DKVF Symposium organised by Roche Pharma: ‚Data use as an end in itself or for the benefit of the patient?'

How patients become pilots of their disease

‚Patients need to know what the data is for, what the data means for them personally and, of course, for other patients,' explained Prof. Tjalf Ziemssen, MD, Director of the Centre for Clinical Neurosciences and Deputy Clinic Director of the Clinic and Polyclinic for Neurology at the Centre for Clinical Neurosciences at the Neurological University Hospital Dresden at the Roche Pharma DKVF Symposium entitled ‚Data use as an end in itself or for the benefit of the patient?'. According to Ziemssen, it has often been the case in the past that although attempts have been made to obtain more and more data from patients in order to conduct research and introduce innovations, this is usually done without the patient benefiting directly or being able to understand what the data means for them personally. As a negative example, Mr Ziemssen cited the electronic patient file, which would have no structure that the patient would not be able to deal with operationally. The concept of the ‚digital twin', which he propagates, is different (see interview page 22 ff).

>> A digital copy of a patient is able to present patient-specific data in a comprehensible form in such a way that the patient can understand it and also derive impulses for action from it. Ziemssen: ‚The patient must take centre stage and help shape their data collection. But they also need to understand what the data means for them personally and how they can use it to make decisions.'

His petition: ‚In research, including healthcare research, we have seen that data is analysed but that patients do not benefit directly from it. We will only take the next step forward if both sides benefit from it, especially the individual treatment of the patient.'

PD Dr Benjamin Friedrich, co-founder and Chief Medical Officer of the Munich-based IT company Temedica, develops apps like those used by Ziemssen. ‚The future of health needs real insights' is the credo of the company, which says of itself that it operates ‚Europe's leading ecosystem for real-world insights in the healthcare sector' with over 1 billion data points already available and linkable, thus ‚overcoming data silos and combining anonymised health data to provide all stakeholders in the healthcare system with a comprehensive understanding of patients'. Friedrich explained at the symposium that digital solutions make it possible to measure the longitudinal course of a patient's illness. However, there must always be feedback in a validated manner. Friedrich: ‚Whenever patients enter their data, it is also reflected back to them.' This would allow patients to observe their own individual disease progression and gradually learn which influencing factors, such as smoking, exercise, obesity, diet, etc., actually have an effect on their own disease progression. Patients could also approach the treatment team with this information in order to change, modify or intensify their treatment.

Nele Handwerker, an influencer, blogger and ‚patient advocate' in the field of multiple sclerosis with her online portal and podcast series ‚MS-Perspektive' (1), explained exactly what this means. She describes her self-imposed mission on her homepage: ‚To educate other MS sufferers about the disease and how they can influence its course so that they can live self-determined, free and happy lives. Ideally from the moment of diagnosis, in order to preserve their health in the best possible way for the long term.

She does this personally with her own ‚digital twin', as she is looked after by Prof Dr Tjalf Ziemssen and his team in Dresden. Nele Handwerker explains that she had her ‚first relapse' over 20 years ago, which is what they call it when you realise you have MS. Initially, she had kept her illness a secret for fear of stigmatisation and also to avoid being patronised, but then changed her mind and founded the podcast ‚MS-Perspektive' in 2020 - there are now 215 episodes online and it is the most listened to MS podcast in the German-speaking world. Like her, around 280,000 people in Germany are currently affected, 72% of whom are women and 28% men. The age of diagnosis is typically between 20 and 40 years. The MS population is therefore very young and 70% of them use health apps to manage their condition. The new diagnosis rate is around 14,600 per year. Although the prevalence rates will continue to rise for some time, they no longer lead to a shorter life expectancy. The reason: there are currently around 20 progression-modifying drugs that manage to slow down the disease, in the best case to stop it, but there is still no cure. Nevertheless, there is always a progressive course of the disease,

At this point, Nele Handwerker took a symbolic step back and asked rhetorically: ‚What does this mean for me and for all the other patients?' For one thing: Fear. On the second: Uncertainty, combined with the questions: ‚What does this mean for my future? ‚What can I do professionally?'; ‚Can I venture into investments?', ‚Can I have children?', ‚Will my partner stay with me?', ‚Can I find someone new if I'm not yet in a relationship?'

According to the blogger, all of these fears can be alleviated to a certain extent with digital data, because ‚as patients, we want to lead a normal life and be affected as little as possible by our illness'. This is precisely why ‚reliable prognoses with individualised treatment options' based on patient data are needed. This is the only way to understand and implement recommendations for action, such as quitting smoking, exercising more and eating healthily. Handwerker: ‚If I do more sport and eat healthily, I can make a positive contribution to a better prognosis myself.' The digital copy also helps the doctor. After all, they should treat a patient ‚not based on gut feeling', but on facts.

