REVIEW ARTICLE

Implementation and Effects of Germany's Minimum Volume Regulations

Results of the Accompanying Research

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SUMMARY

Introduction: Since 2004, Germany has had legal minimum volumes for five surgical interventions (kidney, liver, and stem cell transplantations and complex pancreatic and esophageal interventions). In 2006, minimum volumes for total knee replacement were added. On behalf of the Federal Joint Committee we evaluated the implementation of the minimum volumes and their effects on health service structure, hospitals, and outcome quality.

Methods: We analyzed hospital surveys and secondary data from quality reports for 2004, the Institute for the Hospital Remuneration System, and the Federal Agency for Quality Assurance.

Results: In 2006, the minimum volume regulations affected about half of all acute-care hospitals and about 146 000 hospital cases. Depending on the intervention, 10% to 60% of the hospitals with 1% to 31% of the patients performed the procedures yet failed to attain the minimum volumes. The number of hospitals providing the services did not change between 2004 and 2006, so nationwide coverage remained virtually unchanged. Regarding outcomes, only data for total knee replacement were available. One of three analyzed indicators of outcome, wound infections, showed the introduction of the minimum volumes to be associated with better results for higher numbers of cases.

Discussion: To date, the minimum volumes have affected health care only marginally. Further monitoring of the effects of the minimum volumes requires prospective definition of essential indicators of outcome and access.

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Key words: minimum volumes, health care research, quality assurance, integrated care, case number development

Since 2004, Germany has had legal minimum volumes for five types of surgical intervention, regulated by § 137 of the Code of Social Law, Book V. The Minimum Volumes Directive (Mindestmengenvereinbarung, MMV) of the Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA) provides for exceptions in certain circumstances, e.g., in emergencies, in the case of realignments of staffing or organization, for surgical training, or to ensure comprehensive coverage. For complex interventions involving the organ systems pancreas or esophagus, hospitals initially had to carry out at least five procedures per surgeon and year to be permitted to continue performing such operations. In 2006, the minimum annual volume was set at 10 per year for each hospital but the minimum number per surgeon was abolished. For kidney, liver, and stem-cell transplantation (Tx), the minimum volumes introduced in 2004 were 20 (kidney Tx), 10 (liver Tx), and 12 ± 2 (stem-cell Tx) interventions per hospital and year. In 2006, these minimums were raised to 25, 20, and 25 per year, respectively. Also in 2006, a minimum annual volume of 50 interventions per facility was introduced for total knee joint replacement (TKR).

The introduction of minimum volumes has its origins in a substantial quantity of studies, from a number of different countries, investigating the hypothesis that "practice makes perfect." Starting with a literature review by Luft et al. in 1979 (1), there are now not only numerous studies on the volume-outcome relationship for individual procedures, but also several prominent reviews (2–4). In summary, examination of these studies show first that there is a positive association between number of cases and outcome of treatment, but second that no concrete threshold values can be derived from the studies, third that the methodology of the studies was largely inadequate, and fourth that the question of causality in the volume-outcome relationship has yet to be resolved.

Internationally, various conclusions have been drawn from these studies. While some believe the introduction of minimum volumes is justified as a quality improvement measure (5–8), others counter that systematic or substantive arguments as well as the possible negative consequences speak against it (9–13).

Against the backdrop of potential negative effects and the overall inconsistency of the relevant studies, it was

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TABLE 1

Sources, analytical methods, and topics of the research accompanying the introduction of minimum volumes

Primary data	Methods	Topic
Hospital surveys (2006 and 2007)	Descriptive procedures, chi-square tests	Implementation and effects of the MV ^{*1}
Survey of the 16 state hospital planning authorities, the 17 Medical Associations of the German federal states, and the German Medical Association	Descriptive procedures	Exceptions for the sake of comprehensive coverage/effects of the MV on advanced training, etc.
Survey of experts with regard to outcome quality indicators	Delphi procedures	Agreement on outcome quality indicators
Secondary data		
Hospital quality reports 2004	Descriptive procedures, graphical analyses	Implementation of the MV, structural impact
External quality assurance data (BQS ^{*2}) on TKR ^{*3} 2004 to 2006	Multivariate logistic regression models, generalized estimation equations (GEE) analyses	Implementation of the MV, effects of the MV on outcome
InEK ^{*4} data	Descriptive procedures, <i>t</i> tests, distance analyses	Implementation of the MV, structural impact
Literature databases	Guideline analysis, extraction of quality indicators	Formulation of outcome quality indicators

^{*1} MV, minimum volumes; ^{*2} BQS, Bundesgeschäftsstelle Qualitätssicherung (Federal Agency for Quality Assurance); ^{*3} TKR, total knee joint replacement; ^{*4} InEK, Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System)

agreed when the MMV was negotiated that the introduction of the minimum volumes in Germany would be accompanied by research. The aim of this accompanying research, outlined here, was to investigate the implementation of the minimum volumes and their effects on the structure of patient care, on the hospitals, and on outcomes, and from the findings to derive recommendations on the future evolution of minimum volumes.

