suggest that there is a link between the amount and quality of treatment. "Common experience" does not serve as a sufficient basis. Furthermore, minimum volume standards are not allowed to be used for quantity control of provided services. This was also judicially confirmed by the German federal social court[2].

Leapfrog Group (USA) empfiehlt MM für komplexe und risikoreiche chirurgische Interventionen im stationären Sektor

In the US, the Leapfrog Group – a national organisation formed and funded by the lobbying organisation Business Roundtable – set themselves the task to publicly report the quality and safety of health care services including MVSs for complex surgeries in order to allow people to make informed decisions with regard to health care [99, 100]. Hospitals or surgeons are invited to participate on a voluntary basis. In the course of their reporting, the Leapfrog group recommends MVSs per hospital and per surgeon for eight high-risk procedures[3] [101]. The suggested volumes, however, are also not without shortcomings [102]. For example, it is criticised that current esophagectomy volume may not predict optimal outcomes for all patients, especially at extremes of age and comorbidities [103].

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[1] The criteria include: 1) strength of the association, 2) consistency of the observed association, 3) specificity of the association, 4) temporality of the association, 5) biological gradient or dose-response curve, 6) plausibility of the theory's relationship with reality, 7) coherence with knowledge from other disciplines, 8) experiment with the association, and 9) analogy with other phenomena.

[2] Bundessozialgericht Urteil vom 29.11.2017, B 6 KA 32/16 R

[3] Bariatric surgery for weight loss, oesophageal resection for cancer, lung resection for cancer, pancreatic resection for cancer, rectal cancer surgery, carotid endarterectomy, open aortic procedures, mitral valve repair and replacement

Until 2019, the focus has been on reporting inpatient data, but as of April 2019, the Leapfrog Group began collecting information on day surgery from 321 ambulatory surgical centres (ASCs) and 1,141 hospital outpatient departments (HOPDs) that can freely participate in the survey. In future, the Leapfrog Group plans to report performance measures including minimum volumes for 10 specialities[4] in the day surgery setting as well [104].

in Zukunft möchte die Leapfrog Group auch MM für tageschirurgische Interventionen empfehlen

According to the identified literature, the hand and exploratory search, no country, except for Germany seems to have specific threshold values for day or ambulatory surgery in force [11, 12]. The case of MVSs in ambulatory care in Germany is discussed in detail in chapter 7.

nur für Deutschland konnten MM für die Tageschirurgie/AO identifiziert werden

5.3 Variations in use of minimum volume standards across countries

Various countries have already implemented MVSs in hospitals for selected complex and high-risk surgeries for quality and safety reasons. Among the countries that provide a MVSs framework in the inpatient setting are Germany, Canada, the Netherlands, Switzerland and Austria [10].

verschiedene Länder haben bereits MM für komplexe/risikoreiche OPs implementiert

We provide an overview of the current use of MVSs in five countries on the basis of the identified literature by Morche et al. [10]. The aim is to draw an analogy from inpatient high-risk surgeries to the day surgery setting in order to give some insights in general characteristics and in the organisational framework of MVSs (including reimbursement implications and consequences of non-compliance). The overview in Table 5-1 gives a description of the following aspects:

Analogien zwischen stationärem und tageschirurgischem/ ambulanten Setting

- Countries with an established MVSs (regulatory) framework
- Procedures affected by MVSs
- Characteristics, requirements, and the evidence source of MVSs
- Organisational and/or legal framework
- Reimbursement implications and consequences of non-compliance

Übersicht der Charakteristika und des organisatorischen Rahmens von MM in fünf Ländern

[4] Gastroenterology, general surgery, ophthalmology, orthopaedic, otolaryngology, urology, dermatology, neurological surgery, obstetrics and gynaecology, plastic and reconstructive surgery

Table 5-1: International Variations and Current Use of MVSs

Country	Procedures	Characteristics, Requirements and Evidence	Organisational and legal framework	Reimbursement and consequences
Austria	MVSs for 5 sets of procedures: • Pancreatic surgery • Esophageal surgery • Hepatic surgery • Bariatric surgery • Carotid endarterectomy	• MVSs are implemented on the basis of studies with sufficient evidence, but sufficient evidence is not defined • Thresholds are established by expert consensus, representatives of federal states and the social insurance (Zielsteuerungspartner) • Sets of procedures and thresholds should be reevaluated annually according to international evidence • MVSs serve as a first response to the relationship between volume and outcome	• Legal basis for MVSs is specified in the law (G-ZG) established in the course of the Austrian structural plan on health (ÖSG) in 2013 • MVSs are used to ensure quality of care and as a basis for regional planning of health service provision • Qualified hospitals are determined by the authorised regional health fund (Landesgesundheitsfond) and private hospital financing funds (PRIKRAF) • MVSs refer to annual averages per hospital within three previous years	• Consequences of non-compliance vary across states, but are not explicitily defined
Germany	MVSs for seven sets of procedures: • Pancreatic surgery • Esophageal surgery • Hepatic and Biliary Tract Surgery • Renal transplantation • Stem cell transplantation • Surgery of the knee • Neonatal procedures	• Selection of procedures with MVSs are based on scientific data from international studies and reports from the IQWiG (Limited evidence to inform the selection of specific thresholds) • First evaluation of the impact of newly introdcued MVSs 3 years after implementation • MVSs and sets of procedures are defined by negotiations between care providers and insurance providers according to the legal framework	• MVSs introduced by the Federal Joint Commitee (G-BA) on a legal mandate in the German Social Code Book V (SGB V) in 2004 • Hospital operator must annually demonstrate to the associations of the health insurance funds that the required minimum quantity will probably be achieved in the next calendar year due to justified quantitative expectations based on the attainment in the preceding calendar year (prognosis) • Utilised thresholds were subject of regular legal proceedings	• Hospitals that do not meet the MVSs are not allowed to conduct the particular surgery • In case of service provision, despite violations of MVSs, no reimbursement is provided for that particular surgery • Exemption clause: Hospitals can be exempt from the prohibition of providing services, when elective procedures cannot be provided from the year of introduction of newly estblished MVSs
Canada (Ontario)	MVSs for 4 different sets of procedures and diagnosis set by CCO: • Lung cancer operations • Esophageal cancer surgery • Hepatic, and pancreatic, biliary tract surgery • Gynecologic oncology	MVSs are based on: • Evidence based analysis • Existing recommendations from other jurisdictions • Expert opinion based on experience and consensus (main basis, because the quality of supporting evidence from the volume-outcome literature is gauged to be modest)	• CCO provides guidelines, reviewing data and indicators, organising community of practice events, education and potentially funding agreements with penalty for non-compliance • No legal regulation of MVSs provided by CCO (consequences not legally binding)	• Reimbursement: Global budget plus additional payments for additional cases to reduce waiting times. CCO can withdraw some of the funding of additional cases, if not satisfied with the hospitals implementation of the organisational guidelines • Financial punishment is rather an exception

Country	Procedures	Characteristics, Requirements and Evidence	Organisational and legal framework	Reimbursement and consequences
Netherlands	MVSs recommended by 2 expert societies for: • Cancer care for specific tumour types (SONCOS) • Oncological and gastrointestinal surgery, surgery of the lung, vascular surgery, traumasurgery, and pediatric surgery (NVvH)	• Quality standards and MVSs are based on the consensus of all involved professional associations with an annual update based on suggestions by the associations (SONCOS) • Thresholds are based on expert opinion and evidence because there is no conclusive evidence for single thresholds. MVSs are annually updated (NVvH)	• No explicit legal basis for the quality standards by SONCOS and NVvH • NVvH and SONCOS (yearly) publish reports on QS for MVSs • QS are highly respected and valued due to the commitment by the professional associations (SONCOS) • Once the standards (NVvH) are established they are enforced as field norms by the Dutch Healthcare Inspectorate, IGZ	• Adherence to the QS of SONCOS are utilised for price negotiations between hospitals and the Dutch health care system. If targets are not met, then it is possible that this service is not reimbursed (SONCOS) • MVSs are also used for superintendece by the IGZ. E.g. medical errors due to lack of experience/non-compliance can lead to a prohibition of the respective surgery in the particular hospital
Switzerland	MVSs set for the following procedures: • Visceral surgery (esophageal, pancreatic, liver, deep rectal resection, and complex bariatric surgery) • Neurosurgery • Treatment of strokes	• MVSs are assumed to be an internationally recognised quality criterion • Need for MVSs by referencing to international studies, e.g. MVS for visceral surgery and its re-evaluation (2016) based on scientific evidence	• Since 2011, cantons are mandated by law to conceptualise a strategy on HSM including MVSs called inter-cantonal agreement on HSM • Allocation of services conducted by the scientific body of the IVHSM is dependent on MVSs by law of health insurances	• Hospitals can apply for allocation of specific services and need to fulfil the requirements defined by the agreement on HSM (IVHSM) • To be eligible for allocation, the respective MVSs have to be met • Surgeries with MVSs that are not attained are not allocated to the respective hospital anymore

CCO – Cancer Care Ontario, G-ZG – Gesundheits-Zielsteuerungsgesetz, HSM – Highly specialised medicine, IGZ – Inspectie voor de Gezondheidszorg (Dutch Healthcare Inspectorate), IQWiG – Institut für Qualität und Wirtschaftlichkeit im Gesundheitssystem (Institute for Quality and Efficiency in Health Care), IVHSM – Interkantonale Vereinbarung für HSM (Inter-cantonal Agreement on Highly specialised medicine), MVSs – Minimum Volume Standards, NVvH – Nederlandse Vereniging voor Heelkunde (Dutch Assoc. of Surgeons), ÖSG – Österreichischer Strukturplan Gesundheit (Austrian structural plan health), PRIKRAF – Privatkrankenanstaltenfinanzeriungsfonds (Private hospital financing fund), QS – Quality standards, SONCOS – Stichting Oncologische Samenwerking (Dutch foundation for oncologic cooperation)

5.4 Claimed benefits and consequences

MM als Bestandteil in der Debatte über eine kontinuierliche Verbesserung des Gesundheitssystems

Based on the *practice makes perfect* hypothesis in the volume-outcome relationship (VOR), MVSs find themselves being part of the debate on steady improvement of the health system and its provided services. They are expected to improve outcomes with regard to two aspects:

- Quality aspects: (Clinical) Effectiveness and Clinical Safety
- Economic aspects: Production Efficiency and Economies of Scale

Qualitäts- und Wirtschaftlichkeitsaspekte

Whereas (clinical) effectiveness and safety is understood as outcome and quality of outcome, efficiency is conceived as an optimal input-output mix of resources. Economies of scale suggests cost advantages in the scale of operation in the economic sense [105].

MM sind attraktiv für Gesundheitsplaner, Krankenhäuser und Pflegeeinrichtungen

Against this background, MVSs in day surgery are not only associated with quality and safety, but additionally target economic aspects. Therefore, MVSs are especially attractive for health care planners as a policy tool (to counteract rising costs and ensure an efficient health care system) and for hospitals or care units (to benefit from increased profitability due to lower costs).

5.4.1 Quality aspects

MM können in das Donabedian-Qualitätsmodell für medizinische Versorgung eingebettet werden

In the context of quality development and evaluation in health care, MVSs can be embedded in the Donabedian model of quality in medical care [19, 106]. The Donabedian model distinguishes between three dimensions of quality: structural, process, and outcome quality. Table 5-2 gives an overview and explanation of the three dimensions with examples in the day surgery setting [7, 107].

Table 5-2: Donabedian model of quality in medical care with regard to the day surgery setting

Dimension	Explanation	Factors in the day surgery setting
Structural Quality	Structual quality includes human personnel, facilities and technical equipment, as well as organisational and other characteristics of the system that can be attributed to training and ability improvement	Structural factors: • Surgery personnel: Level of training and skill set of surgeons and non-physician care team members ↔ **Volume** • Hospital/care unit: Management of the hospital or care unit ↔ **Volume**
Process Quality	Process Quality concerns the procedures that are perfomed for the patients. This comprises of clinical as well as non-clinical procedures such as admission process etc.	Process factors (perioperative phase): • Pre-operative: Anaesthesia, diagnostic and screening procedures • Intra-operative: Surgery (techniques) and surgery related tasks • Post-operative: After-care
Outcome Quality	Quality of Outcome is WHAT is realised. This dimension comprises of improvement of health specific outcomes such as mortality or morbidity, but also achievements that are associated with PROMs or PREMs are included	Outcomes: • Mortality, morbidity, Complications and AEs/SAEs • Readmission, rehospitalisation • PREMs/PROMs • etc.

AEs – adverse Events, PREM – patient-reported experience measures, PROM – patient-reported outcome measures, SAEs – serious adverse events

MM zielen auf die strukturelle Qualität ab

MVSs are expected to target the structural quality. Via this dimension, MVSs are seen as an intermediate step to increase quality of outcome and serve as a tool to preserve a certain quality level [18]. It is expected that implementation of MVSs improves the level of training and the abilities of the surgical personnel as well as the management abilities of care units. In the end, only qualified and experienced surgeons, surgical teams, or care units perform particular surgeries that are affected by MVSs. Better outcomes compared to situations without MVSs regulations are expected to emerge [7].

MM in der Chirurgie stellen nicht den einzigen qualitätssteigernden Faktor dar

Minimum volume requirements that are located in the structural quality dimension should not be considered as the only exclusive factor enhancing quality. A prerequisite to make inferences about overall quality is to understand the interrelation of these three dimensions. It is not recommended to neglect the other two dimensions, otherwise a successful pathway in day surgery cannot be realised. Patient-related factors and process related factors such as overall preoperative preparation, anaesthetic management, postoperative recovery and discharge, or follow-up are also relevant for successful and high-quality day surgeries [19, 20].

5.4.2 Economic aspects

Kosten, Ergebnisse und ihre Verteilung sind wichtig in Systemen mit knappen Ressourcen

In a system with scarce resources, such as the health care system, it is always crucial to consider costs, outcomes, and their distribution. This holds especially true when from the theoretical standpoint, the quality of care and health expenditures could be related with each other [108-110].

