IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports - Commission No. V11-01

Literature search and evidence assessment to examine the effects of minimum volume regulations according to the G-BA directive on outpatient treatment in hospitals[1]

Executive Summary

[1] Translation of the executive summary of the rapid report "Literaturrecherche und Evidenzprüfung zur Überprüfung der Auswirkungen der Regelungen über Mindestmengen gemäß der Richtlinie des G-BA über die ambulante Behandlung im Krankenhaus" [Version 1.0; Status: 29.05.2012]). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher:
Institute for Quality and Efficiency in Health Care

Topic:
Literature search and evidence assessment to examine the effects of minimum volume regulations according to the G-BA directive on outpatient treatment in hospitals

Contracting agency:
Federal Joint Committee (G-BA)

Commission awarded on:
23.06.2011

Internal Commission No:
V11-01

Address of publisher:
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This rapid report underwent an external review. The review was performed by Prof. Dr. Max Geraedts Institute for Health System Research, University of Witten/Herdecke, Germany.

External reviewer:

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IQWiG thanks the external reviewer for his comments on the rapid report. However, the external reviewer was not involved in the preparation of the rapid report. Individual sections and conclusions in the rapid report therefore do not necessarily reflect his opinion.

The disclosure of potential conflicts of interest can be found in Appendix E of the full rapid report.

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Background

Every 2 years, compliance with the criteria laid down by law with respect to hospitals and the quality requirements they have to meet, has to be checked. To this end, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct a literature search and evidence assessment of the current literature relating to the minimum volume regulation and thereby check whether the services and diseases listed in the catalogue of the directive on outpatient treatment in hospitals (ABK-RL) need to be updated or extended.

Research question

One aim of the present investigation was to summarize scientific knowledge concerning methods for setting or calculating minimum volumes. A further aim was to demonstrate, on the basis of scientific publications, the influence of minimum volume regulations on the provision of health care as a quality-assuring or quality-increasing effect. In accordance with the assignment and more detailed instructions given by the G-BA, the rapid report was not restricted to the outpatient sector alone, but results concerning the inpatient sector were also described. This report was to consider the transferability of results to the current conditions in the Federal Republic of Germany.

According to the commission from the G-BA, the results were also to provide an assessment of the following questions:

Are there logical exceptions to the agreed minimum volume regulations if a nationwide coverage of the services/treatments named in the catalogue cannot be guaranteed?

Is it possible to identify groups of diseases or services for which the use of a minimum volume regulation routinely appears unsuitable?

According to the commission awarded to IQWiG, the assessment of these 2 questions was to be addressed solely as part of the discussion.

Methods

Sub-goal 1: Calculation principles

For this purpose, a systematic literature search was conducted in the following databases: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (Clinical Trials) and Cochrane Methodology Register (Methods Studies). In addition, a search for relevant systematic reviews took place in the databases MEDLINE and EMBASE in parallel with the search for relevant primary studies. Searches were also conducted in the databases Cochrane Database of Systematic Reviews (Cochrane Reviews), Database of Abstracts of Reviews of Effects (Other Reviews), Health Technology Assessment Database (Technology Assessments) and Cochrane Methodology Register (Methods Studies). The search was performed on 24.10.2011. The “Related Citations” function in PubMed for publications assessed as relevant was also used (the first 20 hits were considered). In addition, the search

results regarding sub-goal 2 were checked to see whether they contained conclusions regarding the formulation or calculation of minimum volumes. Lists of references in relevant publications were used to identify published and unpublished studies.

All the information needed for the research question was extracted from the documents of the included publications and subjected to a structured information synthesis and analysis. To this end, the extracted information was summarized descriptively and typical procedures for the determination and/or calculation of minimum volumes identified.

On the basis of the information synthesis and analysis, the extent to which the identified methods permitted conclusions regarding an alternative or modified operationalization of the minimum volume regulations according to § 116b Social Code Book (SGB) V was then examined.

Sub-goal 2: Minimum volume regulations

A systematic literature search, the search via the "Related Citations" function and the screening of reference lists of relevant studies were carried out as described in sub-goal 1.

For sub-goal 2, observational studies (including analyses of secondary data) were included in which the quality-assuring or quality-increasing effect of a minimum volume regulation in outpatient or inpatient health care were investigated. The intervention to be examined was the specification of a minimum volume regulation in the provision of health care. The comparator intervention was no minimum volume regulation or a minimum volume regulation with a different minimum volume.

Patient-relevant outcomes such as "mortality", "morbidity" (e.g. perioperative or post-operative occurrence of complications) and "health-related quality of life" were used in the investigation. If the studies described other additional outcomes that enabled conclusions to be drawn regarding a quality-assuring or quality-increasing effect of minimum volume regulations, these results were also shown in suitable ways (e.g. structural effects such as the access to health care or length of journeys to access health care).

