The WiZen case: methodological weaknesses?

Schmitt: 'Certification effect extremely likely'

'Every study has limitations,' Prof. Dr Jochen Schmitt from the Centre for Evidence-based Healthcare (ZEGV) and one of the main members of the WiZen study group (1) told 'Monitor Versorgungsforschung'. Anyone who claims that there are studies in health services research without limitations has not understood the basics of scientific work. An important part of any scientific work is therefore the discussion of the results, which includes a discussion of the methodological strengths, but also possible limitations, as was done in detail in the original publication of the WiZen study in the 'Deutsches Ärzteblatt' (2). It is therefore all the more surprising that Prof. Josef Hecken, impartial chairman of the G-BA and chairman of the G-BA's Innovation Committee, in his opening speech at the congress 'The Innovation Fund: Between Consolidation and Further Development' (see p. 22 ff.), referred to - to quote Hecken - 'one or two methodological weaknesses' of the WiZen project on the 'Effectiveness of Care in Oncology Centres' (3), which was supported by the Innovation Fund. MVF does the fact check.

>> Hecken's statement in his opening speech is primarily to be understood in purely political terms. Hecken went on record as saying this so that no one would claim afterwards that he had hyped up the project, when one or two others would argue that it had methodological problems. But which ones?

Hanisch: 'Some points of criticism'

With these words, the head of the G-BA is primarily referring to a discussion article published in the 'Deutsches Ärzteblatt' (DÄB) by Prof. Dr Dr Ernst Hanisch, long-standing Medical Director and Chief Physician of the Clinic for General, Visceral and Thoracic Surgery at the Asklepios Clinic in Langen/Hesse. He currently advises the Frankfurt law firm Dr Buchert & Partner, whose clients include clinics. However, Hanisch wrote his DÄB commentary entitled 'Some points of criticism' as a doctor of surgery specialising in visceral surgery, surgical intensive care medicine, emergency medicine, clinical acute and emergency medicine and as an associate professor at the University Hospital Frankfurt am Main, stating that he had no conflict of interest.

In his contribution to the discussion, as well as in the editorial entitled 'Questioning routine data' published in 2016, Hanisch quite rightly referred to the problematic nature of a paper based on - according to Hanisch - 'a secondary analysis of billing data (DRG system) that is primarily created for invoicing purposes (so-called routine data)'. In his opinion, this 'inevitably leads to the question of whether it is possible to achieve comparability of the two groups (certified versus non-certified) with these non-validated AOK billing data by means of risk adjustment using the Elixhauser score used by the authors'. In his opinion, patient-reported outcome measures should also be used in addition to survival time to assess the quality of hospitals. Hanisch also criticises the fact that the authors address the problem of causality due to their study design and state that it 'seems unlikely that the association between initial treatment in a certified centre and longer overall survival is not causal'. In his opinion, the objection of the non-causal relationship nevertheless remains and could have been countered, for example, with a propensity score analysis (or other causal inference methods such as target trial emulation), which could certainly achieve the potential of a randomised study.

At first glance, this all sounds quite understandable, but it is not entirely consistent. In their concluding remarks to the discussion of the results of the WiZen study (6), the WiZen authors counter that SHI routine data are firmly established in health services research and quality assurance in Germany, including in the Federal Joint Committee, and are the 'best resource for generating evidence in the context of standard care'. Furthermore, it is not DRG data that is used, as described by Hanisch, but cross-sector, audited SHI routine data, which is also the basis

Literature/Notes

1: Zentrum für Evidenzbasierte Gesundheitsversorgung, Medizinische Fakultät Carl Gustav Carus, TU Dresden, Dresden: Prof. Dr. med. Jochen Schmitt, Dr. rer. nat. Veronika Bierbaum, Christoph Bobeth, Dr. rer. pol. Martin Rößler, PD Dr. rer. nat. Olaf Schoffer / Tumorzentrum Regensburg, Zentrum für Qualitätssicherung und Versorgungsforschung der Universität Regensburg: Prof. Dr. med. Monika Klinkhammer-Schalke, Dr. med. Michael Gerken / Wissenschaftliches Institut der AOK, Berlin: Patrik Dröge, Thomas Ruhnke, Christian Günster / Arbeitsgemeinschaft Deutscher Tumorzentren e.V., Berlin: Prof. Dr. med. Monika Klinkhammer-Schalke, Kees Kleihues-van Tol.