She has also been taking part in non-drug studies in Dresden for years, in which her brain volume and jumping power are analysed, but in the meantime she has been using her MS app, in which she enters self-collected data via her own tracking on a weekly, sometimes daily basis. This included data from tests that could be used to recognise any creeping progression. Because, says Handwerker, ‚if there is one, you have to intervene, whether that means a new treatment concept, a change in medication, more physiotherapy or whatever'. However, it is not enough to wait for the next doctor's appointment, which only takes

1: https://ms-perspektive.de

place a few times a year. ‚I go to the doctor four times a year, that's quite often, but there's a black box in between.' However, the more data points are linked in her digital twin, the better she can assess which events happen by chance or are directly related to her illness and are really relevant to her. Like smoking, for example: ‚If I smoke, the probability increases that I will develop MS progression eight years earlier and thus possibly develop a disability that is irreversible.' However, such correlations would not be revealed by individual routine examinations, but only by linking as much data as possible. ‚This is exactly why I use the app with all my personal digital data, so that I can optimise my management of the disease, a healthy lifestyle, interactions with various lifestyle factors and my treatment.' In principle, the idea is that patients are the ‚pilots of their disease' via such instruments and toolkits, because ‚we decide on it together with our practitioners as co-pilots', who are the experts, but ‚it's still my life'.

Of course, she also shares all her data in a cohort to help others: ‚I want to contribute to science.' Because she has a daughter and if she is ever diagnosed with a disease like her - whether MS or another autoimmune disease - she should ‚not start from scratch like me, but at a completely different level' so that she doesn't have to worry and worry so much. <<

by: MVF Editor-in-Chief Peter Stegmaier

Minimum volume for heart transplants at 10 per year from 2026

>> At its meeting on 16 November this year, the G-BA also set the minimum volume for heart transplants :

For heart transplants, a minimum annual volume of 10 - previously it was 0 (sic!) - per hospital site will apply from 2026.

In Germany, 358 hearts were transplanted last year - in some cases, according to the G-BA, in transplant centres that only rarely perform this highly demanding operation. Only locations that are expected to reach the minimum volume according to their forecast to be submitted in 2025 or that have an exemption authorisation from the respective federal state will then still be allowed to perform heart transplants. A transitional regulation applies for the years 2024 and 2025.

The changes to the minimum volume regulations will come into force after publication in the Federal Gazette with effect from 1 January 2024. Hospitals will then initially be subject to a transitional regulation: only for the calendar year 2026 will eligibility for benefits depend on whether the new minimum volume is likely to be met. Hospital operators must submit a positive forecast to the state associations of health insurance funds and substitute health insurance funds by 7 August 2025 at the latest that the minimum volume will be met in 2026. However, the state authorities may grant a clinic an exemption if the provision of comprehensive care could be jeopardised. However, the health insurance funds must agree to this procedure.

In Germany, heart transplants were performed at 21 and 18 hospital sites in 2021 and 2022 respectively. With the new minimum volume of 10 per year, at least 12 hospital sites are expected to remain authorised to continue offering heart transplants. For patients, the average journey time will increase to 49 minutes and the average distance travelled to 77 km.

In the opinion of the G-BA, a higher minimum volume would centralise the range of services even more, but this would possibly be accompanied by disadvantages due to the resulting transport and transfer risks, as well as excessively long distances for pre- and post-operative care and visits to relatives.

On the other hand, this operation is a complex procedure that can be planned, meaning that the pure travelling time should take a back seat to the quality of treatment. The G-BA does not wish to disclose which hospitals could be omitted from the service provision on request, as the distribution of the OPS codes required for this statement to the individual sites was not part of the final report. A look at the White List (www.weisse-liste.de) can be helpful by simply entering the search term ‚heart transplantation'. All hospital sites are then listed here according to case numbers, including quite a few with only one operation per year.. <<

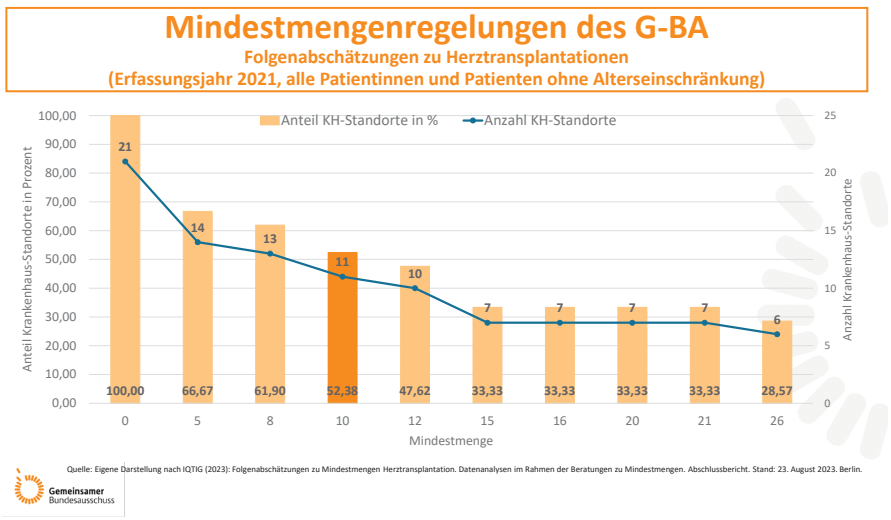


Fig. 1: In its impact assessment on minimum volumes for heart transplantation, the IQTIG carried out 72 models for the OPS code counting method on behalf of the G-BA. For each data collection year (2018 to 2021), simulations were carried out for 9 potentially possible minimum volume case numbers (5, 8, 10, 12, 15, 16, 20, 21, 26) and these were performed once for adults (aged 18 and over) and once for all patients without age restrictions. The model shown here corresponds to the most recent data year and the patient group without age restriction.

Citations

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