MM bieten mögliche effizienzsteigernde und kostenmindernde Effekte

In theory, MVSs are expected to increase production efficiency and reduce costs in addition to the expected cost-reducing day surgery setting. Two effects appear relevant for the health care sector that can be attributed to the cost-effective nature of MVSs (Table 5-3). On the one hand, production efficiency is induced by a learning effect that could lead to improved outcomes. It is expected that high-volume surgeons or hospitals meeting the efficient MVSs threshold are superior to low-volume providers in quality and efficiency aspects because the former are more likely to choose an appropriate treatment. On the other hand, costs are reduced on account of economic theory in the form of economies of scale. Both effects are assumed to reduce the long-run costs.

Table 5-3: Production efficiency and economies of scale

Concept	Explanation
Production Efficiency (Learning Effect)	Facilities, technical equipment, and personnel are utilised in a productivity-efficient way (on the production possibility frontier). E.g. with increasing volume, surgeons are expected to become better and care units improve their organisational abilities resulting in lower resources and costs used in the long run.
Economies of Scale	Economies of scale are present if with increasing prodcution, average costs are decreasing. With increasing surgery volume, care units experience a decrease in fixed costs to a certain point and thereby lower their average cost per patient [111].

Routine bzw. Aufrechterhaltung der Fähigkeiten als entscheidender Faktor höherer Effizienz

The evidence that production becomes more efficient with more experience in monetary terms has been mainly shown in industrial production [6, 8]. While the focus in industrial production is on accumulated experience in form of accumulated volume, accumulated experience over many years is disputable as a single explanatory factor for medical services. It is rather the maintenance of ability or routine combined with experience accumulation over lifetime and the training period of a young surgeon that are deemed relevant [8, 9]. These issues are mostly addressed by health economic literature [9, 105].

weitere spezifische ökonomische Analysen im tageschirurgischen Kontext sind notwendig, um die ökonomische Dimension der MEB beurteilen zu können

According to empirical findings and the mentioned theoretical considerations, production efficiency and economies of scale appear relevant for the health care sector (Table 5-3). The cost-effective nature of increased surgeon volume was empirically tested in some studies for a set of procedures such as thyroidectomy, adrenal surgery, total ankle arthroplasty, and many other interventions in the inpatient setting [112-116]. For the day surgery setting, further surgery specific economic evaluations are necessary for a more concrete assessment of the economic dimension of an increased surgeon volume and MVSs. It is essential to verify the range of output over which costs are expected to fall, and the scale at which costs may start to increase again because of diseconomies of scale.

individuelle Effizienz ≠ allokative Effizienz

Overall, using resources in a production efficient way at the hospital level does not necessarily guarantee efficiency on an aggregated (health care system) level because negative external effects such as inequity of access are not taken into account.

Konzentration von Leistungen (Zentralisierung) und Entstehung von Exzellenzzentren als mögliche Konsequenzen

MVSs are also associated with concentration of surgical procedures and the formation of excellence centres, where only qualified and experienced surgeons and surgical teams perform surgeries. This concentration process of services due to implemented MVSs has been empirically described by a study for complex procedures in the German inpatient setting [117]. Another assumption is that centralisation with formation of excellence centres leads to quality improvement and efficiency gains by reducing unit costs for hospitals by economies of scale (Table 5-3) and releasing resources that can be used in other service areas [7, 9]. An international study verified this presumption for highly specialised procedures by critically assessing concentration policies [118]. To what extent this centralisation process applies for the day surgery setting is not clear.

5.4.3 Quality of access and further consequences of minimum volume standards

Zentralisierung ist nur vorteilhaft und nachhaltig, wenn der Zugang zu Leistungen und die Qualität für die gesamte Bevölkerung gewährleistet ist

However, on a social welfare level, the effect of centralisation of surgical services induced by MVSs can only be beneficial and sustainable if patient outcomes of the whole population certainly improve with increasing hospital volume. One critical argument is that centralisation caused by minimum quantities leads to a deterioration of quality of supply and health service coverage. It could increase inequities in access to quality care in form of increased traveling distance to the next hospital or ambulatory care unit. This seems especially crucial for vulnerable groups such as people with socio-economic disadvantages or elderly people that experience a limited accessibility to health care not only with regard to proximity. Furthermore, centralisation could affect patients' autonomous choices, as they will have little or no choice between different health care institutions.

viele zu beachtende Faktoren für GesundheitsplanerInnen und AkteurInnen im Gesundheitssystem

Another point is that a centralisation due to MVSs may endanger the coordination and continuity of care, as well-established local networks between the various medical service providers lose their importance and competition between health care providers decreases. Residency and education capacities are affected by centralisation that have to be taken into account in health planning. Exemption rules from MVSs are of utter importance, e.g. in case of long periods of illness of the respective surgeon or for regions with a serious shortfall.

mögliche Vernachlässigung von anderen Qualitätsmaßnahmen

Apart from that, a related counterargument against MVSs is that surgeons or hospitals focus only on complying with the minimum requirements in the course of their quality management and neglect other structural- or process related measures of quality improvement such as adhering to procedure guidelines [7]. An oversaturation effect when relying on pure volume as a quality measure is also possible, especially, when no optimal minimum volume threshold is utilised. Outcomes can deteriorate when a surgeon conducts too many surgeries, because she or he is inattentive.

Fehl-, Überversorgung und damit einhergehende Kosten gilt es zu beachteten

The important question of unnecessary health care in the form of overtreatment or over-utilisation and its underlying determinants is scarcely addressed by the studies testing the *practice makes perfect* hypothesis. It is feared that costly controls of appropriate indications will become necessary, as minimum quantities could lead hospitals or surgeons making more generous indication decisions if they are closely just below the minimum quantity. This argument is important to consider in the context of low-risk procedures and demands a continuous evaluation of outcomes in form of monitoring and accompanying research.

6 Organisational aspects and policy implications in the Austrian context

6.1 Implementation requirements

organisatorische Implikationen und Konsequenzen bei der Implementierung von Qualitätsstandards (QS) und –sicherungs-systemen in der Tages-chirurgie

In general, the dynamic nature of the health system makes it imperative to consider also organisational implications and consequences when developing and implementing criteria for quality assurance and quality standards. The IAAS and the BADS suggest that audit and subsequent action is elementary for the successful practice of ambulatory and day surgery [87, 119]. Both associations propose that surgical programmes should be steadily monitored to guarantee high quality services. Before monitoring and benchmarking can be operationalised, the respective quality standard under consideration and corresponding outcome measures are imperative to ensure a safe, effective, and efficient setting in day surgery. To achieve this, establishing key principles that reinforce the implementation of quality standards is key [35, 36].

Berücksichtigung von organisatorischen Implikationen und Konsequenzen von MM sind v.a. in fragmentierten Gesundheitssystemen wichtig

In Austria, due to the fragmented health care system with different legal responsibilities, considering organisational implications and consequences related to MVSs in day surgery appear to be particularly essential. According to the federal contract on Target-Based Governance (Vertrag zur Zielsteuerung-Gesundheit auf Bundesebene – B-ZV) according to article 15a of the federal constitutional law and the federal law on quality of health services (Art. 15a B-VG über die Organisation und Finanzierung des Gesundheitswesen, B-VG Zielsteuerung-Gesundheit and Gesundheitsqualitätsgesetz – GQG), agreed by the federal government, the Main Association of Austrian Social Security Institutions (Hauptverband der österreichischen Sozialversicherungsträger, HVB) [49, 50, 120], all contract parties committed themselves that assurance and further development of the quality of care have top priority and are carried out nationwide, across federal states, sectors and occupations. This also relates to a comprehensive, comparable, and standardised quality measurement in the intramural (inpatient and ambulatory care in the hospital) and extramural (ambulatory care in the outpatient setting including contracted private practice) setting and the specification of optimal quality standards.

NICE und HQO stellen Prozessleitfäden für eine Implementierung von Qualitätsstandards zur Verfügung

Internationally, there are established programs for the provision of quality standards such as programs provided by Health Quality Ontario (HQO) and the National Institute for Health and Care Excellence (NICE) [36, 37]. Such process guides not only make standards available to all relevant stakeholders and the public, but also provide indicators to measure quality. In Austria, the Austrian Public Health Institute (Gesundheit Österreich GmbH – GÖG GmbH) on behalf of the Austrian Ministry for Labour, Social Affairs, Health, and Consumer Protection (BMASGK) recently published an updated version of their methodological handbook for establishing quality standards (Methode zur Erstellung von Qualitätsstandards) based on the mentioned process guides from NICE and HQO [38]. The handbook proposes a three-step procedure for developing quality standards in Austria:

Table 6-1: Three-step procedure for developing quality standards in Austria

Phase	Explanation
Determination of the core elements of the standards	"In the first preparation phase, a brief **overview** of the initial situation including potential fields of action is to be drawn up, on the basis of which the **constituent advisory board** defines the **core elements** of the quality standard."
Creation of the quality standard	"The second phase comprises the **creation of the quality standard** itself. It must be **structured uniformly**; the respective recommendation chapters are structured according to a defined scheme. After researching **evidence** of potentially **effective measures** to **improve the quality of care** in the respective field of action, the recommendations are formulated and justified. With regard to measurability and verifiability, quality indicators for the individual recommendations should be proposed (if possible). The **advisory board comments** on the draft **quality standard**, followed by **quality assurance** through at least two external expert reviews and **public consultation**. Afterwards, the authors finalise the quality standard with the involvement of the advisory board."
Political and organisational implementation of a quality standard	"The third phase, the **political and organisational implementation** of a quality standard, **cannot be described in the methods manual,** as **concrete implementation steps** generally take place **at country level** taking into account regional conditions and requirements. In order to disseminate the contents of the quality standard, however, its **broad publication should be ensured**. The validity of a quality standard is usually set at five years. In good time before its expiry, it should be evaluated and checked for updating requirements."

ein legitimierter, wissenschaftlich korrekter und einheitlicher Qualitätsstandard ist wesentlich für die Akzeptanz und Einhaltung

A legitimised quality standard that should be legally binding is more likely to be accepted and complied with by the affected entities. It further promotes enforcement of possible deviations if a scientifically correct and uniform method for implementation is ensured. As defined in the third step of the quality standard development process in Table 6-1, the political and organisational implementation of a quality standard cannot be described in a method handbook, as concrete implementation steps generally take place at the national level in order to take into account regional differences and requirements [38]. However, after completion of the quality standard, some downstream processes such as monitoring still need to be considered.

6.2 Use and Maintenance (Monitoring)

administrative MM sind abhängig von der Fähigkeit, sie in bestehende Monitoringsysteme zu integrieren

Questions related to the external validity, monitoring and the associated (regulatory) framework of MVSs in the day surgery context remain mostly unanswered in the literature investigating the VOR [10, 13]. Generally, whether administrative MVSs in day surgery are useful, is not only highly dependent on scientific evidence, but also on the ability to integrate them into existing monitoring frameworks to identify possible consequences. Consequences may include possible gaps in comprehensive care, change in waiting times, supply bottlenecks, shifting of patient flows, or excessive burdens in hospitals or care units that have already a high number of cases.

In the quality standard context, monitoring can be understood as maintaining periodic surveillance of performance in a systematic manner on various levels. Self-evaluation is indeed important for quality assurance. Additional (external) monitoring by non-departmental public bodies or third party bodies on national, regional, or sectoral level can support quality assurance by reducing possible biases due to self-evaluation [121]. With regard to the health system, monitoring can be conducted on a micro-level, e.g. surgeon or hospital unit monitoring or on a macro-level, i.e. national or international monitoring [119].

Monitoring = systematische Überwachung der Performance auf verschiedenen Ebenen durch verschiedene (unabhängige) Instanzen

In Austria, the B-ZV stipulates an Austria-wide monitoring of the defined goals differentiated by sectors and regions, to be carried out at federal level and further developed in terms of content [50, 51, 120]. The respective monitoring based on administrative data (Routinedaten) is carried out by the Austrian Public Health Institute including dissemination of a status report to pursue the objective of transparently presenting the realisation and progress of the objectives [122]. It constitutes an integral part of the reform process and represents the degree to which the objectives have been achieved at federal and state level.

in Österreich spezifiziert der Bundesziel-steuerungsvertrag mehrere strategische und operative Ziele

Strategic objective 1 in the federal B-ZV *"aims to ensure needs-based supply structures by strengthening outpatient and ambulatory care while relieving the burden on acute inpatient care and optimising the use of resources"*. In addition, as part of operational objective 8, *"Ensuring the quality of results in the entire outpatient area",* the concept for measuring quality and measurement parameters in the outpatient and ambulatory area is to be further developed. Hence, the operational strategic objective 1, operational objective 8 and the lack of a comprehensive quality measurement system including monitoring of the ambulatory sector opens space for the debate on MVSs and the respective monitoring responsibilities in Austria in the future [123, 124].

2 dieser Ziele bieten nicht nur die Möglichkeit für eine MM-Debatte, sondern auch für eine Debatte über ein einheitliches Monitoringsystem möglicher MM im gesamten ambulanten Bereich

A comprehensive and uniform monitoring system, not only specifically for implemented administrative MVSs, is imperative because of two reasons. First the contract parties committed themselves to quality in the health care system, and second a comprehensive, comparable and standardised quality measurement including monitoring in the inpatient (intramural) and outpatient (extramuraler/niedergelassener Bereich) area represents an essential basis for further developments in the health care system [49].

ein umfassendes und einheitliches Monitoring inkl. Monitoring von möglichen MM im ambulanten Bereich ist essentiell

7 Regulation for day surgery in Germany (Ambulantes Operieren)

7.1 Legal framework

7.1.1 Nationwide contracts and agreements

in Deutschland können mittlerweile viele OPs auf ambulanter bzw. tageschirurgischer Basis durchgeführt werden – ambulantes Operieren (AO)

In Germany, by now a wide range of surgical procedures can be performed on an ambulatory basis by (contracted) doctors in private practise (niedergelassener Bereich). These include arthroscopies, cataract operations, biopsies, and more. In addition, in accordance with § 115 b para. 1 SGB V, the statutory health insurance (gesetzliche Krankenversicherung – GKV), the German Hospital Federation (Deutsche Krankenhausgesellschaft – DKG) and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung – KBV) have agreed by contract to strengthen ambulatory surgery and substitute surgical procedures in the inpatient setting, which is in effect since 01.06.2012 with an editorial update in 2014.

