22nd German Congress for Health Services Research and the ‚WiZen' case

When health services research becomes important

‚Dear health services researchers, we have finally achieved what we have been working for.' With these enthusiastic words, Prof Dr Wolfgang Hoffmann, Chairman of the German Network for Health Services Research (DNVF), opened the 22nd DKVF, which took place at the Urania in Berlin at the beginning of October. The reason for his delight was the fact that - Hoffmann continued - the Innovation Committee recommends the transfer to standard care for 17 projects from the first and second funding waves of the new forms of care, but above all that the results of care research - including those of the ‚WiZen' innovation fund project, which was able to demonstrate the superiority of initial therapy in the primary treatment of cancer patients in certified centres - form an evidence base for the recommendations of the government commission for hospital reform. However, this is also precisely what the DNVF Chairman reminded the research community gathered at the German Congress for Health Services Research. Since health services research is now systemically relevant, this not only entails growing responsibility, but also has serious consequences: ‚Health services research now has critics.' Because, according to Hoffmann: ‚Our results, recommendations and priorities are now more likely to have consequences, they affect care providers, shift the balance of power and change financial flows.'

>> Health Minister Prof Dr Karl Lauterbach also referred to the role of healthcare research and the WiZen project in his video message. In order to further develop healthcare, said the Minister of Health, politics is dependent on scientific orientation, for which ‚healthcare research in particular performs an immense service'. This discipline is particularly in demand ‚where we cannot yet work in an evidence-based manner in medicine because we are breaking new ground'.

The project ‚Effectivenessof care in oncology centres' , funded by the Innovation Fund with 1.6 million euros under the funding code 01VSF17020, also broke new and innovative ground - full of good will to contribute to better care with more evidence. Lauterbach commented on its core statement that initial treatment in a certified - compared to a non-certified - hospital is associated with a longer overall survival of patients with incidental cancer: ‚Anyone who has cancer and is treated in a certified oncology centre has a better chance of survival. This is a great incentive and politically very relevant information for us.' His demand, which he would have to fulfil himself, however, because only the politicians themselves can do this: ‚We must raise the quality requirements for special primary cancer treatment across the board to a level that is comparable with certified centres.'

This is exactly the kind of mined terrain into which healthcare research has now unexpectedly found itself - and thus not only between many fronts, but also between the complex contexts and agendas of the benches that are active in self-administration and play a decisive role in determining the G-BA.

In its resolution (1), the Innovation Committee, which is part of the G-BA, was convinced that, in view of the high relevance of the findings on treatment success in certified oncological treatment facilities and the need for further research, ‚targeted dissemination of the project results' would be useful. According to the resolution text from 17 October 2022, the project successfully investigated the effectiveness of healthcare for cancer patients and provided ‚scientifically sound findings on the effectiveness of healthcare in certified treatment facilities compared to care in non-certified facilities'. Consequently, the project results were forwarded with the ‚request for examination of possible use within the scope of their respective responsibilities' to

- the G-BA Quality Assurance Subcommittee and
- the Institute for Quality Assurance and Transparency in Healthcare (IQTIG).

In addition, the Quality Assurance Subcommittee was asked to include the results in the ‚possibilities for defining minimum requirements for structural, process and outcome quality and for the development of data-based quality assurance procedures' and also to examine their ‚consideration in the G-BA's facility comparison reporting to support patient selection decisions in accordance with Section 136a (6) SGB V.' So far so good.

Transfer? Still no sign

However, so far there has been no visible progress in implementation and transfer, as Prof. Dr Jochen Schmitt from the Centre for Evidence-Based Healthcare at the Faculty of Medicine at the TU Dresden, head of the project consortium and, together with Prof. Dr Monika Klinkhammer-Schalke from the Arbeitsgemeinschaft Deutscher Tumorzentren e. V. (Association of German Tumour Centres) and head of the centre, has pointed out. V. and Head of the Centre for Quality Assurance and Health Services Research at the University of Regensburg, were the main authors of the original paper on the subject, which has already been published in the ‚Deutsches Ärzteblatt', at a symposium organised by the Cancer Society at the DKVF.

