

ORIGINAL ARTICLE

Achieving Minimum Caseload Requirements: an Analysis of Hospital Quality Control Reports From 2004–2010

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SUMMARY

Background: Legally mandated minimum hospital caseload requirements for certain invasive procedures, including pancreatectomy, esophagectomy, and some types of organ transplantation, have been in effect in Germany since 2004. The goal of such requirements is to improve patient care by ensuring that patients undergo certain procedures only in hospitals that have met the corresponding minimum caseload requirement. We used the case numbers published in legally mandated hospital quality control reports to determine whether the hospitals actually met the stipulated requirements.

Methods: We performed a secondary analysis of data supplied by hospitals in their quality control reports for the years 2004, 2006, 2008, and 2010 with respect to six procedures that have a minimum caseload requirement: complex interventions on the esophagus and pancreas, total knee replacement, and hepatic, renal, and stem-cell transplantation.

Results: The total case numbers for these six different procedures rose from 22 064 (0.1% of all procedures) in 2004 to 170 801 (0.9% of all procedures) in 2010. From 2006 onward, procedures to which minimum caseload requirements apply have been carried out in half of all hospitals studied. These procedures account for 0.9% of all inpatient cases in Germany. The percentage of hospitals that continue to perform certain procedures despite not having met the minimum caseload requirement ranged from 5% to 45%, depending on the type of procedure, and the percentage of cases carried out in such hospitals ranged from 1% to 15%. These values remained nearly constant for each of the six minimum caseload requirements over the 4 reporting years for which data were examined.

Conclusion: The establishment of minimum caseload requirements in Germany in 2004 did not lessen the number of cases performed in violation of these requirements over the period 2004 to 2010.

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Minimum caseloads are widely held to be an effective way of ensuring and improving the quality of medical interventions. However, the empirical evidence for this beneficial effect is inconsistent. Difficulties in interpreting the empirical evidence are caused particularly by inhomogeneity of the methods used for data acquisition and calculation (1–4). Debate focuses on the following aspects:

- The type of data used (5)
- The use of valid indicators to measure outcome quality (6, 7)
- Comprehensive adjustment procedures to compare the patient populations treated (8–11)
- The statistical relevance of rare events (12)
- Determination of a concrete case number threshold (13–15)

Moreover, numerous studies have investigated what structural and process-related factors lie behind the proxy indicator “case volume of facility” (16–23).

Nonetheless, the Federal Joint Committee (G-BA) acceded to the demands of German legislators and implemented, with due consideration of the current state of knowledge, “a catalog of planable interventions [...] for which the quality of treatment outcome depends strongly on the volume of interventions performed [...] as well as minimum caseloads per physician or hospital and exceptional circumstances” (§ 137 German Social Code V). Minimum caseloads were established for five inpatient surgical interventions in 2004, for a sixth operation in 2006, and for two further interventions in 2010. No minimum volumes have yet been defined for heart surgery (24). The classes of intervention and the prescribed volumes are shown in *Table 1*.

We set out to investigate the six areas of surgery for which minimum caseload requirements were introduced in 2004 or 2006. The minimum volume for treatment of neonates, introduced in 2010, was excluded—although currently much debated (25, 26)—because only data for the year 2010 were available.

On implementation of the minimum caseloads, hospitals in Germany became obliged to publish a biennial structured quality control report showing the number of patients treated with each of the interventions for which minimum caseloads are required. This report also has to

TABLE 1

Minimum caseload requirements 2004 to 2012: minimum volumes per hospital by report year

Intervention class	2004	2006	2008	2010	2012
Complex interventions on the esophagus organ system	5	10	10	10	10
Complex interventions on the pancreas organ system	5	10	10	10	10
Kidney transplantation	20	25	25	25	25
Liver transplantation	10	20	20	20	20
Stem cell transplantation	12	25	25	25	25
Total knee replacement	–	50	50	50	50*
Heart surgery	–	–	–	–	–
Prematures and neonates with birthweight <1250 g	–	–	–	14	14

* Suspended for 2012

explain any exceptional circumstances leading to failure to meet minimum caseload requirements. The quality control reports are freely available on the internet and can be obtained in electronic form from the G-BA. The data from the quality control reports permit conclusions to be drawn with regard to hospitals, case numbers, and exceptional circumstances. In this article we describe the implementation of six minimum caseload requirements in the period 2004 to 2010.

