



„Patient-centredness must b the benchmark for everythir

Where do the perspectives of patient advocacy and the pharmaceutical industry meet at a common point? Exactly at the point where patient participation, orientation and also benefits are at stake. In the double interview of „Monitor Versorgungsforschung", Dr. Martin Danner, Federal Executive Director of BAG Selbsthilfe, and Dr. Holger Bartz, Managing Director for Medical & Scientific Affairs at Janssen Germany, entered into discourse. „One might assume that the income situation of pharmaceutical companies is not an issue for patients," explains Danner, for example, adding: „But it is, because changes in the regulations by means of the SHI Financial Stabilisation Act will inevitably change the strategies of the companies."

Im Interview: Dr Martin Danner, Federal Executive Director of BAG Selbsthilfe, and Dr Holger Bartz, Managing Director for Medical & Scientific Affairs at Janssen Germany.

>> Herr Dr. Danner, you have been working for the BAG Selbsthilfe since 2001 and have been the national managing director since 2008. This means that you have a good two decades of experience in health policy with several dozen reforms and little reforms. If we leave aside purely scientific medical progress - this point would deserve a separate interview, even a white paper - is the current health system patient-oriented? Is today's health system more patient-oriented than the one of 2010 or 2000? In your view, what has changed in terms of patient orientation - for the better or for the worse?

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Dr. Holger Bartz

Danner: Let's start with the positive. If you compare the state of patient orientation today with the situation 20 years ago, a lot has improved. Patient-relevant outcomes have gained in importance, on the one hand in the scientific discourse, but also in today's benefit assessment. I am thinking here primarily of the methodological approach with which health technologies are evaluated. For us as patient representatives, it was a very important step that the topic of patient benefit is given a completely different status than was the case 20 or even 10 years ago. In addition, the patient perspective is included in many health care bodies much more than it used to be - whether this happens through a single person or in the form of deputy patient representatives. These two achievements, which we as patient representatives have fought for, constitute a significant change in favour of patient orientation in the health care system. Of course, there is also the other side of the coin, because the economisation of the entire health care system is steadily advancing. The ever-increasing economic pressure certainly leads to the fact that the acting actors at the federal and state level are inclined - to put it mildly - to give their own interests a higher priority than the patients' well-being. This aspect runs counter to patient orientation and fills us patient representatives with concern.

You are certainly right to say that patients are being listened to more than in the past. But in Germany, to be heard and to have a say does not mean to have a say. Would you support the idea that patient representatives should not only have a say, but also a right of co-determination, if patients were given the appropriate financial resources?

Danner: If you look at the legislation of the last few years, patient participation has already been implemented in many areas. But more than having a say and sitting at the table, which has certainly already changed the culture of debate, has not been achieved so far. In order to really be able to exercise the right of co-determination and the right to make applications, the patient community lacks the structural prerequisites to be able to carry the knowledge gained from the patient's point of view into the health care process via evidence-based decision-making processes. If the necessary structural prerequisites in budgets and know-how are not strengthened, voting rights cannot be exercised effectively. However, I have the impression more and more that this is not what is wanted. A current example of this is the way politics deals with the Independent Patient Counselling Service. What is currently happening counteracts the idea of the UPD.

This would certainly be worth another conversation, because it will not be wrong in itself if the UPD is made permanent by a foundation under civil law. But as always, the devil is in the detail. Let's stay with patient orientation: Dr Bartz, you are a specialist in medical microbiology and infectious disease epidemiology and have been Managing Director for Medical & Scientific Affairs at Janssen Germany since 2022. Before that, you were Country Medical Director of Janssen Austria. What distinguishes patient-centred care in Germany from patient-centred care in Austria? What does patient-centred care mean to you - on the one hand as a medical doctor and - in the past - for many years as a practising physician and today Medical Director of a large pharmaceutical company?

Bartz: Socialised in the German health care system, I worked in Austria for a while and was able to experience that it is currently much easier for patients in our neighbouring country to access innovative therapies than here. Although historically the differences between the two health care systems are not that great, in Austria one arrives at very different assessments in different places.

You are referring here to the benefit assessment, which in our country is regulated by the AMNOG, while in our neighbouring countries there are recommendations on reimbursability to the Main Association of Austrian Social Insurance Institutions, which are prepared by a Therapeutic Products Evaluation Commission.