AOP-Vertrag definiert einheitliche Rahmenbedingungen zwischen dem Krankenhaussektor und dem niedergelassenen Bereich

The contract for ambulatory surgery (so-called AOP contract) is intended to create a uniform framework for the performance of ambulatory surgeries and inpatient substituting procedures and to support the cooperation between contracted private practice (niedergelassener Bereich) and the hospital sector. Its aim is to ensure patient-friendly and economic care on the basis of § 39 SGB V in order to avoid unnecessary inpatient hospital treatment and to improve cooperation between private practice and the hospital sector, including the joint use of surgical capacities in the hospital.

zusätzlich zum AOP-Vertrag gibt es ein einheitliches Vergütungssystem

Supplementary to the AOP contract, they agreed on an associated uniform remuneration for hospitals and KBV-contracted physicians. The remuneration system of the federal association of statutory health insurance physicians (Einheitlicher Bewertungsmaßstab – EBM) regulates medical and ambulatory services to be provided at the expense of the statutory health insurance fund. Legal basis is § 87 paragraph 1 of the social security statute book V (SGB V) prepared by the evaluation committee consisting of the federal association of statutory health insurance physicians (Kassenärztliche Bundesvereinigung – KBV) and the German association of the statutory health insurance fund (GKV). Ambulatory surgery is administered in Chapter 31 of the EBM.

AOP-Katalog listet alle relevanten ambulanten und tageschirurgischen Leistungen

All relevant surgeries for ambulatory surgery are listed in a catalogue – called AOP catalogue – which has been compiled by the KBV, the GKV and DKG in the course of establishing the AOP contract. Hospitals are obliged to report ambulatory services to their regional association of the statutory health insurance funds (Landesverband der Krankenkassen) and the associations of the substitute funds (Ersatzkassen), the regional association of social health insurance physicians (Kassenärztliche Vereinigung – KV), and the admission committee (Zulassungsausschuss) in accordance with § 1 of the AOP contract. KBV-accredited physicians require approval from their respective regional KV to be eligible for ambulatory surgery.

Durchführung von AO wird durch die regionale KV genehmigt

einige OPs benötigen eine zusätzliche Genehmigung

For some surgeries such as colonoscopy, invasive cardiology, arthroscopy, cataract surgery, photodynamic therapy (PDT), and phototherapeutic keratectomy (PTK) an additional approval must be obtained by the KV – in addition to the general approval to operate on an ambulatory basis.

AOP-Vertrag spezifiziert die Einhaltung von Mindestanforderungen und Frequenzregelungen (Mindestmengen)

The AOP contract specifies that minimum requirements according to the professional qualification have to be fulfilled for a successful approval of the specific surgery in the ambulatory setting (Facharztstandard/Fachliche Befähigung). Furthermore, the contract stipulates that frequency requirements (Frequenzregelung) to maintain the approval to conduct ambulatory surgery have to be fulfilled.

The AOP contract according to § 115b para. 1 SGB V states the following with regard to professional qualifications and frequency regulations [12]:

> *"Medical services in accordance with § 115b SGB V are provided in accordance with the respective* ***professional standard*** *valid at the time of treatment. [...]"*

and

> *"[...] Guidelines and resolutions of the Joint Federal Committee pursuant to § 92 Paragraph 1 Sentence 2 No. 13 SGB V and pursuant to § 137 Paragraph 1 Sentence 1 SGB V shall be taken into account. This concerns in particular the execution of hygiene controls, the adherence to the further structure quality as well as the adherence to* ***frequency regulations*** *.* ***Frequency regulations*** *are to be fulfilled* ***physician-related*** *[...]"*[5]

Frequenzen bzw. MM sind meist konsensbasiert

According to the KBV, in order to try to operationalise the definition of a frequency, the limits often cannot be clearly defined according to the rules of evidence-based medicine, but are consensus-based values [125].

zusätzlich zum AOP-Vertrag gibt es eine Qualitätssicherungsvereinbarung für das AO

As part of the contract, the three parties (GKV, KBV and DKG) have laid down special quality measures in the corresponding agreement on "quality assurance measures according to § 135 para. 2 SGB V for ambulatory surgery" (quality assurance agreement for ambulatory surgery). All service providers including the KV are obliged to ensure and further develop the quality of their services and to adopt the specified structural quality requirements. In addition, a joint declaration of the contract partners also ensures that the structural quality requirements apply to ambulatory surgeries performed in the inpatient sector [126, 127].

die OP-spezifischen MM sind in zusätzlichen Qualitätsvereinbarungen festgelegt

The surgery specific minimum volume requirements to conduct the specific surgery (professional standard) and the frequency requirements to continue the specific surgery are specified in corresponding quality agreements in addition to the general agreement on "quality assurance measures according to § 135 para. 2 SGB V for ambulatory surgery". Table 7-1 in section 7.3 shows the day and ambulatory surgeries for which specific minimum frequencies are defined.

Frequenzregelung ist ähnlich zu den MM im stationären Sektor

The frequency regulation is similar to the minimum volumes for the inpatient sector according to § 136b Abs. 1 Satz 1 Nr. 2 SGB V that determine the amount of the respective annual minimum quantity per physician and/or hospital location for selected plannable inpatient services for which the quality of the treatment outcome depends on the quantity of services provided.

[5] Authors translation

7.1.2 Regional level: Structural contracts/Special Care

"Strukturverträge" auf regionaler Ebene

As mentioned before, some surgeries need additional approval by the regional KV and can also be part of so-called structural contracts. These regional contracts are intended to broaden the scope for health insurance funds and the 17 KVs to design their own policies and remove bureaucratic obstacles of selective contracts. This includes differentiated fee systems, but also additional minimum volume requirements can be part of these contracts.

Strukturverträge werden jetzt im Zuge der „Besonderen Versorgung" festgelegt (alte Verträge behalten Gültigkeit)

The agreement of structural contracts in accordance with § 73a SGB V was possible until July 2015. With the SHI Health Care Strengthening Act (GKV-Versorgungsstärkungsgesetz), this type of contract was replaced by "special care" in accordance with § 140a SGB V (§ 140a SGB V Besondere Versorgung). Structural contracts already contracted continued to apply. In practice, the structural contracts mainly concern practice networks or ambulatory surgery including minimum volume and frequency requirements [128].

7.2 Monitoring and Reporting

die regionale KV prüft die Einhaltung der MM, bei Nichteinhaltung wird die Abrechnungsmöglichkeit widerrufen

The KVs are obliged by law to promote quality in the ambulatory setting of KV-accredited physicians according to § 135b para. 1 SGB V. One aspect of this task is the audit of minimum volumes and the frequency regulation. The regional KVs regularly check whether physicians meet the minimum number of examinations and treatments prescribed. Once the required number of cases has been reached, the audit is completed. If the minimum quantities are not provided within the specified period, the billing authorisation is revoked and the doctor may no longer provide the examination at the expense of the statutory health insurance [125].

Dokumentation und Veröffentlichung der Ziele und Ergebnisse im Zuge von Jahresberichten

Furthermore, the documentation and publication of the objectives and results by the KVs are further aspects in the course of promoting quality in the ambulatory setting. The presentation of the quality of ambulatory care is conducted in the course of an annual quality report by the KV and KBV. The data basis consists of a systematic evaluation of the electronic documentation provided by the KV-accredited physicians in the course of their documentation obligation, random individual case examinations and, in rare cases, medical practice inspections.

Jahresbericht der KV/ des KVB enthält mehr als 50 Themen der ambulanten Versorgung mit Darstellung auf einer aggregierten Ebene

The annual reports contain detailed information on the type, scope, and results of the quality promotion measures undertaken on about 50 topics of ambulatory care at federal and KV level. The reporting is largely performed on an aggregated level [125]. Data reporting at the institution level is not intended in the KBV quality reports. Part of the published report are number of approved physicians to ambulatory surgery, number of approved ambulatory surgeries, and results of the aforementioned audits on compliance frequency regulations.

7.3 Frequency regulation for specific surgeries

7 ambulante/ tageschirurgische Interventionen mit MM auf Bundesebene

Table 7-1 gives an overview of the specific procedures that are affected by a volume regulation framework in the German context. The table provides information on nationwide frequency requirements (seven interventions) and minimum requirements set by the regional KVs in structural contracts on the following aspects:

- Procedure(s),
- Minimum volume requirements to be approved for conducting the surgery in the ambulatory setting (professional standard),
- Frequency requirements to maintain the professional qualification defined in the respective quality assurance agreement or regional structural contract for the specific surgery,
- Consequences of non-compliance with frequency requirements, and
- Restoring of allowance to conduct surgery.

Table 7-1: Minimum volume and frequency requirements for ambulatory surgery (Ambulantes Operieren) in Germany

Procedure	(1.) Minimum volume and (2.) frequency requirements	(3.) Consequences of Non-Compliance with frequency requirements and (4.) Restoring of allowance
Nationwide frequency requirements/regulation in the AOP contract according to § 115b paragraph 1 SGB V		
Arthroscopy [129]	(1.) If facultative further education/training in "special orthopaedic surgery" in the field of orthopaedics was not completed, the surgeon has to certify **180** independently conducted arthroscopic surgeries under guidance of an authorised surgeon[6]. (2.) -	(3.) - (4.) -
Diabetic foot treatment[7] (ablation of extended necroses) [130]	(1.) NA (2.) Treatment of at least **100** patients with diabetes mellitus per quarter on average over the **last 4 quarters** prior to treatment application.	(3.) Loss of reimbursement (4.) NA
Colonscopy/ Polypectomy [131]	(1.) Independent performance of at least **200** total colonoscopies/ **50** polypectomies under guidance of an authorised physician **within** a period of **24 months**. (2.) Independent performance of at least **200** total colonoscopies/ 10 polypectomies without deficiencies in accordance with the quality assurance agreement colonscopy within a period of **12 months**.	(3.) The KV shall determine whether the required evidence has been provided. If no evidence has been provided, the KV shall immediately inform the physician thereof. If the inspection reveals deficiencies according to the quality agreement colonscopy or if less than 200 total colonoscopies/ 50 polypectomies have been carried out, the authorisation shall be withdrawn. (4.) Approval shall be restored upon application if the physician can prove that she/he has performed at least 50 total colonoscopies, including the required polypectomies, under the supervision of an authorised physician, within six consecutive months of revocation of approval. In this case, the other licensing requirements according to the general approval to conduct ambulatory surgery do not have to be proven again.
Colposcopy[8] (comes into force in 2020) [132]	(1.) -	(3.) If the evidence cannot be provided again after further 12 months, the authorisation to perform and bill for this service shall be revoked.

[6] 30 of the 180 surgeries need to be special arthroscopic surgeries such as surgeries with meniscus, plica, Hoffa's fat pad resection and/or removal of corpora liberia, cartilage smoothing, microfracture surgery, patella shaving, lateral release and/or removal of meniscus ganglion, synovectomy, curettage, fixation of a detached cartilage fragment etc. For a full list see the respective quality assurance agreement for arthroscopic services [83].

[7] According to the German diabetes society, inpatient admission is only indicated for severe (or moderate) infections.

[8] If medically indicated, colposcopically controlled biopsies from the most severe lesions (transformation zone type 1 and type 2) and an endocervical curettage (transformation zone type 3) will be performed.

Procedure	(1.) Minimum volume and (2.) frequency requirements	(3.) Consequences of Non-Compliance with frequency requirements and (4.) Restoring of allowance
Colposcopy[8] (comes into force in 2020) [132] *(Fortsetzung)*	(2.) **Annual provision** of evidence of at least **100** clarification colposcopies with abnormal findings of portio, vagina and vulva and at least **30** histologically confirmed cases of intraepithelial neoplasia or invasive carcinomas in the **last 12 months**. Annual proof of regular participation (at least 2 times per half-year) in interdisciplinary case conferences (e.g. tumour conferences). Personal attendance or in justified exceptional cases by videoconference.	(4.) NA
Intravitreal administration of medications (IVM/IVOM) [133]	(1.) Independet implementation of **100** intraocular interventions (without laser therapy) (2.) –	(3.) - (4.) -
Interventional radiology/Interventional angiography[9] [134]	(1.) Independent diagnosis and documentation of at least **500** diagnostic vascular imaging or therapeutic interventions, of which at least **250** are catheter-assisted under guidance within the **last 5 years** prior to the application for approval. The catheter-assisted therapeutic interventions must include at least **100** vasodilative and at least **25** vascular-obliterated interventions. (2.) Independent indication, diagnosis and documentation of **100** diagnostic vascular imaging or therapeutic interventions, of which at least **50** are therapeutic interventions, if necessary including aftercare, **within** a period of **12 months**.	(3.) KV determines whether the required evidence has been provided. If no evidence has been provided, the KV shall immediately inform the physician thereof. If the evidence cannot be provided again after a period of 12 months following the first period, the authorisation is revoked. (4.) Permission to perform diagnostic catheter angiographies and therapeutic interventions is granted again upon application if the physician can prove that she/he has performed at least 50 diagnostic catheter angiographies or catheter-assisted therapeutic interventions, of which at least 25 therapeutic interventions, under the supervision of an authorised physician, are done within six consecutive months of the revocation of permission. In this case, the other licensing requirements do not have to be proven again.
Vacuum biopsy of the breast [135]	(1.) Independent indication and implementation of 25 punch biopsies under ultrasound control and 25 vacuum biopsies under guidance within the last 2 years before application (2.) Independent performance of at least **25** vacuum biopsies **within** a period of **12 months**.	(3.) The KV determines whether the required evidence has been provided. If the evidence has not been provided, the KV shall inform the physician immediately. (4.) If the proof cannot be provided again after the expiry of the initial period of 12 months, the authorisation shall be revoked. The authorisation is restored on application if the doctor can prove that she/he has carried out at least 25 vacuum biopsies under the supervision of an authorised doctor within 6 months of revocation of the authorisation. In this case, the other licensing requirements need not be proven again.

[9] Interventional radiology contains minimal invasive procedures such as interventional angiographies and interventions on the arterial vascular system (PTA, Stents etc.)

