



‚An alliance of evidence-ba cision-makers against pop

In a double cover interview at the start of 2024 with ‚Monitor Health Services Research', Prof Josef Hecken, the impartial chairman of the Federal Joint Committee (G-BA), and Prof Wolfgang Hoffmann, Chairman of the German Network for Health Services Research (DNVF), discuss the future role, significance and position of health services research, which has now come of age. The more frequently its results are incorporated into far-reaching political decision-making processes - such as the current federal hospital reform - the more headwinds are blowing against it. Health services research must learn to deal with this.

In the double cover interview: Prof Josef Hecken, G-BA, and Prof Wolfgang Hoffmann, DNVF.

>> I would like to quote Prof Hoffmann, Chairman of the Board of the German Network for Health Services Research, from his opening speech at the 22nd German Congress for Health Services Research: ‚Health services research is systemically relevant. Our responsibility is growing. Results, recommendations and priorities are more likely to have consequences, shift the balance of power and change finances.' A change of perspective to you, Prof Hecken: Is this a biased or realistic self-image that Professor Hoffmann is painting here? What significance and, above all, what function does health services research have for you today as the impartial chairman of the G-BA?

„‚Health services research must deal with questions that are as relevant as possible.'
Prof. Josef Hecken, G-BA

Hecken: This is certainly not just my own internal view of the system. The role of health services research has changed. In recent years, the findings of this scientific discipline have increasingly been incorporated into political and self-administration decisions in a very relevant way. This makes health services research more important per se. And rightly so, because one of the tasks of health services research is to analyse whether the resources allocated in the system to date are being used at least reasonably accurately and how they could be used better.

Why don't you give us an example?

Hecken: You can illustrate this with relatively few figures. In 2022, we will have spent 498 billion euros on healthcare in Germany if we add up the expenditure in SHI and private health insurance, long-term care insurance and benefits. In SHI alone, we will spend almost 320 billion euros in the next few years - per year. And despite these many billions, we have to realise that other countries that spend a significantly lower proportion of their gross domestic product on healthcare achieve better outcome data. I see the absolute value and therefore the great importance of health services research in repeatedly pointing out weak points, interface problems and misallocations in our healthcare system with vigour and energy - regardless of whether the parties involved like it or not. However, it can only fulfil this function with high scientific quality. And health services research must deal with issues that are as relevant as possible - purposeless research projects are of no use at all, except perhaps to the researchers involved.

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Professor Hoffmann, who pointed out in his opening speech at the 22nd DKVF that health services research has grown up and thus lost its puppy protection, will be happy to take up her words. This also means that it is becoming vulnerable. What role must adult healthcare research play?

Hoffmann: First and foremost, health services research has a great responsibility, as Mr Hecken has just formulated, but one that we ourselves want to bear and will bear. It's not about investigating something that may be interesting but is not really relevant. Rather, it is about using the best methods and the best study designs to investigate the weaknesses and strengths of our healthcare system - in order to eliminate weaknesses, but also to learn from them and identify strengths that can be scaled up for the benefit of all patients in the best case scenario. This is often research against resistance, which such findings will always trigger. On the one hand, this is a great opportunity, but also an obligation to conduct research that is truly relevant and helps to seek and find answers that actually help the system to align itself better and provide guidance in areas that are still unclear - and there are many of these. Only healthcare research is able to bring the necessary evidence into the healthcare system, which politicians and self-administration urgently need in order to make the right decisions for the further development of our healthcare system. In order to avoid inappropriate care and misallocations and thus make the system more effective, fairer, more transparent and more evidence-based, health services research must become much more controversial than it has been in the past and actively contribute its findings. However, we must not forget that we health services researchers should and often can provide the necessary evidence on the basis of which decisions must then be made by politicians and self-government.

You certainly see health services research as an independent scientific discipline - but is it more of a service provider to the system or an external corrective?