2: Schmitt J, Klinkhammer-Schalke M, Bierbaum V, Gerken M, Bobeth C, Rössler M, Dröge P, Ruhnke T, Günster C, Kleihues-van Tol K, Schoffer O, on behalf of the WiZen Study Group: Initial cancer treatment in certified versus non-certified hospitals: results of the WiZen comparative cohort study. Dtsch Arztebl Int 2023; 120. DOI: 10.3238/arztebl.m2023.0169

3: https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/wizen-wirksamkeit-der-versorgung-in-onkologischen-zentren.137

4: https://www.aerzteblatt.de/archiv/238126/Einige-Kritikpunkte

5: Dtsch Arztebl Int 2016; 113: 251; DOI: 10.3238/arztebl.2016.0251b

6: DOI: 10.3238/arztebl.m2023.0265

7: Stang A: Evaluability of the effect of oncology center certification. Dtsch Arztebl Int 2023; 120: 645–6. DOI: 10.3238/arztebl.m2023.0184

8: Dtsch Arztebl Int 2024; 121: 202-4; DOI: 10.3238/arztebl.m2023.0264

9: Raspe H, Pfaff H, Härter M, Hart D, Koch-Gromus U, Schwartz F-W, Siegrist J, Wittchen H-U: Versorgungsforschung in Deutschland: Stand – Perspektiven – Förderung. Stellungnahme. In: DFG-Standpunkte. Weinheim/Berlin: Wiley-VCH 2010; 1-50.

of the quality assurance procedures in accordance with Section 136 SGB V.

Stang: 'Evaluability of the effect of the certification of oncology centres'

In their closing remarks, the WiZen authors also refer to other contributions to the discussion, all of which appeared in DÄB. For example, the editorial by Prof. Andreas Stang from the Institute for Medical Informatics, Biometry and Epidemiology at Essen University Hospital entitled 'Evaluability of the effect of certifying oncology centres' (7). In it, Stang warns of a 'weak evidence base' and a 'risk of systematic bias' and also explains that the authors interpret their results 'with great enthusiasm'. Even if - according to Stang, who also states that there is no conflict of interest - the results appear plausible, 'the critical reader cannot fully comprehend the almost unrestricted optimism associated with the formulations used by the authors such as 'very high robustness', 'reliable and valid', 'high representativeness' and 'transferability basically given'.'

The WiZen authors counter that the existing evidence base in the analysed area is not 'thin'. There are numerous publications that consistently show the benefits of initial treatment of cancer patients in certified centres, including the impact on symptom burden and quality of life. Furthermore, Stang's editorial does not address this evidence base, but cites a Cochrane review that examined other interventions in other countries and in a different context, namely the practical quality of an accreditation process to reduce MRSA infections in hospitals in South Africa and England.

Fröhner: 'Certification does not necessarily reduce mortality'

The third DÄB editorial on the WiZen study was written by Prof. Dr Michael Fröhner, who was still Chief Physician at the Clinic for Urology at the time of the editorial and has been Medical Director of Zeisigwaldkliniken Bethanien Chemnitz since 1 January 2024, pointing out that he is the Chief Physician of a clinic run by a denominational institution that is certified as a prostate cancer centre. In his commentary entitled 'Certification does not necessarily reduce mortality' (8), he opens a completely different can of worms. He writes that 'analyses that are supposed to justify such a redistribution require caution when interpreting the data', which is particularly true 'if they are financed and carried out by interested parties'.

The WiZen authors were not prepared to accept this accusation under any circumstances. In their closing remarks (7), they pointed out that the study had been financed by the Innovation Fund and that it could be assumed that 'all Innovation Committee members are interested in the continuous optimisation of the healthcare system'. In addition, the Innovation Committee assessed the study results 'as evidence of a significant increase in the chances of survival through treatment at certified oncology centres' and classified the study as 'groundbreaking' and 'convincing'.

Interjection



>> In their closing remarks (7), the WiZen authors refer to a DFG statement (9). It states that, according to the German Research Foundation, the task of health services research comprises the description, evaluation and optimisation of health care.

In other words, as long as health services research was limited to describing and evaluating, everything was fine. It doesn't hurt much when the studies, reports and evaluations produced with a great deal of passion, with an ever-increasing amount of manpower and womanpower and some financial outlay - thanks not only to the Innovation Fund - are accepted by the players in the healthcare system, but only taken out of the deep drawers when their own agendas - both professional and monetary - are not greatly affected. However, as healthcare research has increasingly taken on the task of optimising healthcare provision - and this is a good thing - it is facing headwinds.

Prof. Dr Michael Fröhner describes this very well in his DÄB editorial when he says that 'analyses that are supposed to justify such a redistribution require caution when interpreting the data'. By 'such', he means that - if the results of the WiZen study are taken seriously and used as an opportunity to ensure that affected patients can only be treated in certified hospitals - there will clearly be winners and losers. In any case, the winners are the patients, who will benefit from considerable survival advantages, as well as all those centres that are both certified and meet the necessary minimum volumes. The losers, on the other hand, are all those centres that do not do this and are then no longer reimbursed for these procedures. That is also a good thing! Because the results of the WiZen study - according to the authors in their concluding remarks - are very much in favour of all patients receiving initial treatment in certified hospitals, and very little against . They therefore recommend 'that politicians, self-administration, patients and referring physicians take these results of the WiZen study into account in their actions'. This is apparently what politicians are now doing.