Methods

Depending on the individual evaluation goal, the authors employed primary and secondary data as well as literature data and consensus procedures from the accompanying research carried out between December 2005 and November 2007 (*table 1*). Four different data sources were drawn upon for analysis of the implementation of the minimum volumes: first, the legally required quality reports from the hospitals for the year 2004; second, a survey of representative samples of hospitals to establish how many hospitals had carried out relevant procedures in the period 2003 to 2006 and planned them for 2007; third, the case numbers for the relevant procedures in all hospitals in the period 2004 to 2006 with more than one case per minimum volume from the Institute for the Hospital Remuneration System (Institut für das Entgeltsystem im Krankenhaus, InEK); and fourth, data from the Federal Agency for Quality Assurance (Bundesgeschäftsstelle Qualitätssicherung, BQS) on case numbers in hospitals performing total knee joint replacement (TKR). For the implementation analysis, the data from these four sources were worked up descriptively and collated.

For evaluation of the effects of the minimum volumes on the structure of patient care, a geographic information system was used to calculate from the InEK data the

average distance and time traveled by the patients to reach the hospital. The effects of the minimum volumes in the hospitals were documented with the help of the primary hospital surveys for the years 2006 and 2007 (14, 15). In addition, the state hospital planning authorities were surveyed to ascertain to what extent hospitals had recourse to the exceptional circumstance "threat to comprehensive coverage" and whether their applications were granted or denied. Moreover, the state chambers of physicians were asked about the effects of the minimum volumes on advanced training.

Lack of data meant that the effects of the minimum volumes on outcome could be analyzed only for TKR, from the BQS data. With the aid of multivariate procedures, the associations of the outcome parameters "wound infections," "wound hematoma/secondary hemorrhage," and "limited mobility" with five case number categories were calculated. The variables "age," "sex," "ASA (American Society of Anesthesiologists) class," and "radiographic score" were used for risk adjustment, and generalized estimation equations analyses were employed to take account of any correlations within hospitals ("clustering").

Finally, to ensure the future evaluability of the outcomes of procedures subject to minimum volumes, quality indicators for these procedures were formulated on the basis of systematic literature searches and with the aid of an advisory council, and agreement on the indicators was reached.

Results

Implementation of the minimum volumes

Figure 1, compiled using data from all four sources consulted, shows the number of hospitals in Germany that

TABLE 2

Total case numbers and numbers of cases in hospitals that did not achieve the minimum volume (InEK data, procedure definitions 2006)

Intervention	2004			2006		
	Total cases N	MV	MV not achieved	Total cases N	MV	MV not achieved
Liver transplantation	877	10	226 (25.8%)	1100	20	178 (16.2%)
Kidney transplantation	2450	20	105 (4.3%)	2748	25	31 (1.1%)
Stem-cell transplantation	5213	12 ± 2	487 (9.3%)	5940	25	351 (5.9%)
Esophageal interventions	2713	5	969 (35.7%)	3249	10	998 (30.7%)
Pancreatic interventions	7151	5	1728 (24.2%)	8330	10	1581 (19.0%)
TKR	112 166	—	7894 (7.0%)*1	124 693	50	4361 (3.5%)

MV, minimum volume; *1 MV of 2006 would not have been achieved

carried out procedures subject to minimal volume or— with no allowance for exceptional circumstances— would have been permitted to perform such procedures, or planned to do so, in 2004 and 2006. The definitions of the procedures laid down by the GBA for the year 2006 were used for both years.

According to the data in the quality reports, in 2004 about one quarter of acute hospitals in Germany and around 23 000 patients were affected by the minimum volumes (16). According to BQS data the minimum volume for TKR, introduced in 2006, affected about 1000 hospitals and around 120 000 patients.

The data sources varied as to the number of hospitals that performed interventions subject to minimum volumes. For example, taken together, the quality reports from 2004 indicated that a reduction from around 300 to 100 hospitals performing esophageal interventions could have been expected if the higher minimum volumes had been implemented with no allowance for exceptional circumstances. In the primary surveys, about 30% of the hospitals that had carried out esophageal interventions in 2003 reported they would not be performing any planned esophageal interventions in 2007. The billing data from the InEK, however, show a slight reduction in the number of hospitals performing liver transplantation between 2004 and 2006, but no reduction for the other interventions regulated by the MMV.

