Dr. med. Jürgen Malzahn
Prof. Dr. med. Jochen Schmitt MPH

What are the benefits of the hospital reform for the care of patients with cancer?

An impact analysis of the implementation of the WiZen study by means of § 40 KHG (new) provided for in the cabinet draft of the KHVVG

One of the main aims of the current hospital reform is to increase the quality of care by concentrating complex treatments on appropriately qualified service providers. In this context, a concentration of oncological treatment is also planned. The National Cancer Plan adopted in 2008 calls for all people suffering from cancer to receive high-quality care in accordance with evidence-based treatment guidelines in uniformly qualified centres. In order to implement the National Cancer Plan, the German Cancer Society (DKG), in cooperation with all oncological societies, has set up a certification system that ensures these requirements are met. The WiZen study, funded by the Innovation Fund, was able to show by means of controlled cohort studies for 11 cancer entities based on nationwide SHI routine data and regional data from clinical cancer registries that the initial treatment of people with cancer in hospitals with DKG certification is associated with longer overall survival and recurrence-free survival (Fig. 1) [1]. The Innovation Committee of the Joint Federal Committee (G-BA) considered the WiZen study to be evidence that treatment in certified oncology centres can significantly increase the chances of survival for patients and asked the G-BA to examine whether the findings from the WiZen study could be taken into account in a timely manner, e.g. when defining minimum requirements for structural, process and outcome quality [2]. The recommended implementation of the results of the WiZen study in standard care has not yet materialised. Furthermore, a high proportion of patients in numerous entities are treated outside of certified centres.

>> As part of its 5th statement, the Government Commission for a Modern and Needs-based Hospital Reform (Government Commission) calculated the potential of concentrating primary oncological treatment in certified centres at over 20,000 life years per year and showed that the concentration of primary cancer treatment services in certified centres would not have any relevant restrictions on accessibility for the population. [3]

With the Hospital Care Improvement Act (KHVVG), a concentration of 15% is now to be implemented for the area of oncological surgery in accordance with the cabinet draft. Specifically, according to the cabinet draft on Section 40 KHG (new), hospital sites that have the fewest cases with oncosurgical services in an oncosurgical indication area in the reference year 2023 and together account for 15 per cent of cases are to be prohibited from charging certain fees for these cases. The Federal Institute for Drugs and Medical Devices (BfArM), the Institute for the Hospital Remuneration System (InEK) and the German Cancer Society (DKG) are working closely together to implement this plan. Firstly, the BfArM draws up a list of the ICD/OPS codes required for the individual cancer entities (e.g. breast carcinomas) with the involvement of the German Cancer Society. The BfArM adapts this list annually with regard to any changes to the ICD/OPS codes. Based on the BfArM's ICD/OPS list, the InEK draws up a list of hospital sites by 31 May 2025 that are permitted to provide oncosurgery services from 2027 to 2032 because they treated a sufficiently high number of cases in 2023. From the perspective of evidence-based healthcare, several important questions remain unanswered:

1. to what extent does the concentration of services in accordance with Section 40 KHG (new) lead to the implementation of the National Cancer Plan and the results of the WiZen study?
2. what effects can be expected from the planned concentration of services in oncosurgery?
3. what is the relationship between the G-BA's minimum volumes for some indications and the new mathematical minimum case numbers resulting from the implementation of § 40 KHG (new)?

Based on hospital data for 2022, this article examines how the hospital sites identified in accordance with the specifications of the cabinet draft of the KHVVG differ from the DKG-certified centres. The aim of this comparison is to show how the two different quality criteria affect the hospital landscape. The interaction with existing minimum volumes in accordance with Section 136b (1) No. 2 SGB V is also presented.

Methodology

The impact analysis was based on all German hospital cases in hospitals authorised in accordance with Section 108 SGB V with discharge in 2022, with the exception of BG cases in BG clinics and members of the German Armed Forces in Bundeswehr hospitals (data in accordance with Section 21 KHEntgG). The indications were defined with corresponding ICD/OPS codes as combinations of main diagnosis and procedure. For operations on the oesophagus and stomach, the surgical procedures (in accordance with the certification regulations of the German Cancer Society) were divided into open surgical and endoscopic treatments.