Methods

The investigation was designed as a retrospective, cross-sectional, observational study with the quality control report data from the years 2004, 2006, 2008, and 2010 as secondary source data. The XML files were exported to Excel and SPSS for evaluation. The analysis was purely descriptive. The data for each year were analyzed separately. For liver transplantation, the only data analyzed were those from the institutions defined as liver transplantation centers by the German Organ Transplantation Foundation, as previously

described in detail in an evaluation of the data for the year 2004 (27); data from hospitals where other hepatic interventions were performed were not considered. All hospital caseload data for minimum caseload procedures was checked for plausibility. In one year, one hospital was excluded from analysis owing to an implausible six-digit number of interventions. Redundant quality control reports from 12 hospitals were removed from the data set, as were quality control reports from 76 hospitals organized into 34 hospital groups in which the case numbers per minimum volume intervention could not be assigned to the individual hospitals. For these reasons, 2.2% of all hospitals with minimum caseload data and 2 815 (0.6%) interventions involving minimum volume procedures were not included in our analysis.

Results

Hospitals and cases analyzed

Of the 1983 hospitals that published a quality control report for the year 2004, 481 (24%) had carried out at least one class of minimum volume intervention. Following the addition of minimum caseload requirements for total knee replacement (TKR), the proportion of hospitals reporting relevant interventions rose to 52% in 2006, 54% in 2008, and 56% in 2010. After the inclusion of TKR the total number of minimum volume interventions rose sharply from 22 064 in 2004 to 143 058 in 2006; further increases in 2008 and 2010 took the total to 170 850 at the end of the study period. The minimum volume interventions represented 0.1% of all inpatient cases in German hospitals in 2004, rising to 0.9% in 2010 (Table 2). According to the Federal Statistical Office, the total number of inpatient cases increased by 7% between 2004 and 2010 (28).

Number of hospitals and case numbers per minimum volume intervention and report year

The number of hospitals that reported carrying out the individual minimum volume interventions fluctuated hardly at all between 2004 and 2010 (Table 3). The numbers performing complex operations on the esophagus and the pancreas went down from 2004 to

TABLE 2

Number of hospitals issuing quality control reports and number of hospitals performing at least one of the six classes of intervention with minimum caseload requirements in the period 2004 to 2010

	2004	2006	2008	2010
Hospitals with quality control report	1983	1940	1922	1871
Hospitals with at least one MV class, uncorrected	485	1018	1047	1071
Hospitals with at least one MV class, corrected (% of all hospitals with quality control reports)	481 (24%)	1007 (52%)	1032 (54%)	1055 (56%)
Inpatient admissions in Germany	16 801 649	16 832 883	17 519 579	18 026 451
Case numbers of the six MV intervention classes according to quality control reports (% of all cases)	22 064 (0.1%)	143 012 (0.8%)	166 361 (0.9%)	170 801 (0.9%)

MV, minimum volumes

TABLE 3

Number of hospitals performing minimum volume interventions and case numbers per minimum volume and report year

	Year	MV threshold	Hospitals with MV data	Hospitals under MV threshold	Hospitals under MV threshold without exceptional circumstances	Number of cases*1	Number of cases in hospitals under MV threshold
Complex interventions on esophagus	2004	5	297	86 (29%)	–	3302	179 (5%)
	2006	10	279	119 (43%)	47 (39%)	3450	515 (15%)
	2008	10	283	134 (47%)	23 (17%)	3459	573 (17%)
	2010	10	289	128 (44%)	34 (27%)	3610 (+9%)	534 (15%)
Complex interventions on pancreas	2004	5	456	84 (18%)	–	8417	200 (2%)
	2006	10	453	163 (36%)	56 (34%)	8643	741 (9%)
	2008	10	457	139 (30%)	28 (20%)	9161	631 (7%)
	2010	10	471	136 (29%)	29 (21%)	9440 (+12%)	626 (7%)
Kidney transplantation	2004	20	43	4 (9%)	–	2528	39 (2%)
	2006	25	40	2 (5%)	0 (0%)	2784	15 (1%)
	2008	25	40	4 (10%)	0 (0%)	2784	63 (2%)
	2010	25	37	2 (5%)	0 (0%)	2856 (+13%)	32 (1%)
Liver transplantation*2	2004	10	24	0 (0%)	–	2639	0 (0%)
	2006	20	23	1 (4%)	0 (0%)	1381	16 (1%)
	2008	20	23	3 (13%)	0 (0%)	1386	37 (3%)
	2010	20	23	1 (4%)	0 (0%)	1464 (+6%)	17 (1%)
Stem cell transplantation	2004	12	82	13 (16%)	–	5178	77 (1%)
	2006	25	82	18 (22%)	7 (39%)	6206	254 (4%)
	2008	25	74	19 (26%)	4 (21%)	5564	274 (5%)
	2010	25	84	22 (26%)	6 (27%)	6320 (+22%)	290 (5%)
Total knee replacement	2006	50	900	118 (13%)	45 (38%)	120 548	2705 (2%)
	2008	50	936	76 (8%)	19 (25%)	144 007	1842 (1%)
	2010	50	969	81 (8%)	19 (23%)	147 111 (+22%)	2048 (1%)