The BMG's cabinet version of the Hospital Care Improvement Act (KHVVG) states that from 2027, a billing ban on certain fees is to be introduced for cases in which services on the list in accordance with Section 40 (1) sentence 4 KHG are provided in an oncosurgical indication area in which the hospital location is named on the list in accordance with Section 40 (2) sentence 2 KHG. The billing ban is to apply to charges for billing the rDRG, for additional charges, surcharges and discounts, for charges for special facilities and for services that are not yet covered by the flat rates per case and additional charges agreed at federal level, for charges for new examination and treatment methods and for hospital-specific daily charges for cross-sector care facilities. According to the text of the cabinet version, this is intended to 'create an incentive to avoid occasional care in the provision of oncosurgical services, to promote specialisation in the field of oncosurgery and to improve the quality of these services' .

So the politicians seem to have understooden. <<

Ihr Peter Stegmaier (MVF-Chefeditor)

'Consequences of action and inaction of equal value'

In the opinion of the authors, the results of the WiZen study speak very strongly in favour of all patients receiving initial treatment in certified hospitals and very little against it. From an ethical point of view - the WiZen authors continue - 'consequences of action and non-action are of equal value'. They therefore recommend that 'politicians, self-administration, patients and referring physicians take these results of the WiZen study into account in their actions.'

Although the authors write quite clearly in the original publication of their paper (2) that the study evidence to date 'does not allow a conclusive assessment of the effects of treatment in certified hospitals/centres for individual entities', regional analyses would, however, indicate survival and economic benefits of treatment in certified hospitals.

In an interview with 'Monitor Versorgungsforschung', one of the main authors, Prof Dr Jürgen Schmitt from ZEGV, goes one step further. He says quite clearly: 'It is extremely likely that there is a relevant certification effect and that many patients with cancer would benefit from centralisation in certified centres."Consequences of action and inaction of equal value'

In the opinion of the authors, the results of the WiZen study speak very strongly in favour of all patients receiving initial treatment in certifiedd Englands. <<

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Citation

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Immunisations: The key to preventive healthcare

>> To mark European Vaccination Week 2024, the research-based pharmaceutical company GlaxoSmithKline GmbH & Co KG organised a digital event on the topic of 'Closing vaccination gaps through greater data transparency' as part of its 'Science to Go' format 'GSK Breakfast' in mid-April - over 100 participants took part online despite the early hour. The following external speakers were invited: Kristine Lütke (MP, member of the Health Committee), Dr Irmgard Landgraf (internist with her own digitalised GP practice in Berlin) and Prof. Dr Thomas Weinke (Chief Physician and Medical Director of the Centre for Internal Medicine and the Clinic for Gastroenterology, Infectiology and Tropical Medicine, Klinikum Ernst von Bergmann Potsdam). Only Kristine Lütke's speech will be discussed here.



The Federal Centre for Health Education - according to the patron of the event, MP Kristine Lütke (FDP) - found in a representative study just last year that 83% of people in Germany are currently in favour of vaccinations. Ten years ago, only 61% would have stated this - an increase of more than 20 percentage points, despite the heated debates about a possible compulsory vaccination during the coronavirus pandemic. In addition, respondents in eastern Germany were more likely to be in favour of vaccinations than those in western Germany. This is not necessarily in line with the narrative that often portrays East Germans as vaccination deniers. According to Lütke, the question now is 'how we can utilise the momentum of the importance of vaccinations to permanently increase vaccination rates in Germany'. Ultimately, this would create more resilient healthcare systems, which is crucial for her. And: 'We ensure global health with vaccinations, only the supply of clean drinking water is even more important for reducing mortality.' However, Germany lags behind the rest of the world in terms of immunisation rates. According to Lütke, the most alarming example of this is the flu vaccination: of the ten EU countries that have already submitted data for 2022, the proportion of vaccinated people aged 65 and over was highest in Denmark at 78%. Germany, on the other hand, lagged behind at only around 43%. According to Lütke, 'vaccinations are among the most important and effective preventive medical measures.' According to Lütke, one possibility would be a vaccination campaign in which the Federal Centre for Health Education (BZgA) continues to play a leading role. Lütkes hopes: 'With its expertise, it will continue to make an important contribution to vaccination prevention in the future as part of the new Federal Institute for Prevention and Education (BIPAM).' This would serve to strengthen public health, improve people's quality of life and life expectancy and ultimately also reduce costs in the healthcare and social system. Because, according to Lütke: 'Costs arising from vaccine-preventable diseases are avoidable costs.' She is therefore firmly convinced that immunisation is the key to a shift towards preventive healthcare.

Digitalisation is an important factor in making the most of the existing vaccination momentum in Germany, even if it is not a panacea. However, it could be a building block, for example with the electronic vaccination record. However, vaccination must also be better integrated into people's everyday lives in order to actually increase immunisation rates. The e-vaccination card could help here by combining useful functions in a meaningful way. For example, the option of personalised reminders for upcoming booster vaccinations has already established itself as an effective means of increasing vaccination rates in many other countries. Lütke: 'With the Digital Act and the Health Data Utilisation Act, we have already taken some major steps as a coalition. However, the whole thing now needs to be brought to life so that we can achieve higher vaccination rates in Germany and Europe in the future and thus see healthier people..“ <<