The site allocation of cases was based on the site providing treatment at the time of the operation. The 15% percentile limit was determined on the basis of the specifications in the cabinet draft of the KHVVG Article 3 No. 12 (Section 40 (2) KHG). It states: 'The Institute for the Hospital Remuneration System identifies all hospital sites that have provided services on the list in accordance with paragraph 1 sentence 4 on the basis of the performance data

in accordance with Section 21 (1) and (2) no. 2 of the Hospital Remuneration Act for the year 2023 and sorts these hospital sites in ascending order according to the number of cases for which services on the list in accordance with paragraph 1 sentence 4 have been provided, per indication area in accordance with paragraph 1 sentence 3. By 31 May 2025, the Institute for the Hospital Remuneration System shall publish on its website a list, differentiated according to service groups and indication areas in accordance with paragraph 1 sentence 3, of the hospital sites that have the fewest cases and together 15% of the cases of all hospital sites in the respective indication area after sorting in accordance with sentence 1, up to and including all hospital sites whose number of cases leads to 15% being reached.'

All centres certified in 2023 were included in the analysis. To address the above questions, the mathematical minimum case numbers were determined for the entities breast carcinoma, pancreatic carcinoma, bronchial carcinoma, colon carcinoma, rectal carcinoma, gastric carcinoma and oesophageal carcinoma in accordance with Section 40 KHB (new) and these were compared with the respective minimum quantities of the G-BA. All hospital sites that provided services in the respective indications in the 2022 study year were stratified according to certification status according to the DKG (available/not available) and according to the number of cases above/below the calculated minimum case numbers according to Section 40 KHG (new). The proportions of certified and non-certified clinics that would continue to participate in care after the implementation of Section 40 KHG (new) were then calculated.

Results

In total, between 237 (oesophageal carcinoma) and 1,005 (colon carcinoma) sites participated in care for the seven oncosurgical indications examined in the study year 2022. For these indications, the calculated minimum number of cases according to Section 40 KHG (new) was between six (gastric carcinoma) and 123 (breast carcinoma). The complete information can be found in Table 1.

As a result of the redistribution of the 15% of patients treated in the hospitals with the lowest number of cases provided for in Section 40 KHG (new), between 39.6% (gastric carcinoma) and 60.9% (colon carcinoma) of the hospitals would be above the calculated minimum number of cases according to Section 40 KHG