Bartz: Exactly. There are even more evaluation levels in the Austrian system than in ours. But here as well as there, the pharmaceutical industry, for which I have been working for a year, has the self-formulated objective of working and researching in such a way that each patient can receive the best possible therapy at the right time. This is exactly where a big difference between the two systems becomes apparent: While in Austria the stakeholders decide on a macro level how the health care system should look like - of course based on evidence as much as possible - really good networks have been formed. They strive to think about care for and with the patients. This also includes creating good access to innovative therapies that are introduced via clever mechanisms in such a way that the system as such remains intact and capable of acting. There may often be only gradual differences at certain points, but in the end they have a significant impact on the quality of care. Since in Austria we think from the individual patient's point of view, there is also a closer relationship - and thus trust - between practitioners and patients, even in comprehensive care institutions.

Danner: I am invited to Austria from time to time to talk about patient participation, because it is not yet as developed in the Aus-

trian bodies as it is here. Therefore, I can absolutely confirm that our manifested camp thinking and conflictual struggle about what care can and should provide and what not is much less pronounced in Austria. In our neighbouring country, I have only recently experienced very open health insurance representatives who, together with other stakeholders, are trying to build up patient-oriented care structures, whereby monetary considerations are not directly in the foreground.

„I have the impression that the medical profession often no longer has a clear view of which therapeutic options are achievable for a SHI patient:in and how care situations should optimally be designed."
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In preparation for our discussion, I spoke with an acquaintance who has been a chronic patient for decades. She says: „When I go to the doctor, which I unfortunately have to do very often a year, I want to be cared for as well as I can." She cannot imagine anything at all under the term patient orientation, although she has studied it. Are we thinking too much from a system and stakeholder point of view, without asking the patients what they want from the health system?

Danner: It is important that you can go to your doctor without having the feeling that therapy decisions are possibly controlled by some kind of monetary considerations, by modes of payment or contracts with health insurance companies. Only in this way can trust develop. Beyond this, however, there is still a level of knowledge that varies greatly between patients and doctors, although more and more patients are informing themselves before and after visiting the doctor. Furthermore, therapy decisions are supposed to be made on an evidence-based basis, but this is not always the case in the reality of care. I have the impression that the medical profession often no longer understands which therapeutic options are available to a SHI patient and how care situations should ideally be structured. The lack of transparency that becomes apparent here almost inevitably leads to mistakes, but no one monitors them.

Isn't it true that despite the undisputed success of evidence-based medicine (EBM), the strict EBM-based approach has distanced patients from their treating physicians?

Bartz: EBM has achieved what it should: a much higher level of evidence. Nobody denies that, because this movement is essential for medicine and indispensable for the quality of care. On the other hand, EBM has the long-discussed disadvantage that in its basic idea populations are compared with each other. The individual is not the centre of attention. And this is precisely the basic problem: a therapy decision developed by institutions, which may well be optimal for a population, may under certain circumstances only be correct to a limited extent for the individual within this population.

If it weren't for health services research.

Bartz: Exactly. Thanks to the science of health services research, we now have various possibilities to analyse how this population-individual gap can be described and, in the best case, resolved. In this respect, health services research is always patient-oriented. Through the possibilities of digitalisation, which generates ever new data streams, and through the addition of real-world data, this science can manage to bring the EBM concept to the patient level. To do this, however, it is first necessary to understand what a patient wants to achieve with his or her therapy. While for a clinician the focus is on maximum clinical improvement of outcome parameters, this is not necessarily the case from the patient's point of view. Here, quality of life, freedom from pain or social participation may be more important. In other words, and reflected back to EBM: Health services research can contribute to the further development of EBM in the sense of more individual patient care. If patients are treated on the basis of population-based decisions, the individual patient may receive suboptimal care. The care can be good - but then it is more of a coincidence.

Danner: Mr Bartz has just rightly mentioned that a purely study-oriented EBM is schematised and does not take the individual sufficiently into account. In addition, randomised studies on inclusion and exclusion criteria have a high level of internal evidence regarding the sharply defined subpopulation, but the patients seen by the doctors often do not belong to this narrowly defined and researched group. This means nothing other than that the study results obtained in this way may not be transferable to the individual patients at all - or only to a limited, unknown extent. Here, too, health services research can help to make the study results obtained in RCTs more transferable by adding real-word data on the one hand and data collection accompanying the application on the other. Ultimately, however, these are all risk-benefit considerations that the treating physician can discuss together with the patient, but which must ultimately be made by the patient according to individual preferences. That is why evidence-based medicine - as good as it may be - is always associated with the danger that individual considerations can no longer take place, because they have already been anticipated on an upstream macro or meso level. We have to get away from that a bit.