Hoffmann: The most important aspect is the scientific position, which must be objective per se. We are not a lobby, except for truth and evidence. But not for a particular direction in the healthcare system or bank in the G-BA. The primary position of health services research is right next to the system, but it is not part of the system or even part of the self-administration or part of a ministry. However, this does not mean that we do not address questions from all of these stakeholders. We are committed to answering the questions posed to us. That's why we have to be close to the stakeholders and that's what we want to be - we won't get anywhere in an ivory tower. That's why healthcare research is sometimes a balancing act between an objective external view and the necessary integration into the system. And, of course, there are always attempts to capture or manipulate us. Similarly, there are also those among health services researchers who perhaps don't always draw the line just described quite as clearly as we define it in the German Network for Health Services Research as the official representation of the scientific community of German health services research.

Hecken: The so-called service provider debate is often held. For me, it goes without saying that we have to differentiate between health services research that is funded by universities and that which

is funded by the Innovation Fund. What both funding sources have in common is that the freedom of science and research must of course be preserved. However, the Innovation Fund is subject to the restriction that the research question it defines must be addressed. For me, this is self-evident, because this is where insured persons' money is used. However, this does not mean that the freedom of research or even the associated process of gaining knowledge, which is intrinsic to every scientific discipline, should be affected. Nevertheless, applicants occasionally criticise us for the transparent funding conditions of the Innovation Fund. They argue that this would turn them into the Innovation Fund's pawns. However, the Innovation Committee is far from wanting to prejudge results. Just because research projects are financed by the community of insured persons does not mean that a certain result should be triggered in any way. For me, that would be crossing the Rubicon.

Hoffmann: The topic of a commissioned research project is always determined by the client. What happens afterwards is subject to the freedom of research. For all its freedom, research must ensure that its results are valid, even and especially when they are criticised. This is a question of scientific quality - and for more than 15 years there has been a systematic professional development in health services research, starting with the formation of theory, the development of a stringent methodology and the obligation to draw up study plans and evaluation concepts a priori, to register studies and finally to publish all results - regardless of whether they are in line with the hypothesis or not.

Of course, there will always be attempts, especially in innovation fund projects, by stakeholders to - let's say - set certain priorities or more favourable endpoints.

Hoffmann: As a researcher, you have to stand firm here. We are committed to science first and foremost! And in the end, every researcher is responsible for this with his or her reputation. That's what I mean by growing up - no longer so cute and not everybody's darling - but professionally and sometimes with fierce and not always objective criticism. But this brings us to exactly the same point in healthcare research where other areas of research and science have had to assert themselves for decades. If the questions are the right ones, the methods are appropriate and the results are valid and reliable, every effort is worthwhile.

‚It must be the goal of all of us that the results we produce and publish are cited in the next IQWiG review on the respective topic and thus serve to generate evidence.‘
Prof. Dr. Wolfgang Hoffmann, DNVF

Hecken: Particularly in the area of drug assessment, for which I am responsible at the G-BA, we are familiar with the wonderful term ‚rent-a-mouths'. Without wishing to offend anyone personally, they tend to be tempted to take too much of the client's position when categorising results, as long as this is somehow still scientifically justifiable. We are fighting hard against this.

Hoffmann: As everywhere, there are of course black sheep in healthcare research. As a scientific community, we have to deal with this and we do. When we catch people doing this, we are criticised everywhere. It must be the goal of all of us that the results we produce and publish are cited in the next IQWiG review on the respective topic and thus serve to generate evidence. Then our results will be valid and will be used for upcoming decisions in the healthcare system. However, they will only do so if they are objective, unbiased and have been obtained using the best methodology and the highest scientific quality. This applies to all applications, whether a drug is to be authorised or a new care modality is to be introduced. We are committed to this standard. If someone violates this, then we as a professional society are called upon to take appropriate measures. However, it must also be said that the problem I have just described only occurs to a very limited extent in research and is more likely to be found in expert reports prepared by specialised institutes that are primarily financed by expert reports and may therefore be dependent on certain clients.

Health services research undoubtedly generates hundreds, if not thousands, of findings every year. The problem has been the implementation, the translation, for years and years. The reason for this is that - unlike with medicines or medical devices - there is no clearly defined and agreed way to bring healthcare innovations into standard care. Prof Hecken: Do you not want to define this path or can you not because the benches of the G-BA are preventing you?