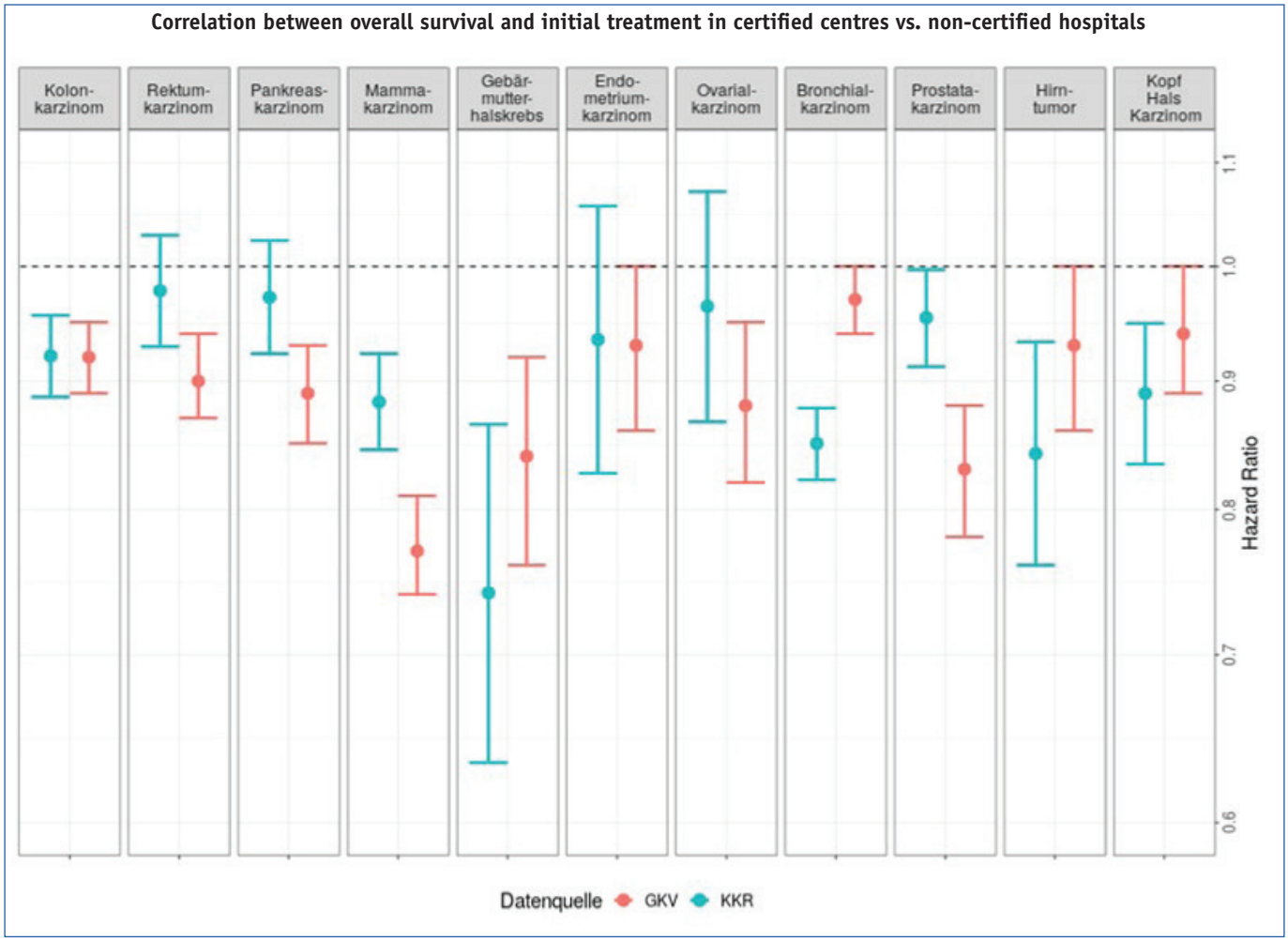


Fig. 1: *Relationship between overall survival and initial treatment in certified centres vs. non-certified hospitals for the 11 cancer entities investigated in the WiZen study (period 2009 - 2017). Legend: SHI data: Statutory health insurance data; CCR data: Data from clinical cancer registries..*

(new) for the indications analysed. This emphasises the extent of the current occasional surgery in the field of cancer medicine, contrary to the available, clear study evidence.

Between 17.9% (breast carcinoma) and 85.5% (gastric carcinoma) of the sites that would fulfil the minimum number according to Section 40 KHG (new) are not certified according to the criteria of the German Cancer Society (see Table 1 and Fig. 2).

Of the DKG-certified hospital sites, between 0% (oesophageal carcinoma) and 17.3% (breast carcinoma) would be below the minimum number of cases according to Section 40 KHG (new) and would therefore not be able to bill the SHI for their care services.

Erfüllungsstatus der Qualitätskriterien und Mindestfallzahlen nach § 40 KHG (neu)

				DKG-zertif. Zentren		Mindestfallzahl n. § 40 (neu) erfüllt	
Entität	Gesamtzahl Standorte 2022	Mindestfallzahl nach § 40	Mindestmenge nach G-BA (gültig 2022 / gültig 2025)	Anzahl Standorte	Anzahl (Anteil) unterhalb Mindestfallzahl nach § 40	Anzahl Standorte (Anteil aller Standorte)	Anzahl (Anteil) ohne DKG-Zertifizierung
Mammakarzinom	640	123	0 / 100	283	49 (17,3%)	285 (44,5%)	51 (17,9%)
Pankreaskarzinom**	429	9	10 / 20	139	9 (6,5%)	221 (51,5%)	91 (41,2%)
Lungenkarzinom	303	34	0 / 75	74	3 (4,1%)	131 (43,2%)	60 (45,8%)
Ösophaguskarzinom *;**	237	11	10 / 26	37	0	105 (44,3%)	68 (64,8%)
Magenkarzinom*	739	6	0 / 0	44	1 (2,3%)	293 (39,6%)	250 (85,3%)
Kolonkarzinom*	1005	20	0 / 0	291	2 (0,7%)	613 (60,9%)	324 (52,9%)
Rektumkarzinom*	886	9	0 / 0	291	5 (1,7%)	453 (51,1%)	167 (36,9%)

Table 1: Fulfilment status of the quality criteria and minimum case numbers according to § 40 KHG (new), according to G-BA and according to certification of the German Cancer Society for 7 types of cancer. Legend: * open; ** the G-BA has not decided on a diagnosis reference for the minimum volume regulations for oesophageal and pancreatic interventions..