There are several reasons why the minimum volumes have had hardly any effect on the number of hospitals performing the operations concerned. First, the numbers of all procedures subject to minimum volumes rose by 10% to 20% within the study period. For each type of intervention, this increase brought around 25% of hospitals up to the minimum volume.

Second, with the exception of liver and kidney transplantations, for each type of intervention there were hospitals in the InEK data that had not met the minimum volume criteria in the previous year. These "new" hospitals compensated for the overall low number of hospitals that had stopped offering a given procedure after failing to reach the minimum volume.

The third reason is the reporting of legally recognized exceptions in special circumstances (17). Of the 10% to 60% of hospitals, depending on the type of intervention, that continued to perform the procedures despite failing to achieve the minimum volumes, around half for each intervention claimed exceptional circumstances. This leaves the fourth reason, that some 5% to 30% of hospitals, depending on the type of intervention, continued to perform procedures subject to minimum volumes in the absence of exceptional circumstances.

The importance of the minimum volumes for hospital inpatients is shown in table 2. According to InEK data, 18 404 cases, i.e., around 1.1‰ of all hospital cases in Germany, were affected by the minimum volumes regulations in 2004. With the addition of a minimum volume for TKR in 2006, the figure for that year was 146 060 cases, about 8.5‰ of all hospital cases. The lowest proportion of cases in hospitals that did not achieve the minimum volumes was for kidney transplantation (4% in 2004, 1% in 2006), the highest for esophageal interventions (36% and 31%, respectively).

Effects on the structure of patient care

The prognoses on the basis of the quality reports for 2004 (figure 1) led to the expectation, for 2006, of a clear reduction in hospitals providing the minimum volumes, with longer average distances and traveling times for patients and in some cases considerable effects on comprehensive coverage (18). According to the survey of the state authorities responsible for hospital planning, up to the beginning of 2007 only 22 hospitals had submitted applications to perform procedures "to ensure comprehensive coverage," 18 of which were turned down.

In contrast to the prognoses on the basis of strict enforcement of the minimum volumes, the small change in the number of hospitals, as shown in the implementation analysis, went along with a mostly minor impact on the structure of patient care.

With regard to the distances traveled by the patients, on the one hand there were large differences among the

FIGURE 1

Implementation of the minimal volumes: number of hospitals that performed procedures subject to minimal volumes in 2004 and could have done so in 2006 based on the number of interventions in 2004 (quality records or BQS data), planned to do so (hospital surveys), or actually did so (InEK data). MMV, Mindestmengenvereinbarung (Minimum Volumes Directive), Tx, transplantation; TKR, total knee joint replacement

Risk-adjusted odds ratios (OR) and 95% confidence intervals (95% CI) for all hospitals in five case number categories for the outcome indicators "wound infection" and "wound hematoma/secondary hemorrhage" in TKR (BQS data 2006)

federal states and among the types of procedures, but on the other hand overall the distances changed little over time. In the case of pancreatic interventions and kidney Tx, there was no difference between 2004 and 2006 in the national average distance traveled by patients. For liver Tx and esophageal interventions the patients traveled significantly farther on average in 2006: 97 km instead of 62 km (factor 1.58) for liver Tx and 42 km instead of 34 km (factor 1.23) for esophageal interventions. For stem-cell Tx and TKR, the distance went down significantly: from 79 km to 68 km for stem-cell Tx (factor 0.86) and from 28.6 to 28 km (factor 0.98) for TKR.

In 2004, the variability in care among the federal states—measured by the range of distances actually traveled by patients—was lowest for TKR (19.4 km for Bremen versus 43.3 km for Schleswig-Holstein; factor 2.2) and highest for stem-cell Tx (30.6 km for Berlin versus 303 km for Hamburg; factor 9.9). In 2006, the lowest range was seen for TKR (19.4 km for Bremen versus 40.7 km for Schleswig-Holstein; factor 2.1) and the highest range for esophageal interventions (7.2 km for Bremen versus 88.8 km for Saarland; factor 12.3).

Effects in the hospitals

According to the results of the hospital surveys, implementation of the minimum volumes has very rarely—with the exception of TKR—been a local issue between hospitals and funding agencies (14, 15). It is equally uncommon for hospitals to come to arrangements regarding the spectrum of care or for a hospital to inform those who refer patients when it discontinues performance of interventions subject to minimum volumes. Hospitals excluded from performing the minimum volume procedures expect a worsening of their competitiveness and their public image, while nonexcluded hospitals see themselves as stronger in

both respects. To date, hospitals have experienced hardly any effects on other areas of performance. In addition, no clear-cut financial differences from fewer or more patients are reported, and no increase in waiting times.