Hecken: The G-BA's hands are tied when it comes to translation. In the individual regulatory areas, the legislator stipulates who is responsible and how. In the pharmaceutical sector, there is the authorisation and, in the case of new outpatient examination and treatment procedures, the method evaluation. The problem with the new forms of care is that the often complex approaches mean that there is a correspondingly diverse need for change.

Let's take as an example a current finding from healthcare research, which is that patients with treatments in certified centres have better chances of survival compared to non-certified hospitals.

Hecken: That is indeed an issue that we could regulate in a quality assurance guideline.

Could?

Hecken: Exactly. Regardless of whether the G-BA or its benches want this, we are currently experiencing a total cancellation of quality assurance as a result of the discussion about the Hospital Reform Act. As things stand at present, the legislative process has agreed on service groups with more or less demanding requirements, which are to replace the previous quality requirements of the G-BA. If this happens, as is currently being discussed, it would be a loss for the quality assurance that we have achieved so far.

Let's come back to the fundamental problem of translation in new forms of care.

Hecken: Our key problem to date has been that the Innovation Committee could only make recommendations in its resolutions in the event of positive project results. Until now, it was even at the

discretion of the addressees whether they responded at all and told us how to proceed - that was something of a merciful moment. Incidentally, this was analysed in great detail at the last healthcare research congress. This has now changed decisively with the recently passed Digital Act. In future, the recipients named by the Innovation Committee in its decision when approving projects will have to report on the implementation of the recommendation within twelve months and we will make this feedback transparent on the website. As Chairman of the Innovation Committee, I introduced this change into the discussion about the law. Previously, this feedback obligation only applied to the G-BA. This means that in future, everyone will be obliged to report what they have done with the recommendations for transfer to standard care; and if they have done nothing, to say why they have done nothing. I will summarise these reports once a year in a separate report to the BMG and will probably also send this report to the Bundestag's Health Committee in order to clearly name the bodies that are doing nothing. Not because I want to annoy the addressees, but because an unjustified non-transfer to standard care is pure waste. If we don't want to and can't improve anything with the findings of healthcare research, we don't need to spend insured persons' money on it. But if there are gains in knowledge and we have a transfer option, we must increase the pressure on those who could do it.

Hoffmann: The new provisions of the Digital Act will certainly help somewhat. However, there is still no fixed path from the project findings of the new forms of care to standard care. It won't be that easy either.

I'm sure you'd be happy to explain.

Hoffmann: Always happy to. The fact is that a successful innovation fund project in Baden-Württemberg may not work as well in Schleswig-Holstein, for example, simply because the context of the actors involved is different there. There would also be little benefit in trying to transfer all successful pilot projects, of which there are now around 50, into standard care. This would mean that multimorbid older people would be overwhelmed by all the pilot visits.

What would be the solution beyond the associated social contacts?



Prof. Josef Hecken

has been the non-partisan Chairman of the Federal Joint Committee since July 2012 and Chairman of the Innovation Committee, which is part of the Federal Joint Committee, since October 2015. In 2015, he was also awarded the title of professor by the Saarland government in recognition of his services to science and research. Since 2018, he has lectured at the Leibniz University of Hanover and the Medical Faculty of Heidelberg and is a lecturer on the Master's degree programme in Pharmaceutical Law at the Faculty of Law at the University of Marburg. Before his appointment as non-partisan Chairman of the G-BA, Hecken was, among other things, President of the Federal Insurance Office (2008-2009), Minister of Justice, Health and Social Affairs of the Saarland (2004-2008) and, from 2008, also Minister of Labour and, at the same time, Chairman of the Health Committee and Deputy Chairman of the Legal Committee of the Bundesrat.