For the four entities with minimum volume requirements set by the Federal Joint Committee in accordance with Section 136b (1) No. 2 SGB V in 2025, there were significant deviations from the calculated minimum number of cases in accordance with Section 40 KHG (new). For breast cancer, the calculated minimum number of cases according to Section 40 KHG (new) of 123 is higher than the minimum volume target according to Section 136b (1) No. 2 SGB V of 100 procedures per year. The requirement under Section 40 KHG (new) would therefore be stricter for breast cancer than the G-BA's minimum volume requirement. The reverse is true for pancreatic carcinoma, lung carcinoma and oesophageal carcinoma. Here, the calculated minimum number of cases in accordance with Section 40 KHG (new) is significantly lower than the minimum volume requirement of the G-BA in accordance with Section 136b (1) No. 2 SGB V. For each of these 3 entities, more than half of the hospitals that fulfil the minimum number of cases according to Section 40 KHG (new) do not fulfil the minimum volume requirement according to Section 136b (1) No. 2 SGB V (see Fig. 3).

Discussion

The aim of the hospital reform is to improve the quality of care by concentrating on appropriately qualified service providers. There is scientific evidence that shows an improvement in the quality of care for certification in accordance with the specifications of the German Cancer Society and for minimum volumes in accordance with Section 136b (1) No. 2 SGB V. There is no such evidence for the regulation in accordance with Section 40 KHG (new).

The evaluations show that due to the regulation according to Section 40 KHG (new), significantly more hospital sites remain in oncological care in all indications with the exception of breast cancer than hospital sites are certified according to the criteria of the German Cancer Society (Fig. 2). The positive aspects with regard to morbidity and mortality are documented in the WiZen study for the certification conditions of the German Cancer Society. [1, 2] There are therefore correlations between these comprehensive criteria and better quality outcomes. The argument that a volume

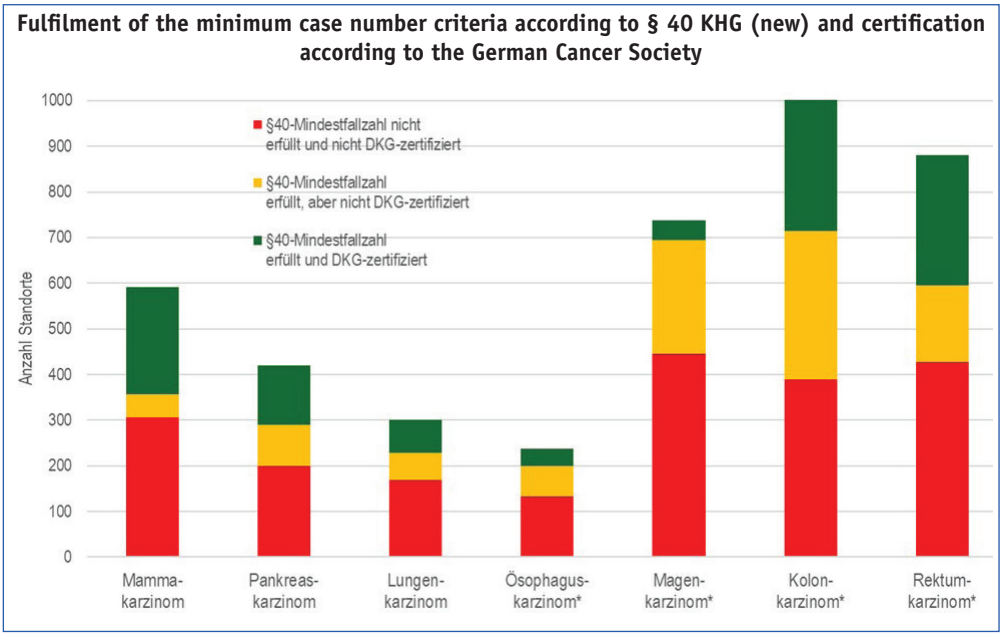


Fig. 2: *Fulfilment of the minimum case number criteria according to § 40 KHG (new) and certification according to the German Cancer Society. Legend: * open operations; ** sites that do not fulfil the calculated minimum number of cases according to § 40 KHG (new) but are certified are not listed in this graph, but can be found in Table 1.*

target alone, which is also not evidence-based, is an appropriate implementation of the results of the WiZen study for reasons of low bureaucracy is not convincing due to the considerable differences between the number of hospital sites. Rather, it can be assumed that the effects on morbidity and mortality are absent because many patients continue to be treated outside of certified centres in accordance with the regulations under Section 40 KHG (new).