Procedure	(1.) Minimum volume and (2.) frequency requirements	(3.) Consequences of Non-Compliance with frequency requirements and (4.) Restoring of allowance
Structural contracts of the respective KV/regulation in the quality assurance agreements according to § 140a SGB V.		
Cataract surgery KV Bayern [136]	(1.) At least **400** cataract surgeries independently performed **until** the date of **submission** of the declaration of approval (surgeries conducted in the inpatient setting can be credited). (2.) At least **50** ambulatory cataract surgeries must be performed **per quarter** on an **annual average**.	(3.) Withdrawal of the right to participate (4.) Entitled to participate again at the earliest after two full quarters. This requires a renewed submission of a declaration of participation by the physician as well as a renewed granting of the participation permit after examination of the general requirements.
Cataract Surgery KV Sachsen-Anhalt [137]	(1.) NA or rather SHI-accredited ophthalmologist (2.) At least **200** cataract surgeries **per year**	(3.) Participation is terminated, if the requirements and contractual arrangements laid down are no longer met or complied with. (4.) NA
Cataract Surgery KV Nordrhein [138]	(1.) At least **100** cataract surgeries independently performed in the **last 4 quarters** (2.) A minimum of **100** cataract operations **per year**	(3.) In the following year the doctors will be excluded from participation in the following quarter on by notification. (4.) NA
Retinal and vitreous surgery (vitreoretinal surgery) KV Nordrhein [139]	(1.) In total, the following operations must have been carried out in the **last 10 years**: **50** independently conducted denting operations in retinal detachments as (not in the context of other procedures such as pars plana vitrectomies), **300** pars plana vitrectomies (PPV), of which at least **80** pars plana vitrectomies in diabetic retinopathy, **70** pars plana vitrectomies in rhegmatogenic retinal detachment or proliferative vitreoretinopathy, **70** pars plana vitrectomies in macular diseases, **5** pars plana vitrectomies in trauma (p.rimary care and/or vitreoreticomplications after trauma) Proof of evidence of at least **150** further specified retinal/vitreous surgeries in the **last 8 quarters** prior to application for participation in the contract. (includes all denting operations and pars plana vitrectomies with or without retinal/vitreous surgery or without supplementary procedures on the posterior segment of the eye, but not only intravitreal drug injections). (2.) NA	(3.) Participation in the contract ends as soon as the participating ophthalmic surgeon does not or no longer completely fulfil the conditions for participation and in the event of breach of contractual or professional obligations. (4.) NA
The KV Nordrhein agreed on a contract to promote ambulatory surgery and inpatient subsituting services. The contract includes minimum frequencies for 4 specialities (surgery/orthopaedics, otorhinolaryngology, gynaecology, urology). Whether these frequencies serve for quality assurance cannot be inferred on the basis of the available documents [140].		

KV – Kassenärztliche Vereinigung (regional Association of Social Health Insurance Physicians), NA – not available, "-" indicates that this point is not relevant for the specific intervention, because consequences and re-storing allowance are dependent on existing frequency requirements and not minimum volume requirements (professional standard)

8 Clinical effectiveness of minimal volumes

8.1 Outcomes

7 unterschiedliche Indikationen und 6 verschiedene entscheidungsrelevante Endpunkte für die Wirksamkeit

Provided that seven different indications are analysed in the scope of this assessment, an extended list of efficacy outcomes is considered *crucial* to derive a recommendation:

- Survival rate
- Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) score
- Revision surgery
- Hospital visit within 30 days
- Non-routine disposition of patients at discharge
- Length of stay (LOS)

zusätzliche Endpunkte

Further outcomes included in the assessment were:

- Re-admission including admission for 23 hrs observation and full admission (obs. longer than 24 hrs)
- (Risk-adjusted) Incidence of postcataract surgery endophthalmitis
- Reduction in pain score units on visual analogue scale (VAS)
- Mean operating time

Thyreoidektomie: 23 h-Beobachtung und stationäre Aufnahme

For the intervention of thyroidectomy (outpatient thyroid surgery), discharge on the day of surgery, **admission for 23 hrs observation and full admission (longer than 23 hrs)** were measured and assessed in relation to surgeon volume.

Katarakt-OP: (risikoadjustierte) Inzidenz einer Endophthalmitis nach der OP und Risiko einer Revisionsoperation

For the intervention of cataract surgery (general), (**risk-adjusted) incidence of post-cataract surgery endophthalmitis** was assessed in relation to annual surgeon volume. Reporting of endophthalmitis was done with respect to total endophthalmitis (TE) cases, overall endophthalmitis rate per 1,000 surgeries (ERpT), relative risk of endophtalmitis (RR), and risk-adjsuted relative risk of endopthalmitis (RARR). The risk-adjustment was applied with regard to age, gender, ethnicity, year, ambulatory surgery centre, and surgeon experience in years. Also, the outcome of **risk of revision surgery** was determined in relation to surgeon volume. Revision surgery included placing of a posterior chamber or sulcus intraocular cataract lenses (IOL) and placement of anterior chamber IOLs.

Hüftarthroskopie: Überlebensrate und Re-operation (Re-OP)

For the intervention of hip arthroscopy, **survival rates** at two, five, and ten years were measured and assessed in relation to surgeon volume. Also, the outcome of **risk of reoperation** was measured in relation to surgeon volume. Reoperation included revision scope, resurfacing, or total hip arthroplasty.

Karpaltunnel-OP: BCTQ-Score und Schmerzreduktion anhand der VAS

For the intervention of open carpal tunnel release, **BCTQ score** was measured at six weeks, three months, and six months postoperatively. It was assessed in relation to surgeon volume. Two domains of BCTQ were assessed in particular: the Symptom Severity Scale (11 items) and the Functional Status Scale (8 items). Each item consists of five response categories ranging from one to five, where higher score represents worse symptoms/lower level of function. Responses to items were averaged to create an overall score for each domain. Also, the secondary outcome of **reduction in pain score units on VAS** was assessed in relation to surgeon volume. The scale ranged from 0 to 100 and was measured six weeks, three months, and six months postoperatively.

OP der RM: nicht-routinemäßige Disposition bei der Entlassung, Aufenthaltsdauer und durchschnittliche OP-Dauer

For the intervention of rotator cuff repair, the outcome of **non-routine disposition of patients at discharge** was assessed in relation to surgeon as well as hospital volume. Non-routine disposition includes transfer to another hospital, skilled nursing facility, intermediate care facility, or home health care (health care provided at home by licensed health professionals). Routine disposition reflected patients who were discharged home. Also, the outcome of **length of hospital stay (LOS)** was assessed with respect to surgeon and hospital volume. LOS was divided into two categories: less than 1 day and greater than or equal to 1 day – that was termed extended length of stay. The outcome of **mean operating time** was assessed as well in relation to hospital and surgeon volume. Operating room time was calculated in minutes for every procedure and defined as the total time spent in the operating room exclusive of preoperative and postoperative time.

LCA-Rekonstruktion/ Meniskekotomie: nicht-routinemäßige Disposition bei der Entlassung und stationäre Aufnahme

For the interventions of anterior cruciate ligament reconstruction and meniscectomy, the outcomes of **non-routine disposition of patients at discharge** and **LOS** (described above) were used. Also, the outcome of **inpatient hospital admissions or emergency department visits within 30 days** of ACL surgery was assessed in relation to hospital volume.

8.2 Included studies

8 Studien erfüllten die Einschlusskriterien, keine Studie wurde prospektiv durchgeführt

For the assessment of clinical effectiveness, eight studies met the inclusion criteria. One of the studies had a control group [21], however, none of the studies was done prospectively – all the studies were retrospective. Two studies were found on the intervention of **ACL reconstruction** [23, 26], two on **cataract surgery** [22, 24], and one for each of the following interventions: **meniscectomy**, **thyroidectomy**, **primary hip arthroscopy**, **open carpal tunnel release**, and **rotator cuff repair** [21, 25, 27, 28].

Study characteristics

2 Single-Center-Studien und 6 Analysen anhand von Daten aus Gesundheitsdatenbanken

7 Studien aus den USA und 1 aus den Niederlanden

While two studies were single centre analyses [21, 22], the remaining six studies were analyses of health care databases [23-28]. Seven studies were conducted in the US [21-26, 28] and the eighth study was conducted in the Netherlands [27]. Information about study sponsors was not disclosed in five studies [21-23, 25, 26], two studies were funded by the NIH/NIAMS [27, 28], and one study was funded by the NEI [24]. Two studies did not report on conflict of interests (COI) [25, 26], four studies reported that none of the authors had COI [22-24, 27], and two studies reported COI of one of their authors [21, 28]. The dates of data collection in all the studies was between 1997 and 2015.

4 Studien nahmen eine ChirurgInnensicht, 1 Studie eine Krankenhaussicht und 3 Studien eine kombinierte Sicht ein

All the studies gathered data on the outpatient setting and while four studies analysed the VOR from the perspective of surgeons [22, 24, 27, 28], one analysed it from the hospital perspective [23], and three from the perspectives of both surgeons as well as hospitals [21, 25, 26]. Follow-up time was not reported in five studies [21, 22, 24-26], it was ten years in [28], six months in [27], and 30 days in [23].

Patient characteristics

The analysis of **primary hip arthroscopy** included 7,836 patients and 8,267 procedures that were performed by 295 surgeons in 137 centres [28]. The analysis of **carpal tunnel release** included 1,345 patients/procedures (712 patients not followed-up) performed by 17 surgeons in 11 centres [27]. The analysis of **rotator cuff repair** included 9,973 patients (961 not followed-up) [25], **ACL reconstruction** included 45,262 patients (14,050 not followed-up) [23, 26], and the analysis of **meniscectomy** included 123,012 patients (72,585 not followed-up) [26]. The number of procedures, surgeons, or surgical centres was not reported in the three studies above. For the single centre analysis of **thyroidectomy**, 109 outpatient and 51 inpatient patients were included with 35 and 26 procedures respectively [21]. For the analysis of **cataract surgery**, 2,289,307 patients were included (200,520 not followed-up) with 3,280,966 procedures conducted by 22,877 surgeons in an unclear number of centres (except for four surgeons that were part of a single centre analysis [22]). Because of the retrospective nature of the studies, loss to follow-up was not reported.

Studien wurden alle retrospektiv durchgeführt --> Lost to follow-up wurde nicht berichtet

Surgeon as well as hospital volume was categorised into low, medium, and high (very high in one study [28]) and the thresholds differed with interventions. The low volume threshold ranged from six to 411 interventions, while the high (or very high) threshold ranged from 30 to 1,336 interventions per year. Inclusion and exclusion criteria were heterogeneous as they varied with interventions. Co-interventions were reported in four studies [21, 23, 25, 27] and the mean age ranged from 29,4 to 73 years.

Leistungsvolumina wurden in Kategorien eingeteilt (niedrig/ mittel/hoch/sehr hoch)

Study characteristics and results of included studies are displayed in Table 13-1 and Table 13-2 and in the evidence profile in Table 13-3.

Charakteristika und Ergebnisse der Studien im Anhang

8.3 Quality of evidence on clinical effectiveness and safety

The quality assessment of individual studies was done using the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force Checklist for Quality Assessment of Retrospective Database Studies [30]. The assessment is presented in Table 13-3 in the Appendix. All the studies included were assessed to be of very low quality.

ISPOR-Checkliste für die Qualitätsbeurteilung der Evidenz

None of retrospective studies provided a rationale for the use of their respective study design, none developed an a priori data analysis plan, and only two studies recognized their study design as a potential limitation [23, 28] (one partially [24]). Furthermore, inclusion and exclusion criteria were clearly described in three studies [24-26] and in only one study was the impact of study findings clearly described (in relation to eligibility criteria) [24]. With respect to the statistical models, only one study explained the rationale for the statistical method used and it was the same study that was also the only one that discussed how well their multivariate statistical techniques predict what was intended [24].

methodische Studienqualität und Berichtsqualität

Generalisierbarkeit, klinische und ökonomische Evidenz

Moreover, in none of the studies did the authors provide a theory for the findings and ruled out other plausible explanations (except for [24]) and only two studies interpreted the statistical findings in terms of their clinical or economical evidence [21, 24]. Limits to generalisability of the retrospective study results were recognised in three studies [23, 24, 28].

Evidenzgrad der MM hinsichtlich Wirksamkeit und Sicherheit sind sehr niedrig

Overall the strength of evidence for the effectiveness and safety of MVSs in the day surgery setting was very low. No comparative prospective evidence was found to answer the PICO question on the effect of MVSs in day surgery.

8.4 Results

Mortality

Hüftarthroskopie: positive Assoziation zwischen erbrachter Menge pro ChirurgIn und Überlebensrate nach 2, 5 und 10 Jahren

Survival rates related to surgeon volume were reported at two, five, and ten years in one study [28]. Yearly volume rates ranges from low (<102), medium (102-164), high (164-340), to very high (≥340). At two years after **hip arthroscopy**, survival rates were 86.5, 87.7, 94.6, and 97.6%, respectively. At five years, survival rates were 78.5, 82.7, 90.2, and 97.6% respectively. At ten years, the same trend was observed with survival rates of 72.7, 82.7, 90.2, and 97.6%, respectively.

Morbidity

Revision surgery

Katarakt-OP: Fallzahl pro ChirurgIn korrelierte negativ mit der Rupturrate der hinteren Linsenkapsel

With respect to surgeon volume, the **cataract surgery (phacoemulsification)** study reports for four surgeons that the number of cases per surgeon was inversely correlated with posterior capsule rupture (PCR) [22]. The surgeon with 411 total cases per year had a PCR and vitreous loss (VL) rate respectively of 3.75%, the surgeon with 536 annual cases had a PCR/VL rate of 0.37%, the surgeon with 1,056 total cases had a PCR/VL rate of 0.28%, and the fourth surgeon with an annual case load of 1,336 had a PCR/VL rate of 0.29%. Overall, 23 of the 3,339 patients (0.68%) needed a revision surgery. Five of the 23 patients did not have sufficient support to place a posterior chamber or sulcus intraocular cataract lenses (IOL) and required placement of anterior chamber IOLs.