Hoffmann: The innovation fund should be expanded to make it possible to analyse all pilot projects together in a kind of meta-view. Then we will see how we can actually do justice to those patients who suffer from several diseases that need to be managed by pilots at the same time. Or to explore how what has worked well in Baden-Württemberg can also be implemented in another federal state. Such findings will make it much easier to introduce the programme into standard care throughout Germany. If the Innovation Committee were also prepared to evaluate the projects implemented in standard care during the implementation phase for two years and, if necessary, even longer, it would be possible to say exactly whether what was originally demonstrated in the research context is actually being implemented in reality. In our view, however, the G-BA should not be solely responsible for this, as many other stakeholders beyond the Federal Committee need to be involved.We would like to further develop this approach together with our colleagues in the G-BA in order to jointly influence politicians to redefine certain regulatory gaps in the law on this basis.

Hecken: It is our joint responsibility to the insured and contributors, but above all to the sick people, to utilise the funding as optimally as possible. There have already been several projects - both in the area of new forms of healthcare and healthcare research - that have provided really important impetus for better care. You are absolutely right to address this. We must set out to gain insights across different projects and link them to a thematic or content-related bracket. Our common question must be: What can be done to generate best practice from the respective model?

To stay with the example of the pilots ...

Hecken: ... the question could be whether there could be a kind of generic pilot who is perhaps not specialised in the respective clinical picture, but who is better able to cover points of contact with other disease-related needs. That would be absolutely expedient, otherwise we would end up needing a pilot to guide the pilots. There must and can be extensions here. When a project is transferred from the G-BA to standard care, we have an obligation to monitor it anyway. What I think is still missing is an extension of the project period through to translation. Here,

too, there is certainly room for improvement. But all in all, I am grateful to the Federal Minister of Health and the majority of the parliamentary group in the German Bundestag that they have decided to make the innovation fund permanent despite some criticism, some of which I can understand. We all know that individual federal states have suggested that the innovation fund be merged into a kind of state fund. Such state funds, with which everyone can try out something in their own state, will do very little for the quality of care in Germany as a whole - especially not in view of the scarce resources in the statutory health insurance system.

Projects often hit the wall despite existing evidence gained from healthcare research projects or new forms of healthcare because wrong or hasty political decisions are made.‘
Prof. Josef Hecken, G-BA

Professor Hoffmann, is healthcare research methodologically and theoretically well enough positioned to really be able to answer these complex questions in such a way that the evidence cannot be challenged afterwards?

Hoffmann: Science should always want to improve. But we are already very good at what we do. And if we are also allowed to do what we can do with the most suitable data, then we will become even better. In general, healthcare research has developed so much in terms of methodology and theory in recent years that it is now possible to make reliable changes to the healthcare system on the basis of healthcare research findings. Nevertheless, in our field of science we are almost always dealing with complex systems and contexts and equally complex interventions. As a result, it will always be the case that in practice, as in real life, new aspects will always arise that were either not taken into account in previous research or that could not be mapped and analysed due to certain limitations, e.g. in the availability of data. This can never be completely avoided because our research area deals with real-life care, which, unlike clinical research, is not a largely inert system that can be precisely defined using scientific parameters. In real care, there are always different points of view among the stakeholders involved, conflicts of interest, as well as inertia tendencies and practices, because it is infinitely difficult for everyone to suddenly do something different because they have always done it this way - but in many cases they have never questioned it or even backed it up with evidence Then there is the question of how much evidence is actually necessary.

Hoffmann: The question is rather when the evidence base is sufficient to want or be able to change something. Up to now, people have usually waited until it is almost too late, only to have to change something in crisis mode that could have been tackled a long time ago if only they had wanted to earlier. We still have the opportunity in this country - but not for much longer - to make far-reaching structural decisions based on facts and data. However, if we don’t do this, the system will eventually become unstable in places where it can only be patched up instead of being developed in a sustainable and resilient way.

Hecken: At this point, I have to intervene and say that it is often not just down to the inertia of certain players or the ability of the system as a whole to survive. Projects often hit the wall despite existing evidence gained from healthcare research projects or new forms of healthcare because wrong or hasty political decisions are made.

An example?