The results were described at 4 levels:

- An overall presentation of the available results on quality-assuring and/or quality-increasing function of minimum volume regulations,
- A presentation of the results relating solely to Germany,
- A presentation of the results with reference to the contents of the ABK-RL catalogue,
- A presentation of the results before and after 2008.

Results

Sub-goal 1: Calculation principles

A total of 41 publications were included for sub-goal 1, of which 32 were primary studies (retrospective observational studies), 6 systematic reviews and 3 publications on methodology.

The principle source of information for the investigations reported in the publications included for sub-goal 1 were clinical data based on registry data, administrative data from hospitals and data from external quality assurance (German National Institute for Quality in Health Care, BQS).

The main aim of almost all publications included for sub-goal 1 was to investigate volume-outcome relationships.

Methods for calculating a threshold value

All the publications included for sub-goal 1 described methods for deriving a threshold value to separate hospitals/physicians with high and low numbers of cases. The explicit aim of 19 of these publications was stated to be the determination of an "optimum" threshold value. The identified publications could be broadly divided into the following groups, depending on the methodological approach:

A) Approaches based on the modelling of individual patient data using regression models that enable a threshold value to be determined as part of the model

B) Approaches based on the variation of the cut-off point for differentiating low and high case numbers, followed by statistical modelling and maximization of a suitable effect measure for high versus low case numbers

C) Approaches based on the calculation of the observed (O) and expected (E) event frequencies per hospital/per physician and/or case number group and/or the ratio of O/E depending on the number of cases and definition of a criterion for determining a threshold value

D) Approaches based on several studies in the context of a systematic review

E) Other approaches

Specific regression models for determining a threshold value were described in 7 publications (Group A), and 17 publications (Group B) were identified for the variation of cut-off points. In 8 studies in Group C, the expected frequencies were calculated using a risk adjustment. Six studies determined a threshold based on a systematic review (Group D). A further 3 papers described other approaches for determining a threshold value.

Alternative or modified operationalization of the minimum volume regulation pursuant to § 116b

The publications included for sub-goal 1 did not apply the disease-independent principles used by the G-BA for setting minimum volumes (treatment of 50 disease cases annually or 0.1 % of the nationwide prevalent cases for diseases with a specific course). Instead, the publications described methods for calculating threshold values that can be regarded as alternatives to the G-BA procedure.

From a statistical and methodological view, an efficient approach to deriving threshold values is to model the relationship between case numbers and outcome quality at patient level, in the context of an adequate statistical regression model. In such an approach, the case numbers are modelled primarily as the continuous variable, an adjustment for important risk factors (confounders) is made and suitable account is taken of a possible cluster effect. The approaches based on modelling using regression models are, in principle, the most suitable way to determine a threshold value for minimum volumes. Due to various deficiencies and limitations of the included publications, it did not, however, appear possible to identify a single one of the proposed techniques as the "optimum" method for operationalizing a minimum volume regulation.

Sub-goal 2: Minimum volume regulations

A total of 10 studies were included for sub-goal 2.

Five of the studies included for sub-goal 2 were based on administrative data from hospitals, 2 on hospital surveys, 2 drew conclusions from secondary data of the BQS and one further study related to data from the BQS and/or the German Institute for the Hospital Remuneration System (InEK) and one hospital survey.

The outcomes considered relevant for the report were "mortality", "morbidity", "structural effects", "length of hospital stay" and "re-intervention". None of the studies considered the outcome "health-related quality of life".

The procedures/diseases considered in the included studies were abdominal aortic aneurysm (AAA) repair, oesophageal and pancreatic surgical interventions, total knee replacement (TKR), liver, kidney and stem cell transplantations and percutaneous coronary interventions.

Quality of studies and publications

No controlled cluster-randomized intervention studies to assess the effects of introducing a minimum volume regulation could be found. The studies identified were retrospective observational studies (some of which, however, contained prospectively recorded data). The description of the evaluated datasets was not always adequate.

Multiple regression models with a comprehensive adjustment in terms of relevant confounders were used in the 6 studies with patient-relevant outcomes. In 4 studies, the modelling considered potential cluster effects; in one study this was not the case and in

another study it was unclear. Only one study contained information about the quality of the model.

Before and after comparisons were carried out in 2 studies which examined structural effects, but the samples were not fully congruent and therefore only very small samples could be compared with each other.

In one German study, a hospital survey using a standardized questionnaire was undertaken in 2 consecutive years. Sampling was undertaken based on a random sample and the available sample was weighted. The results were therefore based on data extrapolated from a single sample to the total population.

Taken as a whole, in addition to a design-related risk of bias, all studies displayed methodological deficiencies that limited the informative value of the results.