Non-routine disposition at discharge

3 Studien berichteten über den Zusammenhang der erbrachten Menge und nicht-routinemäßiger Disposition bei Entlassung

The relationship between hospital/surgeon volume and patients' health condition after day surgery was reported in three studies through the outcome of non-routine disposition of patients at discharge [21, 25, 26]. Non-routine disposition includes re-admission including admission for 23-h observation, full admission (obs. longer than 24 hours), transfer to another hospital, skilled nursing facility, intermediate care facility, or home health care. Over the period of four years, two studies report on the same curve that the higher the hospital/surgeon volume, the lesser the number of patients with non-routine disposition at discharge [25, 26].

For the intervention of **rotator cuff repair** [25], **ACL reconstruction** [26], and **meniscectomy** [26], the surgeon volume rates ranged from low (<15/<25/<75), medium (15-30/25-75/75-175), to high (≥30/≥75/≥175), respectively. In case of **rotator cuff repair**, low and medium volume surgeons were 2.8 (CI 0.9-9.1) and 1.5 (CI 0.7-3.1) times more likely to have non-routinely disposed patients at discharge than high volume surgeons [25]. In case of **ACL reconstruction**, low and medium volume surgeons were 4.5 and 2.25 times more likely to have the same outcome compared to high volume surgeons [26]. And in case of **meniscectomy**, low and medium volume surgeons were 2.8 and 1.4 time more likely to have non-routinely disposed patients at discharge than high volume surgeons [26].

OP der RM, LCA-Rekonstruktion und Meniskektomie: PatientInnen von ChirurgInnen mit niedriger bzw. mittlerer Leistungsmenge neigten zu häufigeren nicht-routinemäßigen Dispositionen

For the intervention of **rotator cuff repair** [25], **ACL reconstruction** [26], and **meniscectomy** [26], the hospital volume rates ranged from low (<75/<125/<600), medium (75-200/125-300/600-1,200), to high (≥200/≥300/≥1,200), respectively. In case of **rotator cuff repair**, low and medium volume hospitals were 2.1 (0.6-8.0) and 1.7 (0.2-11.6) times more likely to have non-routinely disposed patients at discharge than high volume hospital [25]. In case of **ACL reconstruction**, low and medium volume hospitals were 3.33 and 0.66 time more likely and in case of **meniscectomy**, low and medium volume hospitals were 8 and 6 time more likely to have nonrou-tinely disposed patients at discharge than high volume hospitals [26].

Zusammenhang galt auch für PatientInnen in Krankenhäusern mit niedrigeren bzw. mittleren Leistungsmengen

For the intervention of outpatient **thyroidectomy** [21] in the low-surgical volume hospital, there were no re-admission in same-day surgery patients. One patient was discharged from the emergency room for symptoms of paraesthesia with normal calcium levels. The surgeon volume amounted to ten thyroid surgical cases per year on average. The hospital volume averaged of 20 thyroid surgical cases per year.

Thyreoidektomie: keine Wiedereinlieferungen in einem Krankenhaus mit niedriger tageschirurgischer Leistungsmenge

(Risk-adjusted) Incidence of postcataract surgery endophthalmitis

For the intervention of **cataract surgery** (general) an inverse volume-response relationship was observed between endophthalmitis incidence and surgical volume [24]. The surgeon volume categories ranged from 1-50 (1), 51-200 (2), 201-500 (3), 501-1,000 (4) and ≥1,001 (5). Surgeons in category (1) had an overall endophthalmitis rate per 1,000 surgeries (ERpT) of 2.57 with annual total endophthalmitis (TE) cases of 352. The overall ERpT surgeries in the categories (2), (3) and (4) were 1.49, 1.17 and 0.80 with TE cases of 1,1455, 1,512 and 454. Surgeons in the category (5) had the lowest overall ERpT surgeries with 0.62 and 168 cases of TE. The difference in relative risk for endophtalmitis was 4-fold (RR of 4.17) among surgeries performed by surgeons in category (1), completing between 1 and 50 surgeries per year, compared with surgeons in category (5) that served as the reference group, whose annual volume was ≥ 1,000 surgeries. Surgeons in category (4), (3) and (2) had a relative risk of 1.30, 1.89 and 2.42 compared to the reference group (5). After adjusting for risk factors the RR in category (1) was still 3.8-fold higher than in the reference category (5).

Katarakt-OP: inverser Zusammenhang zwischen Leistungsmenge und Endophthalmitis-Inzidenz

Mean operating time

The outcome of mean operating time is reported here for its potential connection with morbidity. Reported in the same studies with the same volume parameters as the outcome of disposition at discharge, mean operating time was reported with respect to both surgeon as well as hospital volume. The general trend remained that the higher the volume, the shorter the operating time.

durchschnittliche OP-Dauer potentiell mit Morbidität verknüpft

je höher die Leistungsmenge pro ChirurgIn, desto kürzer die durchschnittliche OP-Dauer für OP der RM, LCA-Rekonstruktion und Meniskektomie

With respect to surgeon volume, the **rotator cuff** study reports similar mean operating time for low and medium volume surgeons (112±4 and 113±4 minutes, respectively) and shorter time for high volumes surgeon (102±4 minutes with p<0.001) [25]. In case of **ACL reconstruction**, low and medium volume surgeons had a longer mean operating time (149±9 and 137±9 minutes, respectively) compared to high volume surgeons (122±9 minutes) [26]. And in case of **meniscectomy**, low and medium volume surgeons had a longer mean operating time (72±6 and 64±6 minutes, respectively) compared to high volume surgeons (53±6 minutes) [26].

je höher die Leistungsmenge pro Krankenhaus, desto kürzer die durchschnittliche OP-Dauer für OP der RM, LCA-Rekonstruktion und Meniskektomie

With respect to hospital volume, the **rotator cuff** study reports the same inverse relationship of mean operating time and volume. Low and medium volume centres had the mean operating time of 111 and 109 minutes, respectively, while high volumes centres had 105 minutes [25]. In case of **ACL reconstruction**, low and medium volume hospitals had a longer mean operating time (150±9 and 132±9 minutes, respectively) compared to high volume surgeons (129±14 minutes) [26]. And similarly in case of **meniscectomy**, low and medium volume surgeons had a longer mean operating time (71±5 and 66±6 minutes, respectively) compared to high volume surgeons (52±6 minutes) [26].

Progression, Recurrence, and Re-admission

Progression, Rückfall und Wiederaufnahme

The relationship between hospital/surgeon volume and progression or recurrence of the health condition after day surgery was reported through the outcomes of risk of reoperation (in one study [28]), hospital visit within 30 days of intervention (in one study [23]), and LOS (in one study [25]).

Hüftarthroskopie: Risiko der Re-OP bei ChirurgInnen mit höherer Leistungsmenge am geringsten

Risk of reoperation was reported in the **hip arthroscopy** study with yearly volume rates ranging from low (<102), medium (102-164), high (164-340), to very high (≥340) [28]. Patients of surgeons with high annual case volumes had a lower risk of reoperation compared with those operated on by low volume surgeons. The hazard ratio for reoperation (with reference value of <102 cases/year) was 0.90 (CI±0.74) for medium volume surgeons, 0.42 (CI±0.32) for high volume surgeons, and 0.17 (CI±0.07) for very high volume surgeons.

LCA-Rekonstruktion: relative Chance einer Akutversorgung bei KH mit hoher Leistungsmenge am geringsten

Hospital based acute care within 30 days of surgery was reported in an **ACL reconstruction** study with 5 year-volume rates ranging from low (<100), medium (100-500), to high (≥500) [23]. The odds ratio for hospital based acute care within 30 days (with reference value of <100 cases/5 years) was 0.77 (p 0.059) for medium volume hospital and 0.47 (p <0.001) for high volume hospitals.

OP der RM: Aufenthaltsdauer bei LeistungserbringerInnen mit hoher Leistungsmengen am geringsten

LOS was reported in the **rotator cuff** repair study in relation to both surgeon as well as hospital volumes where surgeon volume rates ranged from low (<15), medium (15-30), to high (≥30) and hospital rates ranged from low (<75), medium (75-200), to high (≥200) [25]. The LOS was 2.3 (CI 1.2-4.4) and 1.3 (0.7-2.6) times longer for low and medium volume surgeons that for high volume surgeons. And in terms of hospitals, LOS was 0.5 (0.2-1.1) and 1.1 (0.4-3.1) time longer in low and medium compared to high volume hospitals.

Health-related quality of life

Outcomes related to disease specific quality of life and surgeon volume rates were reported in one **carpal tunnel release** study [27]. The two outcomes in question are reduction in pain score on VAS scale and mean BCTQ score. Surgeon yearly volume rates ranged from low (6-44 cases), medium (47-71 cases), to high (75-163 cases).

Endpunkte zu krankheitsspezifischer Lebensqualität wurde nur bei der Karpaltunnel-OP berichtet

Regarding symptom severity score as well as functional status score, there was no relationship between surgeon volume and BCTQ score at six months' follow-up. The scores were identical for all volume categories (1.7 points).

kein Zusammenhang zwischen Leistungsmenge der ChirurgIn und BCTQ-Score bzw. kein Nachweis bei VAS

Regarding pain score units on VAS scale, the comparison of baseline to six months' follow-up showed no proof of the inverse VOR. While patients of low volume surgeons improved by 29 units, patient of medium volume surgeons by 31 units, and high by 32 units.

Patient satisfaction

No evidence was found to answer this research question.

keine Evidenz zur PatientInnenzufriedenheit

9 Safety

9.1 Outcomes

The following outcomes were defined as crucial to derive a recommendation:

- Serious adverse events (SAEs)

Further outcomes considered were:

- Day surgery related adverse events (AEs) (wound infection, wound dehiscence, major bleed ... etc.)

entscheidungsrelevante Endpunkte hinsichtlich Sicherheit

9.2 Included Studies

For the assessment of safety, eight studies met the inclusion criteria (same studies as described in the section of clinical effectiveness). Two of eight studies listed AEs [27, 28], while none listed SAEs. None of the studies reported on the relationship between SAEs/AEs and surgeon/hospital volume.

Study characteristics and results of included studies are displayed in Table 13-1 and Table 13-2 and in the evidence profile in Table 13-3.

2 Studien berichten über unerwünschte Ereignisse (AEs), keine über schwerwiegende unerwünschte Ereignisse (SAE)

9.3 Results

Patient safety

No evidence was found to answer this research question. The only safety related data reported were without its relationship to surgeon/hospital volume. In the **hip arthroscopy** study, 0.2% of patients experienced procedural complication at 30 days post intervention – the complications were: myocardial infarction ileus, pneumonia, sepsis, mechanical complication, hardware failure, deep vein thrombosis/pulmonary embolism, wound infection, dislocation/iatrogenic instability, major bleed [28]. In the **carpal tunnel release** study, 1.6% of patients experienced procedural complications such as wound infections, wound dehiscence [27].

In the **thyroidectomy** study [21], 19 of the 160 patients experienced complications. Complications included transient hypercalcemia (5%), temporary vocal cord paralysis (2.5%), post-operative seromas requiring aspiration (1.9%), post-operative hematoma requiring aspiration (1.25%), bilateral vocal cord paralysis (0.63%), and inadvertent transection of the recurrent laryngeal nerve (0.63%).

es konnte keine Evidenz zur PatientInnensicherheit und Leistungsmenge identifiziert werden

10 Discussion

Clinical effectiveness and safety

To our knowledge, this is the first systematic review on minimum volume standards (MVSs) applied to the general setting of day surgery. The 2012 IQWiG report on effects of minimum volume regulations was set out to evaluate outpatient evidence only, however, it also included inpatient data [141].

erste systematische Übersichtsarbeit zu MM und MEB in der Tageschirurgie

Summary of evidence from retrospective database analysis

We found no prospective or controlled trials for the analyses of clinical effectiveness and safety. We found eight retrospective database analyses on seven different indications, but none reported on the volume-outcome relationship (VOR) with respect to safety. Each indication included the following number of patients:

Zusammenfassung der identifizierten Evidenz:

keine prospektiven oder kontrollierten Studien

8 retrospektive Studien zu 7 unterschiedlichen Indikationen eingeschlossen

- thyroidectomy – 109 outpatient (and 51 inpatient) patients [21],
- cataract surgery – 2,289,307 patients [22, 24]
- primary hip arthroscopy – 7,836 patients [28],
- open carpal tunnel release – 1,345 patients [27],
- rotator cuff repair – 9,973 patients [25]
- ACL reconstruction – 45,262 patients [23, 26]
- and meniscectomy – 123,012 patients [26].

für 5 Interventionen konnte eine positive MEB bestätigt werden, aber keine der Studien bestimmte MM

All interventions (except for carpal tunnel release and thyroidectomy) confirmed the hypothesis in favour of the VOR. None, however, established minimum volume standards for the respective interventions.

Concerning **thyroidectomy**, there was no VOR observed, but it was suggested that **thyroidectomy** is safe also in low volume centers as in the single low volume center, no cases of readmission occurred [21].

Thyreoidektomie

Concerning **cataract surgery**, the number of cases per surgeon was inversely correlated with the adverse event of posterior capsule rupture (PCR) where PCR and vitreous loss (VL) rate were 3.75% for low volume and 0.29% for very high volume surgeons [22]. The difference in relative risk for endophtalmitis was 4-fold between low and very high volume surgeons [24].

Katarakt-OP

Concerning **hip arthroscopy**, the survival rates for very high volume surgeons were 11.1-24.9% higher than for low volume and the hazard ratio for reoperation (with reference value of low volume) was 0.17 for very high volume surgeons [28].

Hüftarthroskopie

Concerning **open carpal tunnel release**, Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) score did not vary with volume at all while the difference on the visual analogue scale (VAS) scale was 1 point (out of 100) between low and high volume surgeons (18 vs. 19 points) [27]. Such difference is below the threshold of the minimal clinically important difference [29].

Karptaltunnel-OP

Concerning **rotator cuff repair**, patients of low volume surgeons were 2.8 time more likely to have non-routine disposition at discharge, while low volume hospitals were 2.1 times more likely to discharge patients with non-routine dispositions. Surgeon-related mean operating time was 10 minutes shorter and hospital-related mean operating time was 6 minutes shorter for high vol-

OP der Rotatorenmanschette

ume compared to low volume surgeons/hospitals. Length of stay (LOS) was 2.3 times longer for low volume surgeons and 0.5 times for low volume hospitals compared to high volume surgeons/hospitals [25].