Hecken: Let’s take the IGiB-StimMT project in Templin, which was also subsidised by the Innovation Fund and which, as we all know, had a chequered history. It proved what everyone suspected: that there is huge potential for outpatient treatment because too many people are being treated as inpatients in hospitals, even though this is not necessary. One of the consequences of this is that there are too few nursing staff elsewhere. The shortage of specialist staff is now so great that the German Hospital Federation is actually arguing in favour of outpatient treatment. They have recognised that otherwise there will not be enough staff at the back and front and that the necessary processes are no longer profitable. The second major bank involved in the issue - the National Association of Statutory Health Insurance Funds - is in favour anyway because outpatient surgery is more cost-effective. Now politicians want to implement level 1i clinics, which would fit in perfectly with outpatientisation. However, it does not say how the hospitals are supposed to manage this if they are not equipped accordingly. Because the federal states have provided too little investment funding over the years, it is not enough to tweak the EBM or introduce hybrid DRGs. If hospitals have to completely reorganise structures in order to be able to provide outpatient care for the same or better quality for less money outside the current processes, this costs money that they simply don’t have at the moment. This is why both Mr Gaß from the DKG and I made representations to the Federal Minister of Health to argue in favour of a transitional arrangement. This would allow remuneration to be slowly harmonised in order to put hospitals in a position to reorganise their structures accordingly. And then came the judgement of the Federal Constitutional Court, which coincides with the current SHI deficit problem. As a result, we have the status quo that what we have jointly recognised as right is no longer financially feasible. There are not only the good guys, the half-good guys and the bad guys with a knife between their teeth who are trying to stake their claims, but also profane material and financial constraints.

Hoffmann: At this point, I no longer agree one hundred per cent with your comments. I’m missing the fact that the main players in the healthcare system have ignored all warnings over the last 15 to 20 years and have continued for another year as before. The forces of inertia have been allowed to prevail for decades, and only certain personnel changes triggered by a wave of retirements have finally led to some movement. However, this is only because there is now an incredible amount of pressure from outside, whether this is due to the effects of the double demographic or the shortage that is already being felt locally. The fact is that no system wants to change strategically on its own. Why should it do so? In such persistent systems, regulations are needed - and healthcare research can support these. Of course, we don’t have the solutions for everything ourselves, but we can at least find out where they can be found. If we had star-

ted ten years ago, we would be much further along by now. We have to learn from this. For example, that not everything can be left to self-administration, because it is blocked without appropriate changes to the political framework. The parameters required for a rational strategy must come from the evidence, and this in turn must come from healthcare research.

Hedges: I currently need the help of healthcare research above all in the discussion about hospital reform. Even though hospital planning itself is not my job, I am very concerned about it because - as already mentioned - the quality assurance that has been built up over many years with a lot of effort and money is in danger of disappearing into the orcus of history. The current plan is for the legal construction - and the federal states still consider this to be too far-reaching - to agree on a few rather undemanding structural quality requirements via a statutory order requiring approval, which would then replace the entire outcome-oriented quality assurance. This also threatens the minimum quantities.

I'm sure all healthcare researchers are aware of the connection between quantity and quality, but unfortunately not every politician is.

Hecken: It is indeed strange when I am attacked in the Conference of Health Ministers because the G-BA has raised the minimum quantity for the treatment of newborns with a birth weight of less than 1,250 grams to 25 since 1 January this year.

The minimum quantity of 25 instead of the previous 14 is already considered to be quite low and should be seen as a political compromise.

Hecken: And I'm already being told to my face that this would increase the death rate of premature babies in Germany immeasurably because nationwide care is in danger of collapsing. But it's the other way round: the mortality rate will fall by 5 per cent as a result of the increased minimum quantity. Some state politicians are painting terrible supply scenarios on the wall. And it is pretended that minimum volumes are an insubordinate encroachment on the planning sovereignty of the federal states. However, it is not only the planning sovereignty of the federal states, but also the nationwide quality requirement from the Fifth Social Code. And planning sovereignty ends where the quality requirement of SGB V is affected. After all, every insured person has the same right to equally good and safe healthcare, regardless of whether he or she lives in Bavaria or Schleswig-Holstein.