*1 In parentheses, percent increase during observation period; *2 data from liver transplantation centers; MV, minimum volume

2006 but increased again thereafter. The fluctuation was even smaller for liver, kidney, and stem cell transplantations.

The number of hospitals carrying out TKR between 2006 and 2010 increased by around 30 with each new report. The number of cases increased for all minimum caseload interventions between 2004 and 2010. Compared with the 7% increase in total inpatient cases in the same period, the changes in case numbers were slightly lower for liver transplantation (+6%) but somewhat higher for complex interventions on the esophagus (+9%). The changes for complex interventions on the pancreas (+12%) and kidney transplantation (+13%) were much more pronounced. The case numbers for stem cell transplantation and TKR rose even more sharply (+22%).

Number of hospitals below the minimum caseload requirement

The number of hospitals that did not meet the minimum caseload requirements varied among the interventions,

but remained broadly constant for each individual intervention.

With the minimum volume thresholds for esophageal and pancreatic interventions doubling from 5 in 2004 to 10 in 2006, the number of hospitals failing to fulfill the requirements increased sharply. From 2006 onwards, the rate was around 45% for esophageal operations and 30% for pancreatic surgery. For kidney transplantation the rate varied between 5% and 10%, for liver transplantation between 0% and 13%. The number of hospitals that did not achieve the minimum caseload requirement for stem cell transplantation increased when the threshold was raised from 12 to 25 interventions per year; since then the rate has been around 25%. For TKR the proportion of hospitals that did not meet the minimum caseload requirement fell from 13% to 8%.

The case numbers in the hospitals with too few interventions varied widely among the classes of intervention, but remained fairly constant over time for

TABLE 4

Average number of interventions per hospital by minimum volume and report year

	Year	Minimum	Maximum	Median	Mean	Standard deviation
Complex interventions on esophagus	2004	1	236	6	11.1	17.8
	2006	1	150	10	12.3	13.8
	2008	1	124	10	12.2	14.0
	2010	1	112	10	12.5	14.1
Complex interventions on pancreas	2004	1	362	10	18.5	28.8
	2006	1	384	11	19.1	31.7
	2008	1	395	13	20.1	29.8
	2010	1	427	13	20.0	29.8
Kidney transplantation	2004	1	192	48	58.8	36.9
	2006	4	251	57.5	69.6	48.4
	2008	9	255	60.5	69.9	48.7
	2010	12	264	69	77.2	51.7
Liver transplantation*	2004	–	–	–	–	–
	2006	16	143	51	60.0	36.7
	2008	11	146	47	60.3	37.9
	2010	17	160	60	63.7	35.7
Stem cell transplantation	2004	1	370	37	64.0	69.9
	2006	1	349	39	75.7	78.6
	2008	1	306	39	75.2	74.7
	2010	1	320	38.5	75.2	77.5
Total knee replacement	2006	1	979	93	134.3	126.0
	2008	1	1 329	109	153.9	143.3
	2010	1	1 367	108	151.8	140.2

* Data from liver transplantation centers

each individual intervention class. The lowest case numbers were for liver and kidney transplantations, at 1 to 3% and 15 to 63 cases, followed by stem cell transplantation with 5% and 250 to 290 cases. The proportion was also low for TKR in the two most recent report years, at 1%, but this represented approximately 2000 patients each time. The percentages were much higher for complex interventions on the pancreas (7 to 9%, 626 to 741 cases) and the esophagus (15 to 17%, over 500 cases).

Under the minimum caseload regulations, hospitals that do not achieve the caseload thresholds are obliged to itemize any exceptional circumstances. Since 2010, these comprise:

- Emergency interventions
- Extension of services offered
- Staff restructuration
- Decisions taken by the federal state authorities (responsible for hospital planning) to ensure state-wide provision of care.

Two circumstances previously classed as exceptional, “intervention started with curative intent but

finished palliatively or exploratively” and “surgeon training,” no longer count.