Rekonstruktion des vorderen Kreuzbandes (LCA)

Concerning **anterior cruciate ligament (ACL) reconstruction**, the odds ratio for hospital based acute care within 30 days (with reference of low volume hospitals) was 0.47 for high volume hospitals [23]. Low volume surgeons were 4.5 times more likely and low volume hospital 3.33 times more likely to have non-routinely discharged patients compared to high volume surgeons [26]. Furthermore, low volume surgeons had a 27 minutes longer and low volume hospitals 21 minutes longer mean operating time than high volume surgeons/ hospitals [26].

Meniskektomie

Concerning **meniscectomy**, low volume surgeons were 2.8 times and low volume hospitals were 8 times more likely to have non-routinely disposed patients at discharge than high volume surgeons/hospitals [26]. In terms of mean operating time, both low volume surgeons and low volume hospitals had a longer mean operating time by 19 minutes compared to high volume surgeons/hospitals [26].

Gaps in evidence

Evidenzlücke bzw. niedriger Evidenzgrad auch im stationären aber besonders im tageschirurgischen Setting

While the VOR has some standing in the inpatient setting [44], it is argued that that relationship is based on low quality of evidence [142]. That is even more true for the day surgery setting and because of the fact that day surgery centres may operate independently from hospitals and so miss on the safety net in the form of emergency departments, quality assurance in day surgery is of even more importance. That places the extra emphasis on day surgery interventions to go well in the first place and hence also on quality assurance measures such as MVSs.

Relevance of evidence

Relevanz der Evidenz ist zweifelhaft, da retrospektive Analysen nicht die Standards der evidenzbasierten Medizin erfüllen

Due to these gaps in evidence, the relevance of the current evidence base to relative effectiveness assessment of MVSs is questionable. Retrospective database analyses do not fulfil the evidence-based medicine standards as they are prone to a spectrum of biases. For that reason, their conclusions are applicable only in part. In their favour plays the relatively robust body of evidence from the inpatient setting, relatively high number of patients included in the day surgery studies, and studies supporting no significant difference in outcomes between the settings [3]. Against it plays the poor internal and external validity of the present evidence base and the critical considerations related to MVSs in general.

Internal and external validity of the present evidence base

interne und externe Validität der vorliegenden Evidenzbasis

Concerning effectiveness and safety of MVSs, the quality of the evidence base is very low. The main reasons are the retrospective design of all the studies [21-28], the lack of justification for its use [21, 22, 25-27], or the lack of a priori data analysis plan [21-28]. Further reasons include unclear eligibility criteria [21-23, 27, 28], lack of justification for the statistical models used [21-23, 25-28], lack of interpretation of the statistical findings in terms of their clinical or economical evidence [22, 23, 25-28], and limited recognition of the generalisability of the retrospective study design [21, 22, 25-27].

Validität der Endpunkte in den Studien ist fragwürdig

Moreover, the validity of the endpoints used is also questionable. None of the safety endpoints were reported in relation to surgeon or hospital volumes, only one study reported on a mortality endpoint [28], three on morbidity endpoints [23, 25, 26], one on disease specific QoL endpoint [27], and none of patient satisfaction. Day surgery related outcomes such as frequency of hospital infections or venous thrombosis embolisms were not reported in any of the studies.

externe Validität der Daten für administrative MM im österreichischen Kontext ist zweifelhaft

External validity of the data for the sake of establishing MVSs in the Austrian context is questionable as well. Even though the conclusions of all the included studies are based on clinical practice data, the potential patient selection bias or the retrospective study design and the questionable generalisability undermine the external validity. Generalsiability of the data is put in question because all the studies (except for [27]) were conducted in the USA where the definition of day surgery and outpatient surgery may vary [20].

Critical considerations and contradictory evidence

kritische Überlegungen und gegensätzliche Evidenz

A critical synthesis has to be made to draw attention on the complexity of the VOR and thereof derived administrative MVSs. It is crucial to consider the over deterministic nature of this relationship in order to avoid possible methodological drawbacks in the study design and to guarantee explanatory power [8, 143].

Leistungsvolumen kann nur ein Surrogat für eine höhere Qualität sein

Without a doubt, taking into account risk-adjustment and case mix is imperative as the first step toward getting unbiased estimates of the effect of volume on outcome, but volume of surgeries can only be a proxy for higher quality. Halm et al. point out that besides general methodical shortcomings, studies investigating the VOR were not able to determine what surgical abilities or management skills of the surgery unit are enhanced by volume and why they should be uniquely related to volume [107]. Whether high-quality hospitals or surgeons are more likely to be sought by patients in the first place and are therefore capable of accumulating a higher-volume is also important to consider. Word of mouth takes a substantial part in the decision of where to undergo treatment that is often neglected in studies and health care research [95]. Also the question whether patients of high-volume providers are more likely to be selected into treatment by the provider compared to low-volume surgeons or hospitals is mainly unanswered [107].

monokausale Erklärungsansätze sollten vermieden und

Korrelation ≠ Kausalität

Übung macht den Meister vs. *selektive Überweisung*

When conducting volume-outcome analysis, one has to be cautious not to fall in a mono-causal or reverse causality trap when establishing links between two or more variables. An observed correlation does not necessarily indicate causation. Against this backdrop, it is important to synthesise the various approaches to emphasise the complexity of the VOR and its derived policies. The two approaches – *practice makes perfect* and *selective-referral* – imply significantly different policy choices [8]. While the *practice makes perfect* hypothesis gives reasonable arguments to implement a (regulatory) framework in the form of MVSs, the *selective referral* approach would indirectly appeal to healthcare research to understand why phenomena such as centralisation of services in form of volume accumulation of a few hospitals came up in the first place.

eine wissenschaftliche und interventions-spezifische Analyse für evidenzbasierte MM ist von großer Bedeutung

A scientific and surgery specific examination of the study situation is necessary to establish evidence-based minimum quantities. Quality is influenced by other factors such as the application of the best treatment methods. These factors should always supplement quality assurance focused on minimum quantities.

Limitations

identifizierte Evidenzbasis war nur teilweise relevant

The evidence base found was only partly relevant for answering the research questions. The retrospective study design can at best show correlations between surgeon/hospital volumes and day surgery outcomes, however, its results are of limited certainty and none of the studies answered the question on the threshold MVSs.

Daten zur MEB nur für 8 Interventionen

In the systematic literature search, we only found VOR data on eight interventions, which, however, is not a representative sample of all the interventions eligible for day surgery.

versch. Definitionen von Tageschirurgie

Also, the consistency of definitions of the included studies is questionable. The reason is that the US' use of the term day surgery may include 23 hour stay surgery, which in the EU is seen as an inpatient surgery with a one day LOS.

3 Studien konnten erst im Endstadium des Berichts identifiziert werden, wurden aber aufgrund kohärenter Gründe ausgeschlossen

Furthermore, the following studies on arthroscopy, meniscal repair, and colonoscopy [31-33] were excluded from the analysis even though they met the inclusion criteria. The reason was that they were found in an additional search in the end stage of the report when including them was no longer feasible. Additional reason for not including them was their assumed low marginal utility as quality of all studies was low due to their retrospectives study design.

11 Conclusion

Rolle von Mindestmengen (MM) in der Tageschirurgie bzw. beim ambulanten Operieren wurde in diesem Bericht analysiert und kritisch untersucht

The need for a shift of surgical interventions from the inpatient setting to the day surgery setting is advocated in the international literature. The reasons for the shift include organisational, ethical, economic, and medical aspects and quality assurance in the process is argued to be key. Because the VOR does have some standing in the inpatient setting, the role of MVSs applied to the day surgery setting was scrutinised in this report. Surely, identifying possible analogies between the inpatient and the day surgery settings can serve as a valuable decision-making foundation, however, the lack of evidence of clearly established MVSs, methodical issues, and the different nature of inpatient and day surgery settings make the simple transition of inpatient results to the day surgery setting questionable. Hence, we discussed the theoretical explanations of the quantity-quality relationship and the thereof derived reasons for implementing MVSs. Besides the above theory of MVSs, we aimed to provide the data on international variations and current use of MVSs with a particular focus on the German context.

Theorie der MM ist teilweise strittig

aus den Ergebnissen des vorliegenden Berichts können keine eindeutigen MM-Schwellenwerte abgeleitet werden

Anwendung von MM sollte gut konzipiert sein

There is no consensus behind the theory of MVSs and also the results from our systematic review cannot offer any clear-cut MVS thresholds. This present report, however, provides some evidence in favour of VOR, even though it based on low quality retrospective data-analyses. The low quality of the retrospective evidence found does not establish the clear presence of the VOR nor any clear MVSs. Two out of eight studies did not suggest a VOR at all and the generalisability of the results is questionable because seven out of eight studies were conducted in the US context. For these reasons, we argue that the application of MVSs should be well thought out. Moreover, because establishing the VOR and henceforth the MVSs is possible, quality prospective controlled evidence for the day surgery setting is required. Also, other quality assurance standards such as standards focusing on process and outcome quality should be taken into account.

evidenzbasierte MM benötigen geeignete Rahmenbedingungen und Politikmaßnahmen

In terms of adequate policy implications, if optimal surgery specific MVSs can be established as a quality standard and it is secured by a high-quality body of evidence for the VOR, then it is also indispensable to derive an appropriate public policy to disseminate this information to payers, health care consumers, and clinicians. Prima facie, there are three different policy approaches: (1.) utilising the data on volumes and outcomes to enhance performance, (2.) adopting measures to limit the number of hospitals or ambulatory care units permitted to conduct only a certain set of procedures, and (3.) publication or dissemination of the data on volume.

sämtliche diskutierte Aspekte sollten von allen AkteurInnen im Gesundheitssystem bedacht werden

All these aspects are crucial to consider, not only to assure compliance with MVSs and subsequently to assure the intended quality of outcome, but also to establish transparency in the health care system by providing relative performance data between and within healthcare organisations. It is important that not only professional bodies, hospitals, and surgeons conducting day surgery should be obliged to assure evidence based quality standards by implementing, complying, and monitoring any deviations, but also institutions within the health care system responsible for nationwide health care planning need to be involved.

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13 Appendix

13.1 Evidence tables of individual studies included for clinical effectiveness and safety

Table 13-1: Results from retrospective database analyses (joints and carpal tunnel)

	Degen et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)
Country	USA	The Netherlands	USA	USA	USA
Sponsor	National Institute of Health/ National Institute for Arthritis and Musculoskeletal and Skin Diseases (R01AR066069)	National Institute of Health/ National Institute of Arthritis and Musculoskeletal and Skin Diseases (RO1 AR82813)	NA	NA	NA
COI	1 author (B.T.K) has COI due to fees form Arthrex and A-3 surgical	None	NA	NA	None
Study design	Retrospective database analysis of 137 surgical centres (multivariate regression)	Retrospective database analysis of 11 surgical centres (univariate and multivariate regression)	Retrospective database analysis of unclear number of surgical centres (univariate and multivariate regression)	Retrospective database analysis of unclear number of surgical centres (multivariate logistic and linear regression)	Retrospective database analysis of unclear number of surgical centres (multivariate regression)
Conducted in	1998-2012	2011-2015	1997-2000	1997-2000	2009-2013
Indication	Hip arthroscopy	Carpal tunnel syndrome	See inclusion criteria below	See inclusion criteria below	Anterior cruciate ligament injury
Intervention	Primary hip arthroscopy	Open carpal tunnel releases	Rotator cuff repair	ACL reconstruction & Meniscectomy	ACL reconstruction
Setting	Outpatient	Outpatient	Outpatient	Outpatient	Outpatient
Type of volume analysis (surgeon/hospital)	Surgeon	Surgeon	Surgeon & hospital	Surgeon & hospital	Hospital
Comparator	NA	NA	NA	NA	NA
Number of pts	7,836	2,057[10]	10,934[11]	*ACL:* 32,440 *Men:* 195,597[12]	26,873
Number of procedures	8,267[13]	2,057	NA	NA	NA

[10] 1,345 pts included in the analysis.

[11] Number of pts finally included in the analysis was 9,973. Exclusion criteria were applied to exclude diagnoses, which outcomes were expected to differ from outcomes of the included indications.

[12] Number of pts finally included in the analysis was 18,390 for ACL and 123,012 for meniscectomy.

[13] Including 23 simultaneous bilateral and 408 staged bilateral procedures.

	Degen et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)
Number of surgeons	295	17	NA	NA	NA
Number of hospitals	137	11	NA	NA	NA
Surgeon volume categories, n (cases/year)				*ACL/Men:*	
❁ Low	<102	6-44	<15[14]	<25[15]/<75	NA
❁ Medium	102 ≤ x < 164	47-71	15 ≤ x <30	25 ≤ x<75/75 ≤ x <175	
❁ High	164 ≤ x < 340	75-163	≥30	≥75/≥175	
❁ Very high	≥340	NA	NA	NA	
Hospital volume categories, n (cases/year)				*ACL/Men:*	
❁ Low	NA	NA	<75	<125/<600[16]	<100[15]
❁ Medium	NA	NA	≥75-<200	125 ≤ x <300/600 ≤ x<1200	≥100-<500
❁ High	NA	NA	≥200	≥300/≥1200	≥500
Operating time, median in min (range)	NA	NA	102 (30-595)[17]	*ACL:* 125 (NA) *Men:* 55 (NA)	NA
Inclusion criteria	HA for diagnosis with or without synoval biopsy, HA for removal of loose/foreign body, HR & chondroplasty, abrasion arthroplasty & resection of labrum, HA & synovectomy, HA with femoroplasty, HA with acetabuloplasty, HA with labral repair, total hip replacement, re-surfacing hip & partial/total acetabulum & femoral head	Consent, primary carpal tunnel release, baseline and follow-up measurement of BCTQ	Rupture of the rotator cuff, disorders of bursae and tendon, sprains and strains of the rotator cuff capsule	*ACL:* Complete rupture of old disruption of ACL and sprain of cruciate ligament of the knee *Men:* derangement, bucket handle tear, simple tear of the meniscus or cartilage	NA
Exclusion criteria	NA	Unavailable operative report, unidentified surgeon, cases in which surgeons did not perform CTRs for at least 1 year within the cohort	Shoulder bone infection, present surgery as corrective surgery, malignancy, pathologic fracture, fracture due to injury in the bones of the shoulder region, or simultaneous total or partial shoulder arthroplasty	*ACL/Men:* Lower leg bone infections like osteomyelitis, inflammatory reaction due to graft, correction surgery, malignancies or pathological fractures, fractures due to injury, simultaneous knee arthroplasty, rheumatoid arthritis, operating time <45 min & <20 min in case of meniscectomy	Non-New York residents, pts that left against medical advice, mortalities, pts <18 yrs, surgeries from December 2013

[14] Number of cases in the period of 1997-2000.