Three of the four speakers in this appropriately titled track, including the all-important question mark ‚Does the Innovation Fund contribute to improving care?', reported on their experiences after the end of the project. Ursula Marschall from BARMER, for example, shed light on the ‚TRANSLATE-NAMSE' project and the limited possibility of ‚transfer to healthcare through selective contracts'. Prof Dr Martin Lambert from Hamburg's UKE focused his presentation on the ‚RECOVER' project, which could have produced good results, but the positive recommendation failed to materialise. Schmitt spoke about the failure of the ‚WiZen' project, which he played a key role in initiating, to be transferred to standard care despite a positive recommendation.

Fig. 1: A key result of ‚WiZen' on breast cancer care. Source: ‚Wirksamkeit der Versorgung in onkologischen Zentren (WiZen) - Erkenntnisse zur Ergebnisqualität und Erfolg des Datenlinkage', by Prof. Dr. J. Schmitt (1), Dr. O. Schoffer (1), Prof. Dr. M. Klinkhammer-Schalke (2, 3),C. Bobeth (1), Dr M. Roessler (1), Dr V. Bierbaum (1), Dr M. Gerken (2), K.

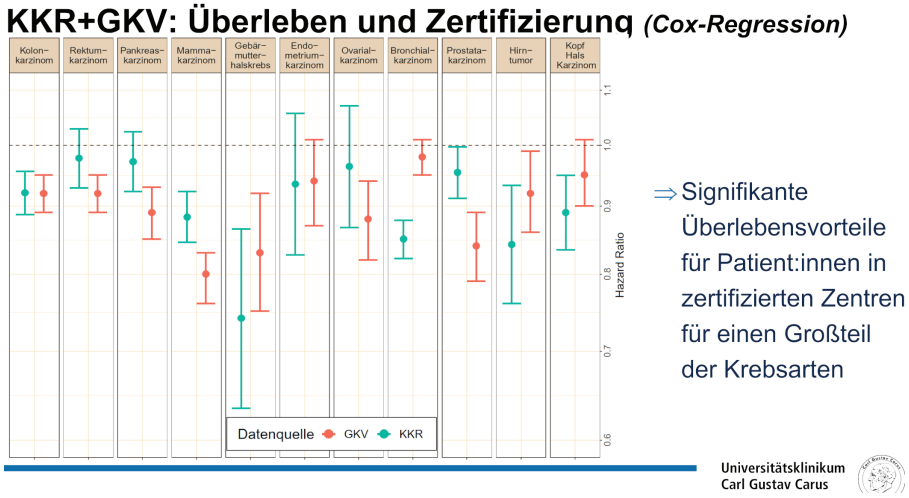


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Klinkhammer-Schalke, Schmitt and the research team behind ‚WiZen' are taking the important step of following up the ‚WiZen' results with further action out of their own initiative and out of the self-imposed obligation and mandate of health services research to really want to improve health services with their work. So far in vain.

The G-BA Quality Assurance Subcommittee, which was asked by the Innovation Committee for ‚targeted dissemination' - i.e. sowing the seeds - has not yet responded. This is apparently because, according to insiders, the subcommittee believes that it should not be bothered to set minimum requirements for structural processes and quality outcomes if the Federal Ministry of Health is doing this anyway as part of the upcoming hospital reform.

However, the BMG is not doing this at the moment. Here comes the next complex area in which healthcare research is currently involved: the federal hospital reform, which should naturally incorporate the results of the ‚WiZen' study - deliberately formulated in the subjunctive.

This in turn is due to the fact that the federal and state governments consulted with the federal states and coalition parties from January to July 2023 as part of a ‚federal-state group for hospital reform' and developed a comprehensive key points paper. In this paper, the federal and state governments have now agreed to take 60 somatic service groups according to the 2022 hospital plan of the state of North Rhine-Westphalia as well as five additional service groups proposed by the Association of Scientific Medical Societies (AWMF) as the starting point for defining the service groups. However, these do not yet include an oncology service group, let alone an interdisciplinary one, which would be needed to sustainably improve oncological care.

‚What consequences will the Federal Government and - to the knowledge of the Federal Government - the Federal Joint Committee (G-BA) draw from the findings of the ‚WiZen - Effectiveness of care in oncology centres' project, if any, and how should these be implemented in practice? In July of this year, the CDU/CSU member of parliament Sepp Müller addressed this question to the German Bundestag (2). The written answer from Parliamentary State Secretary Dr Edgar Franke states that the ‚future differentiation and further development of the performance groups is to take place with the involvement of the AWMF in particular'. In addition, ‚minimum structural requirements for quality-orientated service provision' are to be defined for the service groups on the basis of medical evidence. To this end, Franke continued in his answer, the AWMF has set up an ad hoc commission ‚Care Structures', which includes the German Cancer Society as the sponsor of the ‚OnkoZert' certification system for oncological facilities. Proposals for comprehensible and guideline-based criteria could also be introduced for requirements for oncological service groups, which also take into account the results of the ‚WiZen' project.

