

## **Minimum volume standards – complex surgeries, no supervision**

Some highly complex surgeries may only be carried out by clinics in Germany if doctors and nursing staff have enough routine. However, according to an investigation by the Bavarian public broadcaster, this regulation was not adequately audited and undermined year after year.

Surgery successful, patient dead. What may sound funny as a figure of speech is serious in a hospital. To prevent this scenario from happening, the so-called minimum volume standards regulation was created: At German hospitals seven complex surgical procedures are currently only permitted to be carried out if a minimum level of experience exists. Studies show again and again that a lack of routine in complex surgeries puts the survival of the patient at risk.

Hospitals are required to regularly publish how many minimum volume surgeries they have performed in quality reports. BR Data, the data unit of the Bavarian public broadcaster has analyzed about 5,700 quality reports from German hospitals which were published between 2008 and 2016 and contained information on minimum volume sets. The result: The minimum volume threshold regulation designed to guarantee patients' safety and wellbeing has been repeatedly undermined in recent years.

## **Guidelines failed, operated anyways**

According to hospitals, around 170,000 procedures were classified as minimum volume sets throughout Germany in 2016. Almost two percent of those surgical interventions - around 3,000 operations - were performed in hospitals that did not meet the minimum volume standards. If this happens, clinics are obliged to stop performing this kind of surgery.

Exceptions of this rule are only permitted in certain cases, for example in emergencies or when a hospital has just hired a new surgeon. And yet, even after the deduction of these exceptional cases, hundreds of surgeries were performed without citing any of those exemptions – every year. In 2016 there were 923.

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*Due to court proceedings a part of the minimum volume standards was temporarily suspended. This is reflected in the number of procedures between the reporting years 2012 and 2014. Source: quality reports of German hospitals*

The former secretary general of the German Society for Surgery, Prof. Hartwig Bauer, criticizes the non-observance of minimum volume standards. The experience from other countries shows that higher minimum volume amounts could cut the mortality rate in half in some fields.

‘Minimum volume sets are most needed for complex surgeries with high mortality rates. Their outcome depends not only on the experience of the surgeon, but on the whole team. People don’t primarily die because of the operation, but due to uncontrolled complications.

- Prof. Hartwig Bauer, former Secretary General of the German Society of Surgery

And yet, surgeries that should not have been performed appear in hospitals' quality reports from all over Germany. BR Data has analyzed the published figures for Bavaria in more detail. Again, in the period from 2008 to 2016, about two percent of all minimum volume procedures were below the guideline. And of those, in turn – as it is seen in Germany as a whole – every third case listed no exemption justifying this. This means that 912 surgeries were performed in Bavarian hospitals that did not have the necessary routine but operated anyway.

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### **Intransparent agreements, flawed reports**

The quality reports show that 39 of around 400 clinics in Bavaria fell below at least one minimum volume standard between 2008 and 2016 without stating an exemption. 18 of them even violated the minimum volume standards for several years. So why did they perform surgeries without permission?

When confronted, some hospitals pointed out that they did not reach the minimum volume amount but there was an agreement with health insurance companies to continue performing those surgeries.

‘The surgical procedures performed in the period you defined were operations which solely accompanied other surgeries [...] For this reason no exemptions were listed. All these measures had been discussed with health insurance, were approved and agreed upon.’

‘In accordance with the then valid procedures, the respective shortfalls were reported to the benefactors, together with an objective estimation of the number of cases for the following year. Since there was no objection to our estimates

from the payers, the surgeries were further performed and compensated by the benefactors as well.'

Upon BR request several health insurance in Bavaria confirm that arrangements like these exist. Other clinics reported having submitted the data incorrectly in the quality reports.

'In the cases described by you a transmission error occurred which remained unrecognized even by reviews according to the four-eyes principle.'

'The information on the minimum volume sets was evidently not checked and remained without correction, the data from 2015 was wrong and hence re-published incorrectly in the 2016 report.'

- statements from Bavarian hospitals

And there's something else that becomes apparent when analyzing the quality reports: 18 Bavarian hospitals have given figures that are very close to the required minimum volume sets in at least three of the seven analyzed reporting years. Their data is either slightly above or below the standards or even on point. No hospital confirmed that it's common practice to work towards minimum volume amounts.

'According to the responsible chief physician, there is no anticipatory scheduling in this field.'

- statement of a Bavarian hospital

## **Nobody is responsible**

Individual agreements between hospitals and health insurance companies, unchecked information, wrong figures – all this is not comprehensible for patients. They can solely rely on and trust in the information given in the quality reports. What is the Federal Joint Committee's (G-BA) comment on the results of the BR analysis? The body is instructed by the Federal Ministry of Health to set and regulate the minimum volume standards for German hospitals.

The G-BA decided to pass a two-week deadline twice, then sent a ten-page letter containing generic statements. One point is emphasized several times:

'This offers the reporting hospitals, [...] the opportunity to present their respective range of services according to type, number and quality on their own responsibility. Consequently, the responsibility for the correctness of the content in the quality

reports lies with the reporting hospitals.’  
- statement of the G-BA

The G-BA points out that given the complexity of the subject ‘only the full response of the G-BA presents the facts comprehensively and appropriately’. You can read the entire answer [here](#). Some passages were blackened out for data protection reasons.