[15] Number of cases per 4 years.

[16] Number of cases per 5 years.

[17] Data missing on 123 pts (0.01%)

	Degen et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)
Co-interventions	NA	Trigger finger release, cubital tunnel relese, Guyon release, radial tunnel release, fasciotomy Dupuytren, other, standard postoperative care – nerve and tendon-gliding exercises	NA	NA	NA
Age, mean, yrs (range)	38 (7-84)	54 (41-67)	56 (43.6-68.4)	*ACL:* 29.4 (18.9-39.9) *Men:* 47.3 (31.9-62.7)	Average 33.3 (22.0-46.6)
Sex, female:male, n	4,443:3,801	986:359	3,785-6,188	*ACL:* 7,481: 10,908[18] *Men:* 50,108:72,889[19]	9,811:17,049
BMI±SD	NA	27 ± 5	NA	NA	NA
Comorbidities	NA	Diabetes mellitus, Rheumatoid arthritis, Dupuytren's disease, Trigger fingers, CMCI joint arthritis, compression neuropathy, tendinitis, history of wrist trauma, scaphotrapeziotrapezoidal joint arthritis, radiocarpal arthritis, peripheral neuropathy, cervical radioculopathy, ulnocarpal impingement	Mean Deyo score: 0.1-0.9	NA	Mean Deyo score: 0.06
Follow-up time, yrs	10[20]	0.5	NA	NA	30 days
Patients excluded from the analysis, n (%)	?	712	961	*ACL:* 14,050 *Men:* 72,585	NA
Efficacy					
Survival, %	At 2/5/10 yrs				
❁ Low ❁ Medium ❁ High ❁ Very high	86.5/78.5/72.7 87.8/82.7/82.7 94.6/90.2/90.2 97.6/97.6/97.6	NA	NA	NA	NA

[18] Records missing on 1 pt.

[19] Records missing on 15 pts..

[20] Analysis of volume/risk of reoperation relationship assessed at 5 years.

	Degen et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)
Reduction in pain score units on VAS scale, baseline/6 mo by volume, mean n (SD)					
❁ Low	NA	Low: 47/18[21]	NA	NA	NA
❁ Medium		Medium: 51/20			
❁ High		High: 51/19			
❁ P value		NA			
BCTQ, mean n					
❁ Symptom severity score	NA	Low&Medium&High: all 1.7[22]	NA	NA	NA
❁ Functional status score	NA	Low&Medium&High: all 1.7	NA	NA	NA
Hospital based acute care within 30 days, odds ratio n at 5 years (p value)					
❁ Low volume	NA	NA	NA	NA	x
❁ Medium volume	NA	NA	NA	NA	0.77 (p 0.059)
❁ High volume	NA	NA	NA	NA	0.47 (p <0.001)
Risk of reoperation, hazard ratio n (95% CI)					
❁ Low volume	x				
❁ Medium volume	0.9x (CI-0.74)	NA	NA	NA	NA
❁ High volume	0.42 (CI 0.32)	NA	NA	NA	NA
❁ Very high volume	0.17 (CI 0.07)	NA	NA	NA	NA
Non-routine disposition of pts at discharge[23], surgeon, n (95% CI)					
❁ Low volume	NA	NA	2.8x (0.9-9.1)	*ACL:* 0.9% *Men:* 1.4%	NA
❁ Medium volume	NA	NA	1.5x (0.7-3.1)	*ACL:* 0.4% *Men:* 0.7%	NA
❁ High volume	NA	NA	x	*ACL:* 0.2% *Men:* 0.5%	NA
Non-routine disposition of pts at discharge, hospital, n (95% CI)					
❁ Low volume	NA	NA	2.1x (0.6-8.0)	*ACL*: 1% *Men:* 1.6%	NA
❁ Medium volume	NA	NA	1.7x (0.2-11.6)	*ACL:* 0.2% *Men:* 1.2%	NA
❁ High volume	NA	NA	x	*ACL:* 0.3% *Men:* 0.2%	NA

[21] The scores were reported only in a table and so the following numbers are only authors' estimates.

[22] The scores were reported only in a graph and so the following numbers are only authors' estimates.

[23] Non-routine disposition included transfer to another hospital, skilled nursing facility, intermediate care facility, or home health care. Routine disposition reflected patients who were discharged home.

	Degen et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)
Mean operating time volume, surgeon, min (±SD)					
❁ Low volume	NA	NA	112 (4)	*ACL:* 149(9) *Men:* 72(6)[24]	NA
❁ Medium volume	NA	NA	113 (4)	*ACL:* 137(9) *Men:* 64(6)	NA
❁ High volume	NA	NA	102 (4)	*ACL:* 122(9) *Men:* 53(6)	NA
❁ p value	NA	NA	<0.001	NA	NA
Mean operating time volume, hospital, min (±SD)					
❁ Low volume	NA	NA	111	*ACL:* 150(9) *Men:* 71(5)[24]	NA
❁ Medium volume	NA	NA	109	*ACL:* 132(9) *Men:* 66(6)	NA
❁ High volume	NA	NA	105	*ACL:* 129(14) *Men:* 52(6)	NA
LOS and surgeon volume, n (95% CI)					
❁ Low volume	NA	NA	2.3x (1.2-4.4)	NA	NA
❁ Medium volume	NA	NA	1.3x (0.7-2.6)	NA	NA
❁ High volume	NA	NA	x	NA	NA
LOS and hospital volume, n (95% CI)					
❁ Low volume	NA	NA	0.5x (0.2-1.1)	NA	NA
❁ Medium volume	NA	NA	1.1x (0.4-3.1)	NA	NA
❁ High volume	NA	NA	x	NA	NA
Safety					
SAE	NA	NA	NA	NA	NA
AEs, n (%)	NA (0.2)[25]	23 (1.6)	NA	NA	Unclear[27]
❁ Day surgery related AEs	MI, ileus, pneumonia, sepsis, mechanical complication, hardware failure, DVT/PE, wound infection, dislocation/iatrogenic instability, major bleed[26]	Wound infection, wound dehiscence	NA	NA	NA

ACL – Anterior cruciate ligament, BCTQ – Boston Carpal Tunnel Questionnaire, COI – conflict of interests, CTR – carpal tunnel release, DVT – deep vein thrombosis, ED – emergency department, HA – hip arthroscopy, LOS – length of stay, THA – total hip arthroplasty, Men – Meniscectomy, MI – myocardial infarction, NA – Not available, PE – pulmonary embolism

[24] Only restricted to the New York state database pts.

[25] 30 days procedural complication rate.

[26] Not reported in what n of pts, nor in relationship to surgeon volume.

[27] Listed complication are not necessarily intervention related, they are merely the reasons due to which pts visited EDs within 30 days of ACL surgery.

Table 13-2: Results from retrospective database analyses (thyroid and cataract surgery)

	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
Country	USA	USA	USA
Sponsor	NA	NA	National Eye Institute: R01EY016769. K.K funded by an Australian National Health and Medical Research Council post-doctoral fellowship. E.W.G. recipient of an Ernest and Elizabeth Althouse Special Scholar's Award from Research to Prevent Blindness.
Conflict of Interest	One author (Yencha) was involved in all cases either as primary or assistant surgeon	None	None
Study design	Retrospective single centre analysis	Retrospective single centre chart review	Retrospective analysis of Medicare beneficiary claims data
Conducted in	2006-2014	2011-2012	2003-2004
Indication	Benign or malignant thyroid carcinoma	Cataract	Cataract
Intervention	Outpatient thyroid surgery/Thyroidectomy	Cataract Surgery (Phacoemulsification)	Cataract Surgery
Setting	Outpatient and Inpatient[28]	Outpatient Surgical Centre	Outpatient surgery centres
Type of volume analysis (surgeon/hospital)	Surgeon & Hospital	Surgeon	Surgeon
Comparator	Inpatient Thyroid surgery/Thyroidectomy	NA	NA
Number of pts, I vs C	160 (109 vs 51)[29]	3,339	2,285,968[30] Both eyes: 1,005,826 (44%) One eye: 1,280,142[30] (56%)
Number of procedures, I vs C[31]	Total: 35 vs 26 Hemi: 62 vs 20 Completion: 11 vs 5	NA	3,280,966[32]

[28] Patient who were eligible for same day discharge were observed typically for 2–4 h. Patients with significant co-morbidities, lack of social support, and/or patients not comfortable with outpatient recovery were admitted for observation.

[29] 43 pts were kept for 23 h observation and 17 (40%) of these patients were found to have social factors requiring an overnight stay (due to long distance, absence of responsible adult caregiver); remaining 26 pts requiring a 23 h observation had significant co-morbidities.

[30] Own calculation on the basis of the given numbers of patients (absolute and relative) with surgery on both eyes.

[31] Outpatient (Intervention) vs Inpatient (Comparator)

[32] 35,068 surgeries could not have been attributed to a specific surgeon and also contain surgeries for which surgeon characteristics data were missing. Hence in the analysis 3,245,898 were included.

	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
Number of surgeons	NA	4	11, 873[33]
Number of hospitals	1	1	NA
Surgeon/Surgeon volume categories, n (cases/year)	Unclear[34]	Surgeon 4: 411 Surgeon 1: 536 Surgeon 2: 1,056 Surgeon 3: 1,336	(1): 1-50; (2): 51-200; (3): 201-500; (4): 501-1000; (5): ≥1001
Hospital volume categories, n (cases/year)	Unclear	NA	NA
Operating time, median in min (range)	NA	NA	NA
Inclusion criteria	Patients in ASA class 1,2,3 and 4	Use of topical anaesthesia and performance of the intervention at an outpatient centre/setting	Patients with max. 2 cataract surgeries per beneficiary during the 2-year study timeframe; Medicare beneficiaries ≥65 years
Exclusion criteria	NA	Patients requiring additional anaesthesia and those who were operated on in a hospital setting	Records were excluded if data indicated the surgery was not performed, the procedure was a return to the operating room for a related procedure or due to data coding issues; surgeries performed in the last 42 days of 2004
ASA class, n, I vs C	1 and 2: 90 vs 39 3 and 4: 19 vs 12	NA	NA
Co-interventions	Intravenous dexamethasone, intravenous antibiotics, anaesthesia at surgeon's discretion, Prophylactic calcium carbonate and vitamin D (calcitriol) supplementation for pts undergoing total or completion thyroidectomy	NA	NA
Age, mean, yrs (range) [SD]	41.8 (14-75)/47.8 (19-77)	73 (60-86) [3]	NA (≥65[35])
Sex, female:male, n, I vs C	82:27 vs 25:26	13:10	NA
BMI±SD	NA	NA	NA

[33] Own calculation on the basis of the descriptive statistics of the endophthalmitis rate by annual Medicare surgical volume found in Table 4.

[34] Thresholds for MVS classification (i.e. low, medium, high) is not clear.

[35] Age info is not given in detail

	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
Risk Adjustment	NA	NA	Age (65-74, 75-84, ≥85 Gender, Race, Year, Ambulatory surgery centre (No, Yes), Surgeon experience in yrs (1-10, 11-20, 21-30, ≥30)
Other influencing factors (Comorbidities etc.), n (%)	NA	Shallow chamber: 8 (35); Miosis: 7 (30); Restlessness: 6 (26); Floppy Iris: 6 (26); Pseudoexfoliation: 5 (22); Zonular dehiscence: 5 (22); Small eye: 1 (4)	NA
Patients excluded from the analysis, n (%)	NA	NA	165,452 and 35,068[36]
Efficacy			
Revision Surgery	NA	23[37] of 3,339	NA
Re-admission[38], n (%), I vs C	0[39] vs NA	NA	NA
Surgical volume, n (cases/year) – Risk of AE related to surgery	NA	411 – 3.75; 536 – 0.37; 1 056 – 0.28; 1 336 – 0.29 PCR in 23 (0.68) in total	Nr. of TE cases: 1-50: 352; 51-200: 1,455; 201-500: 1,512; 501-1000: 454; ≥1001: 168 Overall Endoph. Rate/1,000 surgeries[40] (95% CI): 1-50: 2.57 (2.30-2.83); 51-200: 1.49 (1.42-1.57); 201-500: 1.17 (1.11-1.23); 501-1000: 0.80 (0.73-0.88); ≥1001: 0.62 (0.52-0.71)

[36] 165,452 Surgeries performed in the last 42 days in 2004 were excluded and in the analysis of the endophthalmitis rate by annual medicare surgical volume 35,068 surgeries with unique physician identification numbers that cannot be attributed to a specific surgeon and surgeries for which surgeon characteristics data were missing.

[37] 5 of the 23 patients did not have sufficient support to place a posterior chamber or sulcus intraocular cataract lenses (IOL) and required placement of anterior chamber IOLs.

[38] Re-admission includes admission for 23-h observation or full admission (observation longer than 24 h)

[39] One pt. was discharged from the ER for symptoms of paresthesias with normal calcium levels.

[40] This rate is overall for all surgeries within a specific annual volume category and does not reflect the average rate of endophthalmitis within each category.

	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
Surgical volume, n (cases/year) – Risk of AE related to surgery *(continuation)*			PCR: Unadjusted RR (95% CI): 1-50: 4.17 (3.47-5.01); 51-200: 2.42 (2.06-2.84); 201-500: 1.89 (1.61-2.22); 501-1000: 1.30 (1.09-1.55); ≥1001: 1.00 (Reference) Adjusted RR: (95% CI): 1-50: 3.80 (3.13-4.61); 51-200: 2.32 (1.97-2.74); 201-500: 1.84 (1.56-2.17); 501-1000: 1.30 (1.09-1.56); ≥1001: 1.00 (Reference)
Safety			
SAE	NA	NA	NA
AEs, Volume, n (%),	19 pts of 160 pts (11,90%)[41] Transient hypercalcemia: 5%; Temporary vocal cord paralysis: 2.5%; Bilateral vocal cord paralysis: 0.63% Inadvertent transection of the RLN: 0.63%; Post-operative seromas requiring aspiration: 1.9%; Post-operative hematoma requiring aspiration: 1.25%	NA	NA

NA – Not available, PCR – Post Cataract Endophthalmitis, SDS – same day surgery, SDT – same-day thyroidectomy, TE – Total Endophthalmitis, TT – Thyroidectomy, RLN – recurrent laryngeal nerve, RR – Relative Risk

[41] It was unclear what AE occurred in the respective intervention arm.