This at least gives cause for hope, even if it will take much longer than healthcare research would like in the interests of patient welfare. Schmitt, who is still disappointed by the G-BA's and politicians' transfer successes to date: ‚Although everyone is praising the project, we haven't been able to implement it yet, but patting ourselves on the back doesn't help much - least of all the patients.' The G-BA could use the example of ‚WiZen' to impressively demonstrate its ability to act.

Reason for the transfer to standard care: years of life lost

Above all, the transfer to standard care, which has not yet taken place, does not help the patients who are treated in non-certified centres and die far too early. In order to make the statistical survival figures of the hazard ratios, which are not always easy to understand, more comprehensible, the government commission for modern and needs-based hospital care, in which Schmitt is also involved, has prepared an analysis of potential. With the 5th statement entitled ‚Improving the quality and safety of healthcare - potential analysis based on exemplary diseases' (3), the Government Commission (RK) wanted to contribute to objectifying the discussion. The reason: The German Hospital Federation (DKG) had already argued in the context of the 3rd opinion of the RK, which recommended a concentration of care on clinics with high structural quality, that this could contribute to hospitals being closed and also that quality equals accessibility, which, according to Schmitt, is certainly not a tenable statement.

The potential analysis has been recalculated as the 5th opinion of the RK with current treatment figures from 2021. In addition, the methodology for estimating a nationwide, absolute effect of patient benefit through centralisation from the relative effect measures (hazard ratios) determined in the ‚WiZen' study has been published as an original paper in the DNVF journal ‚Health Care Research & Implementation' (4), which was first published for the DKVF and integrated into the journal ‚Gesundheitswesen'. The results of the Government Commission's potential analysis are also impressive. Here, the Germany-wide potential for avoiding years of life lost (YLL) and preventable deaths in stroke and arthroplasty was calculated for cancer, stroke and arthroplasty.

In the case of cancer, it was again possible to refer to the ‚WiZen' project and show how high the annual potential of concen-

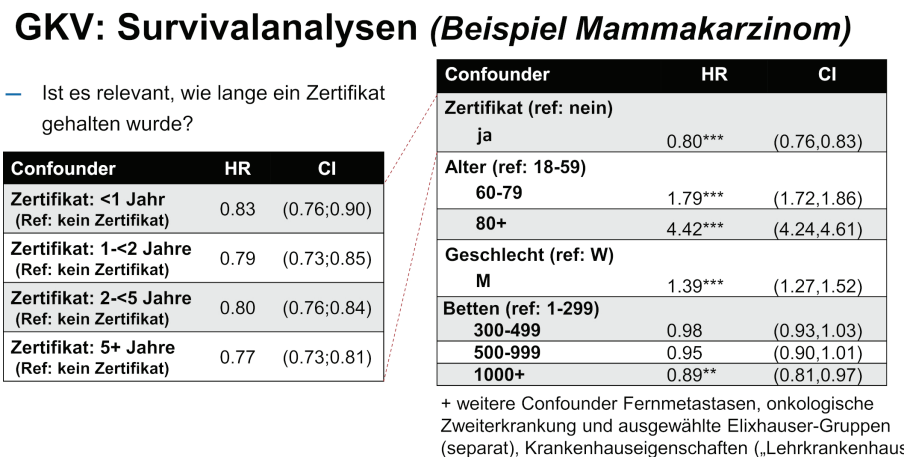
trating primary cancer treatment at DKG-certified hospitals (in life years saved) really is. The Germany-wide potential for concentrating primary treatment in DKG-certified hospitals is calculated as the product of the quality potential per patient and the number of patients receiving primary treatment in non-certified hospitals in the status quo.

This shows relevant quality potential for each of the 11 cancer entities analysed - from endometrial to breast to cervical cancer. Between 665 (cervical carcinoma) and 4,873 (colon carcinoma) years of life could be saved per year for the individual types of cancer by concentrating initial treatment exclusively on certified clinics. With regard to breast cancer, the potential is particularly high because, according to the 5th statement, the number of cases and the advantage of treatment in a certified centre are particularly high. Overall, the quality potential for all entities for the initial treatment of cancer diagnoses amounts to 20,404 life years per year.