Mortality

Four studies from Germany, the USA and Canada contained results on the effects of minimum volume regulations on the outcome "mortality".

Only one study showed a statistically significant risk reduction for mortality in pancreatic surgical interventions following the introduction of a minimum volume regulation. Two studies – one on PCTA and the other for AAA repair or for pancreatic or oesophageal surgery – were unable to demonstrate any statistically significant results in terms of mortality rates. Another study on TKR merely produced raw results rates without any conclusions regarding statistical significance.

Morbidity

Five studies from Germany and the USA contained conclusions about the effects of minimum volumes on the outcome "morbidity".

Three German studies showed statistically significant results in terms of the outcome "morbidity after TKR". One of these studies was able to demonstrate sometimes statistically significant risk reductions for the general complications (pneumonia, thrombotic events and pulmonary embolism) and nerve injuries following TKR. The results on vascular injuries also showed a reduction in complication rates that was statistically significant for all years after the introduction of the minimum volume regulation. The same study found no statistically significant difference for cardiovascular complications. An increase in rates of implant malpositioning occurred, but was statistically significant only for 2006 and 2007. There were also increases in risk for fractures (surgical complication), but these were not statistically significant. On the other hand, one of the German studies showed a statistically significant risk reduction also for the surgical complications of postoperative wound infection and haematoma/secondary haemorrhage after TKR. Another German study found a statistically significant risk reduction with regard to postoperative wound infection.

One of the US American studies demonstrated a statistically significant increase in risk for 30-day complications after pancreatic resections. In the same study, a statistically significant risk reduction was shown in AAA repair. The other US American study found a reduction in morbidity rates for percutaneous transluminal angioplasty (PTCA) in Florida, but this was not statistically significant.

Health-related quality of life

None of the included studies considered this outcome.

Re-intervention

Two studies investigated the effects of minimum volume regulations on the basis of the outcome "re-intervention". The German study showed a risk reduction for re-intervention (re-operation) following TKR, but this was not statistically significant. The American study found a statistically significant reduction for the 90-day rate of re-interventions (re-admissions) following oesophageal resections. On the other hand, for pancreatic resections, the same study showed a statistically significant increase in re-intervention rates after 30 and 90 days.

Length of hospital stay

Two studies considered the duration of hospitalization. Both the US American (for oesophageal resections) and also the German study (TKR) found no major change in the length of hospital stay between the control and intervention groups. There was a statistically significant reduction in the average hospital stay following pancreatic resections and AAA repair in the American study.

Structural effects

Of the 10 studies included for sub-goal 2, 6 from Germany and 2 from the USA and Canada described the effects of minimum volume regulations on the structure of care.

Number of cases/number of hospitals

Most German studies showed no major changes in the total number of hospitals participating in the provision of care following the introduction of or increase in the minimum volume regulation for TKR, liver, kidney or stem cell transplantations or for pancreatic or oesophageal surgical procedures. A small number of hospitals withdrew from providing such care or the number of hospitals remained overall constant. In terms of case numbers, apart from liver transplantations, all German studies showed an increase in virtually all types of procedure after the introduction of or increase in the minimum volume regulation.

In the US American study, a decrease was observed in the total number of Evidence-Based Hospital Referral (EBHR) hospitals following introduction of the Leapfrog standard. The total number of AAA repairs and oesophageal resections increased after the Leapfrog standard was introduced, whereas pancreatic resections fell. In addition, the study showed a statistically significant increase of cases in EBHR hospitals for oesophageal and pancreatic resections

following introduction of the Leapfrog standard. The Canadian study was unable to show any clear tendency in the development of the number of hospitals and of cases after introduction of the minimum volume regulation for pancreas cancer surgery in Ontario. However, this province already recorded an increase in number of cases with a simultaneous decrease in number of hospitals prior to introduction of the minimum volume regulation.

Distances to hospital

Three studies investigated the distances patients had to travel to reach the hospital after the introduction of minimum volumes. Two German studies showed statistically significant results in terms of changes in distance to the hospital for TKRs, liver and stem cell transplantation, as well as for oesophageal surgical interventions. In the case of TKR and stem cell transplantation, distance fell after the introduction of or increase in the minimum volume regulation. The distance rose in the case of liver transplantations and oesophageal surgery after the minimum volume was increased. The results with regard to change in distance following the introduction of the minimum volume regulation were not statistically significant for renal transplantation and pancreatic surgery. No conclusions could be drawn in the North American study about the statistical significance of results on distance changes with regard to pancreatic resections.

Presentation of results relating to Germany

Seven of the studies included for sub-goal 2 originated from Germany. Two were restricted to data from hospitals of the Cologne-Bonn Regional Group and another study evaluated quality assurance data from North-Rhine Westphalia (NRW). The other studies used nationwide data. These German studies produced the following results in terms of patient-relevant outcomes:

The mortality rates after TKR did not differ.