Moreover, neither the surveyed hospitals nor the medical associations of the German federal states, which were also asked about effects of the minimum volumes, reported any noticeable effects on advanced medical training.

Effects on the outcome of patient care

The limited data on the outcome of interventions subject to minimum volumes meant that the associations between case numbers and three quality indicators of outcome could be investigated only for TKR. So many data were missing for "limited mobility," however, that this outcome indicator could not be meaningfully analyzed. Figure 2 shows the odds ratios for the two remaining outcome indicators, "postoperative wound infection" and "wound hematoma/secondary hemorrhage," in relationship to five case number categories between <50 and >299 cases annually in the year 2006. The outcome indicators of hospitals with 300 or more cases were used as reference values.

For both outcome indicators, higher numbers of cases were associated with better results in 2006. However, the odds ratios under the minimum volume of 50 were not significantly worse than in the next category, 50 to 99 cases per year. For wound infections, the hospitals with fewer than 50 interventions per year did not differ significantly from the reference value. For the outcome indicator "wound hematoma/secondary hemorrhage," only the group of hospitals with 200 to 299 cases per year differed from the category immediately below.

Analysis of the temporal evolution of the outcome indicators showed a statistically significant reduction of

22% in the risk of postoperative wound infection from 2005 to 2006 (odds ratio 0.78; 95% confidence interval 0.7 to 0.86). This effect can be explained by changes in the numbers of hospitals in the different case number categories, which in turn can be largely statistically attributed to the factor "minimum volume regulation."

Furthermore, analyses of the change in risk of wound infection showed clearly that the odds ratios of the BQS data decreased considerably between 2004 and 2006. While in 2004 the risk rose steadily from 1 in the reference category (>299 interventions per year) to 3.8 in the category below the minimum volume (<50 interventions per year), in 2005 and 2006 the odds ratios for this latter category were only 2.3 and 1.4 respectively.

Finally, the documented quality of all outcome indicators rose over the course of time in all case number categories, so that in 2006 there remained only slight differences in outcome between hospitals with low and those with high numbers of cases.

Discussion

The implementation of minimum volumes in German hospitals has been a step-by-step process of adaptation. Above all, the legally recognized exceptions in special cases have enabled allowance to be made for particular local circumstances. In addition, the GBA has not yet introduced any specific sanctions for failure to achieve the minimum volumes. Nevertheless, the survey results showed that statutory health insurance providers are increasingly putting the minimum volumes on the agenda of their annual negotiations with the hospitals, with the implied threat of refusal to assume the costs. These conditions seem appropriate for a change in the organization of patient care, but also explain why no drastic changes have been observed in the first three years since the introduction of minimum volumes—neither the predicted changes in care structures (18), nor in patient flow, nor again, as far as can be measured, in outcome.

Altogether, therefore, the results of the accompanying research permit no scientifically substantiated statement on the suitability of the minimum volumes introduced to date. Thus the debate on the usefulness of minimum volumes will continue (5–13), and the following recommendations as to the future evolution of the MMV in Germany should be viewed as no more than points for discussion:

- Since transplantations are already subject to quality control on the basis of the German law on transplantation and through the BQS procedures, and since the results of the accompanying research do not lead one to expect any further centralization, the instrument of minimum volumes should not be pursued further for transplantations. The established quality management measures could, however, be supplemented, for example by the setting up of benchmarking networks, which might be advisable for stem-cell transplantation.
- For esophageal and pancreatic interventions the minimum volume could be reduced from 10 back

to five cases per hospital and year, in order to avoid "occasional surgery" without an undue impact on accessibility.

- For TKR the existing minimum volume seems acceptable. There has been hardly any increase in the distance patients have to travel, and a trend towards improved outcome has been observed in all case number categories. In addition, the available data indicate that raising the minimum volume would bring no fundamental benefits for the patients.
- With regard to comprehensive coverage, before altering minimum volumes or introducing them for additional procedures it would appear pertinent to refine the underlying concepts and define benchmarks for accessibility as an important aspect of overall access to health care. This specifically requires cooperation among federal states.
- The accompanying research—according to § 137b of the Code of Social Law, Book V—into the effects of the existing minimum volumes and any new minimum volumes that might be introduced should comprise two components: first, prediction of the possible effects of planned minimum volume regulations on care, and second, investigation of the effects of existing minimum volume regulations on performance and outcome. At the same time, it is important to refine the quality indicators of outcome and the models for geographic analysis that are used in the accompanying research. Until these crucial parameters have been prospectively defined, the GBA should refrain from establishing further minimum volumes.

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Conflict of interest statement

The authors declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

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