According to more recent projections based on 2021 figures, the potential across all eleven types of cancer still adds up to over 20,000 avoidable years of life lost - every year, mind you! The decline could be due to the fact that more clinics have now been certified than in 2017 or that patients are opting to undergo surgery in certified centres. Either way, Klinkhammer-Schalke and Schmitt say in unison: ‚Even the 20,000 years of life lost are still too many.'

The estimate of years of life lost, as well as the estimated potential to avoid deaths five years after diagnosis (4,729 cases per year), should prevent misinterpretation of the hazard ratios usually used in survival analyses. The presentation, according to the original paper, could help to achieve a ‚presentation of results for important actors in the healthcare system without specialised background knowledge in statistics'.

In order to also invalidate the narrative that care close to home is then at risk, the commission also analysed the effects for colon, breast and prostate cancer and for brain tumours. According to the study, more than half of the population can reach a certified colon or breast cancer centre from their own home in well under 20 minutes. For prostate and brain tumours, the median accessibility for the German population is just over 20 and 30 minutes respectively. Travel times to a certified cancer centre of more than 40 minutes exist for around 11% of the population for bowel and breast cancer, 20% for prostate cancer and around 40% for brain tumours.



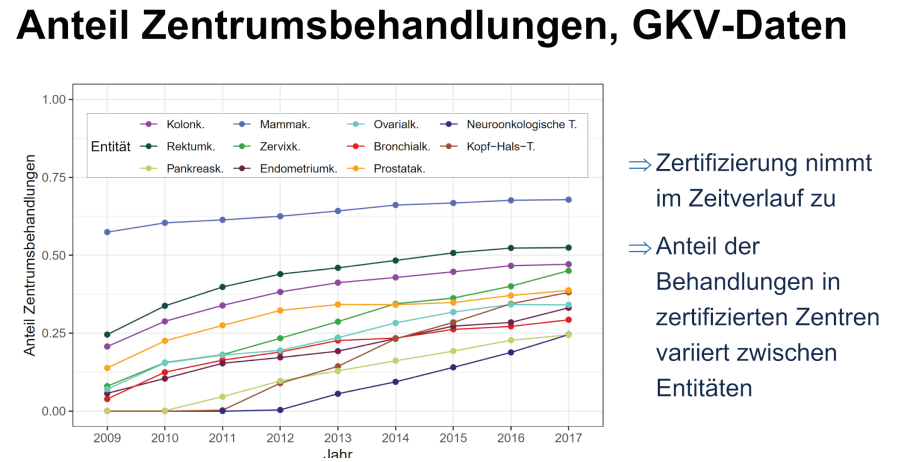


Fig. 2: Further results of ‚WiZen' on breast cancer care regarding the effect of the duration of certification and the number of certified centres by cancer entity. Source: ‚Effectiveness of care in oncology centres (WiZen)'.

The government commission's interpretation of the concentration of cancer care in certified clinics: ‚The analysis of potential shows a high potential for improving the quality of care by concentrating the initial treatment of patients with cancer in certified centres while maintaining nationwide care and good accessibility for the population.' In addition, the initial treatment of cancer is not an emergency where travelling time is medically relevant. He continued: ‚The structural requirements for service groups that are authorised for the initial treatment of people with cancer should be based as closely as possible on the DKG's certification criteria. This includes requirements that ensure the necessary interdisciplinary and interprofessional cooperation as well as the expertise of the treatment partners.'

It is also important that the present impact analysis, as well as the ‚WiZen' study, addressed the initial treatment in the centre and thus generally the surgical treatment of the types of cancer examined. Further treatment could then be carried out close to home by cooperating hospitals and/or outpatient service providers in coordination with the clinic providing the initial treatment - a network of regional service providers should be promoted here.

So why the delay of over a year? There is the highest possible level of evidence that - according to the Government Commission in its 5th statement - ‚specialisation and concentration of healthcare through evidence-based minimum requirements for structural quality offer considerable potential for improving outcomes and quality for the population without leading to significant restrictions in accessibility'.

It is therefore all the more disappointing that no concrete steps have yet been taken to save lost years of life, but also to minimise unnecessary pain and suffering for those affected and their relatives. There is no other way to understand the perceived standstill in the urgently needed transfer of the ‚WiZen' results to standard care after the end of the project a good year ago.