Prof. Dr. med. Wolfgang Hoffmann MPH

has been Managing Director of the Institute of Community Medicine since 2007 and has held the W3 professorship for Population-based Healthcare Epidemiology and Community Health at the University Medical Centre Greifswald since December 2011. Since 12/2009, he has also been head of the Greifswald sub-site of the Rostock/Greifswald partner centre of the German Centre for Neurodegenerative Diseases (DZNE) and has been spokesperson for the Rostock/Greifswald partner centre since 12/2012. In May 2012, he was elected to the Executive Board of the German Network for Health Services Research (DNVF), in June 2016 as Chief Executive Officer and in May 2018 as Deputy Chairman. In October 2022, he was elected Chairman of the DNVF..

Where do you need the help of healthcare research?

Hecken: I would like to see healthcare researchers helping me to back up the G-BA's perfectly correct decisions on minimum volumes with even more evidence. I have experienced many an event where I felt very lonely.

Hoffmann: Health services research is on the side of evidence when it comes to minimum volumes, as it is in many of the other areas you mentioned. We always need health services research to create and provide evidence, especially when such discussions are dominated by gut feelings and fears or are in danger of being overturned by populist arguments. At the moment, all of us who represent the evidence are in opposition. But that won't last for long, because at some point the insiders and evidence-ignorers will be counted out.

Really?

Hoffmann: There is a lot of evidence in favour of the minimum volume regulation improving the chances of survival of particularly small premature babies. Nevertheless, a petition was organised in our federal state with the aim of ensuring that a very specific hospital can continue to treat premature babies, even though the minimum volume is significantly undercut there. Politicians have to endure such discussions - because in case of doubt, quality is more important than proximity to home.

Hecken: You should know that the Petitions Committee of the German Bundestag recently dealt with a petition calling for the implementation of the prenatal minimum quantity to be stopped on 1 January 2024. Thank goodness the Federal Minister of Health is not doing this because he is well aware of the connection between quantity and quality. This would have been a classic case where the G-BA and the scientific community could have sat down together to argue against political populism with scientifically sound arguments. After all, we want

to protect the lives of premature babies together. We could agree on such support right away, because this year we will certainly be faced with the same discussion on raising the minimum quantity for breast cancer. We are trying to limit breast cancer operations to hospitals that have at least 50 interventions next year and at least 100 interventions from 2025. Unfortunately, there are currently too many hospitals that perform such operations less than ten times a year - what I like to call ‚experimental surgery'. Raising the minimum quantity will certainly cause outrage again instead of leading to an objective discussion. Yet we must all be concerned about the well-being of the women operated on here - very rarely men are also affected. With such operations, there is exactly one chance in a lifetime to be treated in a curative setting. The second time, it is highly likely to end in a palliative situation, even if the final endpoint may not occur until later. However, palliative patients are palliative patients. We must join forces to make this very clear to people. We must also emphasise what everyone knows from their own life experience: practice makes perfect. These kinds of operations are now so complex that they require a high degree of professionalism from the entire team. The federal states repeatedly demand that we should be able to deviate from our minimum requirements for structures and processes for an unlimited period of time and without justification. This is what I call patient endangerment. We also have to argue against this with a high level of evidence and involve all the specialist associations concerned.

If everyone is on board.

Hecken: The German Society for Prenatal and Obstetric Medicine is on my side when it comes to the minimum quantity for premature babies that I just mentioned. The German Society for Paediatrics and Adolescent Medicine, on the other hand, is not, because it wants to stake its claim. If you want to survive in a discussion like this, the only thing that helps is evidence and an insistence on its importance for healthcare. We are mutually dependent on each other.

Hoffmann: As a healthcare research community, we are in complete agreement with the G-BA in this respect. The G-BA's task is to keep the requirements for the quality of care high and to continue to improve them. We health services researchers must ensure that the quality of our research is so high that the evidence we generate is robust; this is the only way we will achieve long-lasting and far-reaching changes for the better together.

Is this another example?