For each class of intervention, between 20 and 40% of hospitals that lay under the minimum volume thresholds reported no exceptional circumstances at any time during the period 2006 to 2010 (Table 3). No equivalent statement can be made for the year 2004 because of differences in the reporting format.

Average numbers of interventions per hospital

The average numbers of minimum volume interventions per hospital and year are listed in Table 4, together with the statistical measures of central tendency. Inspection of the number of operations per class of intervention in each individual hospital reveals that the number of interventions per hospital peaked at exactly the minimum volume threshold, as illustrated for complex interventions on the esophagus in the Figure.

In 2004 there were nine hospitals with four esophageal interventions and 49 hospitals (5.4 times as many) with five operations on the esophagus. From 2006 onwards, after the threshold was raised from 5 to 10

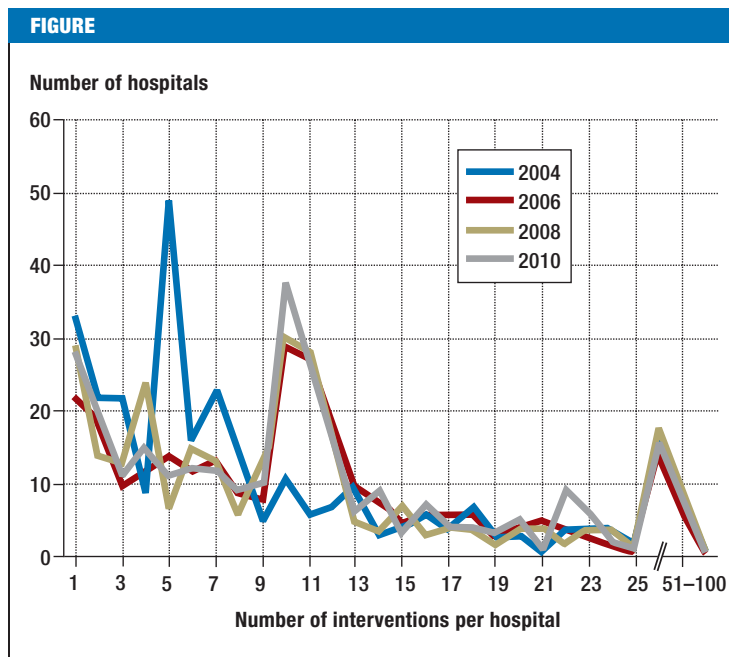
interventions per year, the number of hospitals with 10 operations on the esophagus was 2.3 to 3.8 times higher than that with nine interventions. Comparable differences precisely at the threshold value in all report years were found for TKR (3.3- to 5.0-fold), while the differences were somewhat less pronounced for complex interventions on the pancreas (2.4- to 3.2-fold) and stem cell transplantation (2.0- to 4.0-fold). No such increase was found for liver or kidney transplantation.

Discussion

The caseload requirements for the six minimum volume interventions we investigated, which involve more than half of all hospitals in Germany—although they comprise scarcely 1% of inpatient cases—are not always fulfilled. The goal of the minimum caseload requirements, namely to carry out the defined interventions exclusively in hospitals that achieve the minimum volumes, is therefore not being achieved.

The number of hospitals that performed such interventions without reaching the threshold remained constant throughout the study period, as did the proportion of patients treated in such hospitals. This was not affected by the fact that for most of the defined classes of intervention the percentage rise in the number of cases exceeded the increase for surgery in Germany overall. There has therefore been no increase in centralization for the minimum volume interventions. The existing extent of centralization can be described as the proportion of interventions carried out in hospitals that do not meet the minimum caseload requirements. By this yardstick liver transplantation, kidney transplantation, and TKR, with 1 to 2% of interventions in such hospitals, have achieved a high degree of centralization. The corresponding proportions of cases are much higher for pancreatic and esophageal interventions, at 7% and 15% respectively, while stem cell transplantation occupies an intermediate position with 5%.

How do these figures compare with other countries? Esophageal and pancreatic interventions are of particular interest, and comparable studies have been published. In the USA, where minimum volumes have been promoted in various ways since the 1990s, Learn and Bach (29) found tendencies towards centralization for many different interventions in a nationwide sample. For instance, the proportion of pancreatectomies carried out in hospitals with fewer than 10 cases per year fell from 67% in the three-year period 1997 to 1999 to only 51% in 2004 to 2006. Over the same time span, the proportion of esophagectomies performed in hospitals with fewer than six cases per year sank from 69% to 53%. This degree of centralization is nowhere near that achieved in Germany. In the Netherlands, however, the situation is comparable with that in Germany: a minimum volume threshold of 10 interventions was introduced for pancreatectomy in 2006, and the proportion of interventions carried out in hospitals with fewer than 10 interventions per year decreased from 47.2% in 2004 to 9% in 2009 (30).