Like the minimum volumes according to Section 136b (1) No. 2 SGB V, the regulation according to Section 40 KHG (new) only includes the surgical interventions per (carcinoma) entity - and thus does not take into account relevant other structures, processes and therapy steps such as 'decisions in the tumour board' or the availability of psycho-oncological resources or adjuvant chemotherapy. Consequently, the planned regulation in accordance with Section 40 KHG (new) and the minimum volumes in accordance with Section 136b (1) No. 2 SGB V only concentrate surgical interventions, while all other cancer treatment can continue to take place anywhere. However, a key success factor of the certification of the German Cancer Society is the complete treatment in the certified network structures, consisting of hospital sites and outpatient treatment partners [4,5]. This is particularly important because significant progress in cancer treatment is being made in the area of medication and surgical procedures are tending to decline. Nevertheless, the application of new drug therapies in particular requires extensive expertise and interdisciplinarity, as must be provided by cancer centres certified by the German Cancer Society.

This does not mean that each individual treatment step can only be carried out at the hospital site of a certified centre; rather, this can also be done decentrally by partners in the network. However, therapeutic coordination remains at the hospital sites of the certified centres, for example by involving the tumour boards in relevant treatment decisions.

With the exception of breast cancer, the minimum volumes of G-BA 136b para. 1 no. 2 SGB V are significantly higher than the minimum case numbers according to Section 40 KHG (new). The G-BA has provided high-quality justification for these minimum volumes based on the scientific literature. It seems incomprehensible to override these well-founded minimum requirements without sufficient scientific justification by generating a random value by setting a percentage for a disease group. If evidence from studies such as WiZen or the G-BA guideline is available for disease groups, this procedure should be avoided. For disease groups for which there are no comparable quality-based guidelines such as the G-BA minimum volumes or DKG certification, setting a percentage value may be better than 'no action' in order to end occasional surgery. This is supported by the very homogeneous evidence on volume-outcome relationships in large parts of medicine. [6] The Government Commission has presented an impact analysis of the effects of the certification of the German Cancer Society with reference to journey times. A corresponding concentration of services would predominantly only be associated with minor increases in journey times [3].

If Section 40 KHG (new) is implemented in the version of the cabinet draft, there are also other aspects that offer legal targets. Since only the number of cases in 2023 is decisive for the continuation of billing for cancer cases in 2027, it is possible that a hospital site had particularly low case numbers in 2023, but these will increase significantly in 2024 or 2025. The case numbers in these years may be significantly higher than the G-BA's minimum volumes in accordance with Section 136 (1) No. 2 SGB V. In these cases, it will be difficult to justify the withdrawal of a billing authorisation. Changes in the service structure of clinics in a positive, but also a negative direction, can certainly be expected in a four-year period.

Limitations

The final list of ICD/OPS codes for identifying the oncosurgical procedures relevant for Section 40 KHG (new) is not yet available, so we have made a categorisation that is plausible from the point of view of the authors and their institutions. The G-BA's minimum volumes in accordance with Section 136b (1) No. 2 SGB V also include some non-oncological indications that we were unable to take into account in this analysis. However, the vast majority of pancreatic and oesophageal procedures result from oncological indications. Nevertheless, this limitation will have led to a slight underestimation of the proportion of clinics that have fulfilled the respective minimum quantity of the G-BA. In this respect, the analysis may not be quantitatively correct for individual sites, but important patterns and qualitative effects are presented overall.

Fulfilment of the minimum case number criteria in accordance with Section 40 KHG (new) and/or the G-BA minimum volume regulation applicable from 2025