In terms of morbidity, one German study demonstrated a significant reduction in the risk of postoperative wound infection following the introduction of a minimum volume regulation. Another German study showed a reduced risk of wound infections but the reduction was not statistically significant. For general complications (pneumonia, thrombotic events, pulmonary embolisms) and for nerve injuries following TKR, risk reductions were only sometimes statistically significant. The frequency of vascular injuries showed a statistically significant decrease in all 3 years. There was a statistically significant increase in risk of implant malpositioning in 2006 and 2007. There was also an increase in risk of fractures (surgical complication), but this was not statistically significant.

Another German study demonstrated a statistically significant reduction in risk of postoperative wound infection as well as for wound haematoma/secondary bleeding.

In terms of structural effects, most German studies showed no major changes in the total number of hospitals participating in the provision of care after the introduction of or increase in the minimum volume regulation for TKR, liver, kidney or stem cell transplantations or for

pancreatic or oesophageal surgery. In terms of case numbers, apart from liver transplantations, most German studies showed an increase in the total number of cases for almost all types of surgical procedures following the introduction of or increase in the minimum volume regulation.

Two studies produced statistically significant results in terms of changes in distance to the hospital for TKR, liver and stem cell transplantations, as well as for oesophageal surgical procedures. In the case of TKR and stem cell transplantation, the distance fell after the introduction of or increase in the minimum volume regulation. After the minimum volume was increased, the distance rose in the case of liver transplantations and oesophageal surgery. The results with regard to distance changes following the introduction of the minimum volume regulation were not statistically significant for renal transplantation and pancreatic surgery.

One German study analysed the changes in hospital stay after TKR and found no major change in length of stay before and after introduction of the minimum volumes.

The results of a German study on the outcome “re-intervention after TKR” showed a risk reduction but this was not statistically significant.

Presentation of the results relative to the catalogue contents of the ABK-RL

A search of the current scientific literature conducted for this report found no studies that dealt with a quality-assuring or quality-increasing function of minimum volume regulations relative to the catalogue contents of the G-BA directive on outpatient treatment in hospitals. However, 5 studies investigated procedures that are of interest for the rare diseases and diseases with a specific course that are named in the ABK-RL.

Presentation of results before and after 2008

According to the evaluation of the included publications, 8 of the 10 studies were published after the G-BA resolution in February 2008. Seven studies contained data from the period prior to the resolution and one study included the year 2008. The literature search found no studies that would enable data after 2008 to be presented.

Conclusions

Sub-goal 1: Calculation principles

The publications included in this report described several methods for calculating threshold values: approaches based on modelling using regression models, approaches based on the variation of the cut-off value for differentiating low and high case numbers, approaches based on the calculation of the observed and expected event frequencies per hospital/per physician and/or the ratio depending on the number of cases, and approaches based on several studies in the context of a systematic review.

The approaches based on modelling using regression models are, in principle, the most suitable for determining a threshold value for minimum volumes. Due to various deficiencies and limitations it does not, however, appear possible to identify a single one of the proposed techniques as the "optimum" method for operationalizing a minimum volume regulation.

Sub-goal 2: Effects of minimum volume regulations

Overall results of the included studies

In terms of the relevant outcomes, the studies identified for this report showed heterogeneous results. The studies looked at the effects of minimum volumes on the outcomes "mortality", "morbidity", "structural effects", "length of hospital stay" and "re-intervention".

The studies showed contradictory effects for the outcomes "mortality", "morbidity" and "re-intervention", so no clear trend could be identified.

Following the introduction of the minimum volume regulation, the results on structural effects showed, on the one hand, a tendency for the number of cases to rise whilst the number of hospitals remained the same or fell. On the other hand, changes in the distance patients had to travel to reach the hospital showed contradictory effects depending on the procedures involved.

There were no major changes in the outcome "length of hospital stay".

Results relating to Germany

The results correspond to the overall results reported above.

Results relating to the catalogue contents

A search of the current scientific literature conducted for this report found no studies that dealt with a quality-assuring or quality-increasing function of minimum volume regulations relative to the catalogue contents of the G-BA directive on outpatient treatment in hospitals.

Results before and after 2008

Based on the literature found for this report, no studies were identified that enabled the effects of the minimum volume regulations after 2008 to be described.

Due to their non-uniform results and the design used (high risk of bias), with a sometimes poor quality, the studies identified for this report did not allow any robust interpretation regarding the quality-assuring or quality-increasing effect of minimum volume regulations.

Keywords: minimum volume regulation, minimum volume, systematic review

The full report (German version) is published under www.iqwig.de.