Complex esophageal interventions: number of cases per year and hospital over the study period. The minimum volume threshold was five cases in 2004, ten cases from 2006 onwards

It remains to be seen how the proportion of cases in hospitals that do not meet the minimum caseload requirements will develop. Three fourths of these hospitals mentioned exceptional circumstances. “Emergency interventions” will continue to be cited as a reason, and “extension of services” and “staff restructuring” are signs of evolution in the hospital sector. To date, “ensuring state-wide provision of care” is practically irrelevant in this regard. As for the hospitals that cited no exceptional circumstances as reasons for failing to achieve minimum caseloads, the potential for and barriers to regional cooperation with regard to low-volume interventions should be investigated.

The impact of the German minimum caseload regulations on the quality of care is outside the scope of this study. Nevertheless, the fact that no substantial trend towards centralization has yet occurred makes such an effect seem unlikely. It remains difficult to furnish concrete proof of shifts in the quality of treatments in Germany, as early evaluations have shown (28, 31). However, this may change. Since 2006, hospitals have been obliged to document some of the quality indicator outcomes of external quality assurance in their quality control reports, e.g., for TKR and for liver and kidney transplantations. One crucial factor in assessing evolution over time will be consistency in definition of the indicators. However, because hospitals are obliged to respect patients’ privacy and quality indicators are reported only from five cases upward, quality assessment remains restricted for the particularly interesting low case numbers.

Limitations

With regard to the method, the data quality of hospitals' reports of their own activities has to be questioned. It is astounding, for example, how many hospitals precisely fulfilled the minimum caseload requirements for the non-transplantation interventions. This may point to distortion by falsification of the data in the quality control reports or to dubious extension of indications for the interventions concerned. Clarification of the reason would require separate empirical investigation of these two factors. The hospitals themselves state that they use their quality control reports not only for internal quality management and comparison with other hospitals, but also for purposes of external presentation (32). In this regard, a public statement of whether or not a minimum caseload requirement was met could well be important, although patients practically never use information of this kind (33). The quality control reports are also addressed to health insurance funds; however, an analysis published in 2008 yielded no indication that these bodies made systematic use of the information on minimum volumes in budget negotiations (34). It should be investigated whether health insurance funds have since changed their behavior in this respect.

Prospects

Further research should link the individual hospitals' quality control reports over the years to allow longitudinal analyses to establish how consistently hospitals adhere to minimum caseload requirements. Moreover, geographical analyses could examine questions of regional availability from the patients' perspective (35–39). Furthermore, the results could prompt comparison of the relevance and impact of the minimum volumes regulation with other structure-related quality initiatives, such as that for the development of breast centers in North Rhine–Westphalia (40).

Summary

The overall conclusion is that health services research should continue to evaluate the politically heavily favored requirements for minimum caseloads with the aim of identifying not only the possible positive effects of these regulations but also any negative consequences. The impact of the minimum caseload requirements on patients' health outcomes should also be investigated in comparison with other measures that are actually implemented and may exert a more sustained influence on the quality of care.

Conflict of interest statement

Prof. Geraedts has received payment from the German Medical Association for acting as a consultant on minimum caseloads. He has received honoraria for lectures on minimum caseloads and reimbursement of travel costs from the Federal Joint Committee (G-BA). His research on minimum volumes has been supported by the Federal Ministry of Health.

The other two authors declare that no conflict of interest exists.

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KEY MESSAGES

- Minimum volume thresholds were introduced for five classes of interventions (complex esophageal and pancreatic surgery, transplantation of liver, kidney, and stem cells) in German hospitals in 2004; total knee replacement was added in 2006, neonatal interventions in 2010. Hospitals are obliged to disclose how many of these interventions were performed in their quality control reports.
- The minimum caseload requirements introduced in 2004 and 2006 affect half of the hospitals in Germany, but involve only 0.9% of all inpatient cases.
- Depending on the class of intervention, 5 to 45% of reporting hospitals fail to achieve the minimum volume threshold.
- The proportion of patients treated in hospitals that do not fulfill the minimum caseload requirements varies among the different interventions from 1% to 15%, but remains broadly constant over time for each intervention.
- The strikingly high numbers of hospitals that precisely attain the minimum volume thresholds for the non-transplantation interventions prompts questions regarding data quality and/or indication quality, at least for this case number segment.

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