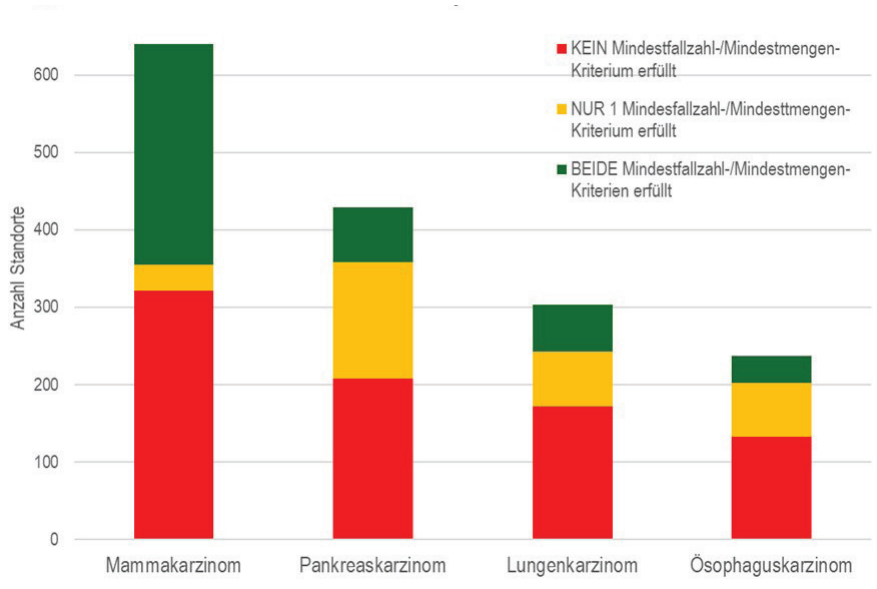


Fig. 3: *Fulfilment of the minimum case number criteria in accordance with Section 40 KHG (new) and/or the G-BA minimum volume regulation applicable from 2025 in accordance with Section 136b (1) No. 2 SGB V.*

As billing data is used in the regulation in accordance with Section 40 KHG (new), the use of billing data is not a limitation. The billing data is updated annually and was not yet available to us for 2023, so we had to work with the data from 2022. Even if the case numbers and thus the proportion of hospital locations that fulfil certain minimum case numbers change slightly over the years, the patterns described and the associated conclusions are nevertheless valid.

Take Home Messages - Conclusion

There is high-quality scientific evidence for the quality-enhancing application of relevant certification conditions of the German Cancer Society as a basis for concentrating services in the treatment of oncological diseases [1, 2]. With regard to surgical outcomes, this also applies to the minimum volumes in accordance with Section 136b (1) No. 2 SGB V.

In contrast, no correlation with the quality of outcomes has been described for the calculated minimum case numbers in accordance with Section 40 KHG (new). The hospital locations affected by the different regulations and the hospital services affected differ considerably from one another. A scientific basis comparable to the certification or G-BA minimum volume regulation is lacking for the planned regulation according to § 40 KHG (new). Experience with legal steps taken by hospital operators regarding minimum volumes in accordance with Section 136b (1) No. 2 SGB V must be taken into account. According to this, interventions in professional freedom require sufficient legitimisation and have otherwise been rejected by the social courts in the past. An analogous assessment of lawsuits against decisions based on Section 40 KHG (new) can therefore by no means be ruled out.

Overall, in order to achieve the objective of the hospital reform, namely to improve the morbidity and mortality of patients with cancer, it would appear much more expedient to limit oncological care exclusively to those facilities that meet the certification requirements of the German Cancer Society, as provided for in the National Cancer Plan, and thus demonstrably ensure guideline-compliant, evidence-based care for cancer patients. For legal reasons, the essential quality criteria from the certification procedures would have to be used - and thus a corresponding extension from surgical to conservative and thus the entire oncological care would have to be realised. Consideration of the network structures for individual treatment steps must be ensured in the concentration of services at the certified centres so that therapies close to the patient's home nevertheless remain possible. <<

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Author's statement

Jürgen Malzahn is head of department at the AOK-Bundesverband. Jochen Schmitt is a university professor at TU Dresden and a member of the government commission for modern and needs-based hospital care. The preparation of the data, the analysis and interpretation of the data and the preparation of the manuscript were carried out solely by the authors without the involvement or financial support of third parties.

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Dr. med. Jürgen Malzahn ORCID: 0009-0006-2165-6684

studied human medicine in Berlin and Frankfurt am Main. He has worked for the AOK Federal Association since 1997, until 2000 in the Hospital Case Management Department. He then moved to the Hospitals Division. He has been head of the Inpatient Care/Rehabilitation Department since 2007.
Contact: Juergen.Malzahn@bv.aok.de



Prof. Dr. med. Jochen Schmitt MPH ORCID: 0000-0003-0264-0960

After studying medicine and public health, he initially worked for around ten years as a (senior) doctor at the Clinic and Polyclinic for Dermatology at Dresden University Hospital. In 2011, he was appointed Professor of Social Medicine and Health Services Research at TU Dresden and has been the founding director of the Centre for Evidence-based Healthcare (ZEGV) at Dresden University Medicine since 2012. He is a member of the Government Commission for Modern and Needs-based Hospital Care, a member of the German Advisory Council on Health and Care and Deputy Chairman of the German Network for Health Services Research (DNVF). Contact: Jochen.Schmitt@ukdd.de.