### **More surgeries in fewer locations**

Experts such as Prof. Hartwig Bauer, former Secretary General of the German Society of Surgery, are calling for a greater centralization of these procedures in order to ensure that minimum volume sets are satisfied more often. In his opinion complex surgeries should be performed at fewer hospitals that have more routine dealing with them.

Especially hospitals in rural areas argue that the population has a right to health care nationwide. For Hartwig Bauer this is not a durable argument in terms of predictable minimum volume surgeries:

‘We are not talking about emergency cases but plannable operations. Therefore it is reasonable for a patient to maybe drive 50 to 60 kilometers to a center. No surgeon – if it would concern himself – would go to a hospital where the procedure is performed only twice a year. Instead he would, of course, go to one where he assumes more experience in dealing with this clinical picture. And he would also recommend this to relatives or friends.’  
- Prof. Hartwig Bauer, former Secretary General of the German Society of Surgery

A 60 kilometers drive to be operated in a hospital with more experience is reasonable, according to professionals. It is also feasible according to our quality report evaluation.

For example, almost 2,000 complex surgeries on the oesophagus and pancreas were carried out in 2016 in Bavaria – more than 5 percent of them in hospitals that did not meet the minimum volume sets. A hospital with more routine would not have been far away. Especially in urban areas like Munich or Nuremberg hospitals with little or much routine often lie only a few kilometers apart from another.

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## Any improvement in sight?

Following a change in law in November 2017 the G-BA adopted a fundamental revision of the minimum volume standards. From now on, hospitals have to specify exactly how many minimum volume surgeries they are forecasting for the following year on July 15 of a calendar year. A similar predicting procedure has already existed before the revision, but the requirement was much more general. As a result, hospitals faced virtually no sanction for breaches of the minimum volume standards:

‘[...] Nevertheless, it should be noted that the minimum volume standards for certain surgeries didn’t have the expected effect on supply structures since their introduction. Among other things, this was due to the lack of possible sanctions by health insurance in case of non-compliance by the hospitals but also to the sometimes missing support by state authorities.’  
- statement of a Bavarian health insurance company on BR request

In other words, health insurers lacked the legal support to sanction hospitals in case of non-compliance with the minimum volume standards. This should change now. As early as December 2017 the AOK, a big health insurance company, announced that it would no longer reimburse certain clinic services if the respective minimum volume surgeries per year were not met and not explained with one of the existing exemptions. In addition, the medical service – an auditing body of statutory health insurances – is supposed to improve reviewing ‘the validity of information published by hospitals and their compliance with quality requirements’, writes the G-BA upon request (see the [entire answer](#)).

Whether or not the adopted changes regarding minimum volume sets are indeed effective can only be verified in 2020 at the earliest due to transitional provisions.

## Definition of terms

The guideline for **minimum volume standards** states that a range of specific complicated surgeries may only be performed if the hospital has enough experience dealing with them. Minimum volume standards have existed in Germany since 2004, currently for the following seven fields:

Procedure (minimum volume amount)

- Liver transplantation, including living-donor liver transplant (20)

- Kidney transplant, including living transplantation(25)
- Complex procedure on the Organ System Oesophagus (10)
- Complex procedure on the Organ System Pancreas (10)
- Stem cell transplantation (25)
- Total knee replacement (50)
- Care of premature babies and newborns with a birth weight of <1250g (14)

*Source: current catalog of minimum volume surgeries in Germany*

There are currently two other areas under discussion for a minimum volume set. The surgical treatment of breast cancer and lung cancer. A decision can be expected by 2010, according to the G-BA.

Since 2005 German hospitals are required to publish the number of performed minimal volume surgeries in their **quality reports**. The reports give an overview of the structures and services of hospitals, for example of the spectrum of diagnosis and treatment and of staffing. The information in the quality reports can be found, among other things, in hospital search engines which shall enable patients to choose hospitals according to specific criteria and compare them with another in regard to forthcoming procedures.

From the patient's point of view quality reports have a great advantage: they are free of charge and usually available on the hospital's website. In contrast, many other hospital records are not available to the general public or can only be obtained at high costs.

The **Joint Federal Committee (G-BA)** in Berlin collects and publishes all quality reports. It is the supreme decision-making body of the joint self-administration of doctors, dentists, psychotherapists, hospitals and health insurance companies in Germany. As a decision-making body with the authority to issue directives it determines, within the framework already prescribed by the legislator, which medical care benefits are covered by the statutory health insurance. The G-BA is thus also responsible for the guideline regarding minimum volume amounts.

## Methodology

In order to be able to analyze the quality reports throughout Germany for the largest possible period of time, we requested the documents in XML format through the G-BA. The count of performed minimum volume sets for each reporting period is indicated in part C-5 of each quality report. If exemptions were referenced, they should have also been listed there.

If a hospital specified a value below the minimum volume amount, we counted that as *below minimum volume set*. If in addition no exemptions were indicated, we have categorized that as *below minimum volume set without exemption*. Hospitals with multiple locations must submit one report per location and one overall report. We did not take the overall reports into account. However, some hospitals have submitted individual reports and labeled them incorrectly as overall reports. We considered these reports as a single report.

Some hospitals entered the details of their overall reports into all individual reports per location. In this case we only considered one report. We did not include several reports showing completely unrealistic entries such as a hospital giving 100,000 complex procedures for three years in a row.

The file name of each quality report shows the hospital's institution code and the type of report: single, location or overall report. The federal state can be inferred from the third and fourth place of the institution code.

>> see original text (German) at:

<http://web.br.de/interaktiv/mindestmengen/>