A search for the why

However, we can try to shed some light on the background and identify the banks involved here with their own agendas. An exciting AOK symposium in April of this year, at which the results of the ‚WiZen' doctors'programme and practice networks were presented to a broad public via streaming (5), provided a deep insight into the complex situation lurking in the background. After introductory presentations on the results of the study, Dr Carola Reimann, Chairwoman of the AOK Federal Association, Prof. Josef Hecken, Impartial Chairman of the G-BA, Dr Gerald Gaß, Chief Executive of the DKG e. V., discussed the results of the study under the moderation of Klinkhammer-Schalke (Arbeitsgemeinschaft Deutscher Tumorzentren e. V. and representative of the ‚WiZen' research group), Markus Algermissen, Head of the Medical and Professional Law Division at the Federal Ministry of Health, and patient representative Hedy Kerek-Bodden, Chairwoman of the Board of Haus der Krebs-Selbsthilfe - Bundesverband e. V. in Bonn.

The patient representative will not have been able to believe her ears when she heard the arguments put forward here as to why sensible, because better, cancer care in certified centres is not so easy to implement.

Theoretically, according to Hecken, the G-BA naturally has the option of defining certain structural requirements in Section 136 SGB V, such as the minimum quantities required for the treatment of oncological diseases. The Federal Committee could also define certification, as demanded by the government commission, as a requirement in a guideline. Hecken: ‚We could do that very quickly, but with the consequence that the federal states would be hampered in their hospital planning.'

According to Hecken, minimum volumes also have another effect - namely on the number of hospitals authorised to operate. According to the figures presented by Hecken, 220 of the 564 hospitals currently operating on women (and rarely men) with breast cancer perform fewer than 10 operations. And that is not even per year, because the minimum quantities have been stretched over two years by the G-BA. In return, the minimum volume would be gradually increased from 50 to 100 - but only from 2024 or 2025.

With a minimum volume of 100, only 355 hospitals in Germany would be allowed to operate on breast cancer instead of the current 732. This would allocate these operations to the remaining hospitals, which would then be able to perform them more successfully - because they are much more frequent - with better equipment, a more experienced treatment team and more routine processes.

If the change in the minimum volume were to remain at these 355 clinics, the distance would also increase, which is naturally the case in the area of conflict between local and specialised care. According to the G-BA chairman, the average journey time for breast cancer care would then increase from the current 15 to 18 minutes. Hecken: ‚If I had breast cancer, which is quite rare for men, I would gladly accept the 18-minute journey.' Mind you: on average. He is of course aware that the journey time in rural areas would be somewhat different, but would not be longer than 35 to 40 minutes.

As DKG Managing Director Gaß emphasised during the discussion, the hospital association is not at all opposed to minimum volumes. The DKG had proposed raising the minimum volume to 50 instead of 100, which would have been a significant increase (from the current 10). However, as minimum volumes are a control instrument, because all those hospitals that remain below the specified operating theatre level are then no longer allowed to offer these operations at all, this is tantamount to interfering with the commercial operations carried out by hospitals.

Gaß also had figures to go with it: Raising the minimum volume to 50 would mean a significant reduction in the number of hospitals currently authorised to operate on breast carcinomas: to just 428, or just under half. This demonstrates the ‚tension between, as Gaß ‚deliberately provocatively put it, ‚optimal treatment of the individual patient and the question of care close to home'. Although the sheer size or number of cases of a hospital is correlated with this, the quality of treatment provided by the hospital is much more important, as emphasised by Gaß. The certification carried out by the German Cancer Society, to which many hospitals have so far voluntarily submitted (note: depending on the cancer entity, this is 25 to 60% - Fig. 2), defines an ideal treatment process, so that certified hospitals can ‚provide good treatment results in the sense of this study' even with a minimum volume of less than 100. Gaß's suggestion for healthcare research: ‚This fact should be further analysed.'

So far, the ‚WiZen' study has provided an important and additional indication that the survival effect increases if a hospital has been certified for a longer period of time. For example, the survival advantage for breast cancer changes depending on how long a hospital has been certified: from 17% if a hospital has been certified for less than a year, rising to an impressive 23% if the certificate has been held for more than 5 years (Fig. 2).

In view of these figures, does the question really still arise as to where women suffering from breast cancer or cancer sufferers in general should seek initial treatment? <<

by: MVF Editor-in-Chief Peter Stegmaier

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