Hoffmann: There are always painful interim phases that you have to get through. Let's think of the delegation of medical tasks to medical specialists, which we were instrumental in pushing through in 2008. It really wasn't an easy time back then. My team and I were sometimes verbally abused. But today, everyone thinks it's the right thing to do. Times are changing. Supply research is sometimes not a job for wimps or cowards. If you want to change something, you have to stand up for it and fight for it.

Hecken: The lower the bullets fly, the more motivated I feel to stand up to people and keep going. Because once you reach a certain age, you are relatively free in your decision-making (laughs) . As long as the criticism comes evenly from all sides, there is something to be said for the fact that you seem to be doing your job properly.

Hoffmann: A similar phenomenon applies to healthcare research. Particularly harsh criticism from the system can be an indication that you've been drilling in the right place.

But to be right, you also need the right data and access to data.

Hoffmann: That is crucial. The Health Data Utilisation Act, which was passed on 14 December 2023, has unfortunately been weakened compared to the original draft in key areas that we urgently needed - for example, the deletion of the Section 75 SGB-X procedure for research with health insurance data if patients have given their consent. But at least it is a step in the right direction. The more data that becomes available more quickly and easily, the faster we can generate evidence on unanswered questions that are important for local care. A large part of the system's inertia is due to the fact that we cannot yet prove some things or cannot yet prove them well enough. If research doesn't get the data it needs, it costs time that could be saved. We therefore need the new research data centre at the Federal Institute for Drugs and Medical Devices (BfArM) in a form that healthcare research can work with. Not only must the health insurance data be made more accessible there, but other data sources must also be linked - whether this is social or register data. Research-friendly regulations for the RDC are a key to better data access. And this data must then also be allowed to be released to researchers - at least in the case of consent, but also otherwise in pseudonymised form. The ePA is not an alternative to this; it will not become a significant research resource in the foreseeable future.

A final question to both of you, who have conducted the whole discussion so marvellously almost on your own. Thank you for that. If you think about the insistence of the federal states on almost every single hospital site almost beyond all quality: shouldn't the G-BA and health services research really declare loudly: ‚You are jeopardising patients' lives!'?

Hoffmann: Health services research certainly does that. For example, we have published a study, for which we also received an award (1), which shows that it was absolutely necessary to close the inpatient paediatrics department at Wolgast District Hospital in the district of Vorpommern-Greifswald in Mecklenburg-Vorpommern - and that care did not collapse (2). Nothing like this has ever been done anywhere else in Germany because the system is too opaque. However, such cases need to be investigated much more systematically than is currently the case. Above all, we need better access to data in the healthcare system. In addition, healthcare research needs the opportunity to test interventions against each other - in a kind of experimental free space. This is something that doesn't exist at all in Germany at the moment, because everything always has to take place within the very narrow legal framework of the SGB-V regulations. If we had such an experimental field, a ‚real laboratory', we could investigate much better than before whether people live better or longer with a certain new form of care than with the previous one. These are the really big questions that, beyond the quality and benefits for patients, will reallocate billions of euros in the healthcare system. That's why I think it would be sensible for us to be granted these research opportunities and to create room for experimentation - under both federal and state law.

Hecken: My answer to the question is a resounding yes! We have

Particularly harsh criticism from within the system can be an indication that you've been drilling in the right place."
Prof. Dr. Wolfgang Hoffmann, DNVF

to say loudly, much louder than before: You are jeopardising patients' lives! To do this, we need an alliance of evidence-based decision-makers against populist statements in public. That would be a good alliance, because the path that is being taken at the moment cannot be in the interests of patients. We need more common sense in the whole discussion - I hope that we can use the next few months to achieve this.

Hoffmann: The German Network for Health Services Research is absolutely part of an alliance of evidence-based organisations. We are on the same side as the G-BA. In this respect, we very much hope that you can continue to push through your ideas and that the G-BA will consistently position itself in favour of evidence. <<

Mr Professores, thank you for the interview.

The interview was conducted by MVF editor-in-chief Peter Stegmaier.

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