13.2 Quality assessment checklist

Table 13-3: ISPOR Task Force Checklist for Quality Assessment of Retrospective Database Studies [30]

Study reference/ID	Degan et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
1. Relevance: Have the data attributes been described in sufficient detail for decision makers to determine whether there was a good rationale for using the data source, the data source's overall generalisability, and how the findings can be interpreted in the context of their own organisation?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Reliability and Validity: Have the reliability and validity of the data been described, including any data quality checks and data cleaning procedures?	No	Yes	Yes	Yes	No	No	Yes	Yes
3. Linkages: Have the necessary linkages among data sources and/or different care sites been carried out appropriately, taking into account differences in coding and reporting across sources?	Yes	NA	Yes	Yes	Yes	NA[42]	NA[42]	Yes
4. Eligibility: Have the authors described the type of data used to determine member eligibility?	Yes	Yes	Yes	Yes	Yes	No	No	Yes
5. Data analysis plan: was a data analysis plan, including study hypotheses, developed a priori? Was the study conducted prospectively?	Partial[43]	Partial[43]	Partial[43]	Partial[43]	Partial[43]	No[44]	No	Partial[43]
6. Design selection: has the investigator provided a rationale for the particular research design?	No	No	No	No	No	No	No	Partial[45]
7. Research design limitations: did the author identify and address potential limitations of that design?	Yes	No	No	No	Yes	No	No	Partial
8. Treatment effect: for studies that are trying to make inferences about the effects of an intervention, does the study include a comparison group and have the authors described the process for identifying the comparison group and the characteristics of the comparison group as they relate to the intervention group?	NA	NA	NA	NA	NA	NA	NA	NA
9. Sample selection: have the inclusion and exclusion criteria and the steps used to derive the final sample from the initial population been described?	Partial[46]	Partial[47]	Yes	Yes	Partial[48]	No	Partial[47]	Yes

[42] Single data source

[43] It is indicated in the text that a hypothesis was created a priori, but no more information is revealed.

[44] It is not explicitly stated in the text that a hypothesis was created a priori.

[45] They state that population-based studies can be generalised to the community more easily than center-specific studies because they represent the broad range of conditions under which surgeries are conducted on diverse populations in a wide range of settings by many surgeons with varying levels of experience.

Study reference/ID	Degan et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
10. Eligibility: are subjects eligible for the time period over which measurement is occurring?	NA	NA	NA	NA	NA	NA	NA	NA
11. Censoring: were inclusion/exclusion or eligibility criteria used to address censoring and was the impact on study findings discussed?	Partial[49]	Partial[49]	Partial[49]	Partial[49]	Partial[49]	No	Partial[49]	Yes
12. Operational definitions: are case (subjects) and end point (outcomes) criteria explicitly defined using diagnosis, drug markers, procedure codes, and/or other criteria?	Yes	Yes	Yes	Yes	Yes	Partial[50]	Yes	Yes
13. Definition validity: have the authors provided a rationale and/or supporting literature for the definitions and criteria used and were sensitivity analyses performed for definitions or criteria that are controversial, uncertain, or novel?	NA	NA	NA	NA	NA	NA	NA	NA
14. Timing of outcome: is there a clear temporal (sequential) relationship between the exposure and outcome?	NA	NA	NA	NA	NA	NA	NA	NA
15. Event capture: are the data, as collected, able to identify the intervention and outcomes if they actually occurred?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
16. Disease history: is there a link between the natural history of the disease being studied and the time period for analysis?	NA	NA	NA	NA	NA	NA	NA	NA
17. Resource valuation: for studies that examine costs, have the authors defined and measured an exhaustive list of resources affected by the intervention given the perspective of the study and have resource prices been adjusted to yield a consistent valuation that reflects the opportunity cost of the resource?	NA	NA	NA	NA	NA	NA	NA	NA
18. Control variables: if the goal of the study is to examine treatment effects, what methods have been used to control for other variables that may affect the outcome of interest?	Yes	Yes	Yes	Yes	Yes	None[51]	None[52]	Yes

[46] Only inclusion criteria were described.

[47] The inclusion/exclusion criteria were described only in part.

[48] Only exclusion criteria were described.

[49] Criteria were mentioned, but the impact on findings was not discussed.

[50] No explicit procedure codes were used.

[51] Only bivariate statistical analyses were conducted – no multivariate regression model was applied.

[52] Only causative factors are listed descriptively.

Study reference/ID	Degan et al. [28] (2017)	Evers et al. [27] (2018)	Jain et al. [25] (2005)	Jain et al. [26] (2004)	Liu et al. [23] (2018)	Ayala and Yencha [21] (2015)	Chen et al. [22] (2014)	Keay et al. [24] (2012)
19. Statistical model: have the authors explained the rationale for the model/statistical method used?	No	No	No	No	No	Partial[53]	No	Yes
20. Influential cases: have the authors examined the sensitivity of the results to influential cases?	NA	NA	NA	NA	NA	NA	NA	NA
21. Relevant variables: have the authors identified all variables hypothesised to influence the outcome of interest and included all available variables in their model?	Yes	Yes	Yes	Yes	Yes	No[54]	No	No
22. Testing statistical assumptions: do the authors investigate the validity of the statistical assumptions underlying their analysis?	Yes	Yes	Yes	Yes	Yes	No	No	No
23. Multiple tests: if analyses of multiple groups are carried out, are the statistical tests adjusted to reflect this?	NA	NA	NA	NA	NA	NA	NA	NA
24. Model prediction: if the authors utilise multivariate statistical techniques in their analysis, do they discuss how well the model predicts what it is intended to predict?	No	No	No	No	No	NA	NA	Yes
25. Theoretical biases: have the authors provided a theory for the findings and have they ruled out other plausible alternative explanations for the findings?	Partial[55]	Partial[55]	Partial[55]	Partial[55]	Partial[55]	Partial[55]	No	Yes
26. Practical versus statistical significance: have the statistical findings been interpreted in terms of their clinical or economic relevance?	No	No	No	No	No	Yes	Partial[56]	Yes
27. Generalisability: have the authors discussed the populations and settings to which the results can be generalised?	Partial[57]	No	No	No	Partial[57]	No	No	Yes
Overall level of quality								

[53] Reasons for using the conducted statistical tests were given

[54] Only a low volume hospital with outpatient thyroidectomy was the object of analysis

[55] The authors did not rule out other possible interpretations.

[56] Authors refer only to one paper that also tests the respective hypothesis.

[57] It is stated that the current results are of limited generalisability.

13.3 Applicability table

Table 13-4: Summary table characterising the applicability of a body of studies

Domain	Description of applicability of evidence
Population	The appropriate patient population was not pre-defined before the systematic search, but was identified through the iterative process of finding the indications/interventions for which the volume-outcome relationship and/or MVSs are documented. Generalisabiliy of the patient population is undermined as seven out of eight studies included for the analysis were conducted in the US context, while one was conducted in the Netherlands.
Intervention	The eight studies included report on seven different interventions. The retrospective study design provids real world data on the following interventions: primary hip arthroscopy, open carpal tunnel release, rotator cuff repair, ACL reconstruction, meniscectomy, throid surgery/ thyroidectomy, cataract surgery (phacoemulsification). None of the studies provide clear MVSs.
Comparators	We defined comparators as the same or comparable surgical interventions in the day surgery setting without minimum volume standards implemented. No studies with such comparators were found.
Outcomes	In principle, each study reported on a different set of outcomes. The outcomes that we considered crucial were relating volume data to mortality, morbidity, quality of life, and satisfaction outcomes. One study reported on the mortality outcome of survival, one on quality of life outcomes of pain on the VAS scale and BCTQ score, and none on satisfaction. Six studies reported on morbidity outcomes of hospital based acute care within 30 days, risk of reoperation, non-routine disposition of patients at discharge, mean operating time, and LOS. Three studies reported on AEs.
Setting	Because seven out of eight studies were conducted in the US context, the appropriateness of the setting is put into question. The reason is that in the US context, outpatient care/day surgery is not always defined in the same way as it is in the European context. The potential challenge is that the US' use of the term day surgery includes 23 hour stay surgery, which in the EU is seen as an inpatient surgery with a one day length of stay.

13.4 Literature search strategies

13.4.1 Search strategy for Cochrane

Search Name: Minimum Volume Standards	
Search Date: 12/07/2019	
ID	Search
#1	MeSH descriptor: [Hospitals, High-Volume] explode all trees
#2	MeSH descriptor: [Hospitals, Low-Volume] explode all trees
#3	(volume NEXT outcome):ti,ab,kw (Word variations have been searched)
#4	("minimum volume* standard*") (Word variations have been searched)
#5	(fallzahl*) (Word variations have been searched)
#6	(mindestfallzahl*) (Word variations have been searched)
#7	((surgeon* OR surgic* OR surger*) NEXT volume*):ti,ab,kw
#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9	MeSH descriptor: [Ambulatory Surgical Procedures] explode all trees
#10	MeSH descriptor: [Outpatient Clinics, Hospital] explode all trees
#11	((ambula* OR outpatient* or day*)) (Word variations have been searched)
#12	#9 OR #10 OR #11
#13	#8 AND #12 with Cochrane Library publication date Between Jan 2000 and Jul 2019 (Word variations have been searched)
#14	#8 AND #12 with Publication Year from 2000 to 2019, in Trials (Word variations have been searched)
#15	#13 OR #14 (Word variations have been searched)
Total: 62 Hits	

13.4.2 Search strategy for CRD

Search Name: Minimum Volume Standards	
Search Date: 12/07/2019	
ID	Search
#1	(minim* volume* standard*)
#2	(volume-outcome)
#3	((surgeon* OR surgic* OR surger* OR hospital* OR procedur*) NEXT (volume* OR case-load* OR caseload*))
#4	#1 OR #2 OR #3
#5	(ambula* OR outpatient* OR day*)
#6	MeSH DESCRIPTOR Ambulatory Surgical Procedures EXPLODE ALL TREES
#7	MeSH DESCRIPTOR Outpatient Clinics, Hospital EXPLODE ALL TREES
#8	MeSH DESCRIPTOR Outpatients EXPLODE ALL TREES
#9	#5 OR #6 OR #7 OR #8
#10	#4 AND #9
#11	(#10) FROM 2000 TO 2019
Total: 24 Hits	

13.4.3 Search strategy for Medline

Search Name: Minimum Volume Standards	
Search Date: 12/07/2019	
ID	Search
#1	exp *Hospitals, High-Volume/(1087)
#2	exp *Hospitals, Low-Volume/(654)
#3	(volume adj outcome).ti,ab. (806)
#4	((surgeon* or surgic* or surger* or hospital* or procedur* or case or minim*) adj (volume* or case-load* or caseload*)).ti,ab. (8048)
#5	1 or 2 or 3 or 4 (8866)
#6	exp Ambulatory Surgical Procedures/(12921)
#7	exp Outpatient Clinics, Hospital/(17805)
#8	surgery.fs. (2161180)
#9	9 and 10 (397)
#10	((ambulatory* or outpatient* or day*) adj3 (surge* or surgic* or procedure*)).ti,ab. (67012)
#11	8 or 11 or 12 (72907)
#12	7 and 13 (356)
#13	minim* volume* standard*.mp. (42)
#14	14 or 15 (398)
#15	remove duplicates from 16 (314)
#16	limit 17 to yr="2000 - 2019" (288)
#17	exp *Hospitals, High-Volume/(1087)
#18	exp *Hospitals, Low-Volume/(654)
Total: 288 hits	

13.4.4 Search strategy for Embase

Search Name: Minimum Volume Standards	
Search Date: 12/07/2019	
ID	Search
#1	'surgical volume'/exp
#2	'hospital volume'/exp
#3	'high volume hospital'/exp
#4	'low volume hospital'/exp
#5	(volume* NEAR/1 outcome*):ti,ab
#6	((surgeon* OR surgic* OR surger* OR hospital* OR procedur* OR case OR minim*) NEAR/1 (volume* OR 'case load*' OR caseload*)):ti,ab
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	'ambulatory surgery'/exp
#9	((ambulatory* OR outpatient* OR day*) NEAR/2 (surge* OR surgic* OR procedure*)):ti,ab
#10	#8 OR #9
#11	#7 AND #10
#12	'minim* volume* standard*':ti,ab,de
#13	fallzahl*
#14	mindestfallzahl*
#15	frequenzregel*
#16	#12 OR #13 OR #14 OR #15

#17	#11 OR #16
#18	(#11 OR #16) AND [2000-2019]/py
#19	#18 AND 'conference abstract'/it
#20	#18 NOT #19
Total: 346 hits	

13.4.5 Search strategy for Livivo

Date: 12/07/2019

Freie Suche: (((mindestfallzahl* OR mindestmeng* OR fallzahl* OR frequenzregel*) AND (chirurg* OR operat* OR eingriff* OR OP)) AND (Ambula* OR Tages*))

Publikationsdatum eingeschränkt auf: 2000-2019

Total: 33 hits

13.4.6 Search strategy for the hand and exploratory search:

Search term	(optionally) linked with
English terms	
minimum volume standard* volume-outcome relationship volume-outcome relation(ship) minimum volume requirement surgeon volume* hospital volume* case load	day surgery day care ambulatory surgery ambulatory care same-day surgery outpatient surgery
German terms	
Mindestmenge* Mindestmengenregelung* Mindestfrequenz* Mindestfallzahl* Frequenzregelung*	Tageschirurgie Tagesklinik ambulante Operation ambulantes Operieren ambulante Versorgung tagesklinische Operation tagesklinische Versorgung

* *indicates that also the plural was used in the search*

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