A question for both of you: How do we get away from this? If you read through the definition of patient orientation that the Federal Government follows, it says in Chapter 5.9 „Patient orientation" (Health in Germany, 2015): „Patient orientation means that the health system and the professionals acting in it are oriented towards the wishes, expectations and satisfaction of patients. In this context, patient orientation is considered at the different organisational levels - the macro level with a view to socio-political developments and legal framework conditions, the meso level with a focus on institutions and associations, and the micro level, which focuses on the relationships between professionals and patients." This means that even at the micro level with patient orientation, only the relationship between professionals and patients is understood, but not the patient's perspective. Which is no wonder, because the patient's view is a black box. Do you see it that way too?

Danner: I would put that into perspective a little. The individual doctor-patient relationship is different. With more and better information, patients are empowered not only to discuss treatment options with their doctors, but also to confront them with their findings, which means that doctors have to argue more and more. It is clear that this is not yet the case across the board, but it is a clear trend. However, this requires good - and of course as evidence-based as possible - patient information that is understandable to

the layperson. Patient participation has also long since arrived at the more abstract level, for example in the design of medical guidelines. This is particularly important because the guideline process is an important forum for introducing weighing decisions from the patients' point of view. In the best case, this results in therapy corridors that are relevant and important in the real doctor-patient relationship. Incidentally, this also happens to some extent in disease management programmes and other forms of care, in which the patient's point of view is to be consistently included.

Is it being done?

Danner: Not yet sufficiently. There is still room for improvement.

Bartz: In the field of medical research, the treat-to-target principle has been around for a long time. This is a strategic approach that should enable doctors and patients to participate as much as possible in the therapy process in different indications. For this purpose, the goal to be achieved must be defined in advance. The patient's point of view is decisive here! In the field of rheumatology, for example, it must be discussed and decided in each individual case whether every joint should really be pain-free or whether the goal is to completely stop progression. Depending on the decision, a quadruple combination of synthetic drugs with sometimes high side effect rates does not have to be administered, but a more targeted form of therapy can be chosen. Behind this, however, there is always an individual value decision: Do you accept one or two painful joints but no nausea in the morning? This decision is highly individual. That is why, in my opinion, it makes sense to involve those affected in the development of guidelines, disease management programmes or even study protocols and treat-to-target concepts. But if you want that, you also have to cushion it in terms of infrastructure. Patient participation at this level requires time, resources and manpower, especially on the part of patients, who will only be able to participate adequately in this way. Patient participation without sufficient funding will therefore always remain a fig leaf initiative.

Danner: I would also like to point out that we still have a lot of untapped potential here. Digitisation can lead to patient organisations being able to aggregate the patient perspective much better and more easily in the future, because they can collect and aggregate views on therapy situations in the membership via digital offers and then also bring them into a decision-making process in a structured way. This is another reason why it is important to strengthen the resources of patient organisations. However, if it is just a matter of sending someone somewhere, patient participation will never be effective. In order to gather and contribute aggregated patient experiences, appropriately qualified people are needed who, for example, know the methodology of guideline development and are familiar with the work involved. But this does not happen on its own. It needs an impulse from politics.



Dr. Martin Danner

has been the national director of BAG Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen e. V. since 2008. He is a lawyer and after his studies in Heidelberg, he worked for several years as a lawyer specialising in health law before taking over the management of the health policy and self-help promotion department of BAG SELBSTHILFE. Dr Martin Danner is also the spokesperson for patient representation at the Federal Joint Committee (G-BA) and is active in the scientific advisory board of the Medical Centre for Quality in Medicine (ÄZQ).

Does this impulse exist?

Danner: Unfortunately, it seems that patient participation is often given lip service. In the current coalition agreement, a further development of patient participation was set as a goal, but so far no concrete steps have been taken as to how this is to be done in this legislative period. Since the legislative period is already quite far advanced, a massive final spurt would now be needed if adequate progress is to be made in this area.

Where does patient participation come into play, for example, in the SHI stabilisation law or in the federal hospital reform? Of course, more quality is always good for the patient, but once again I don't see the patients' perspective.

Danner: In the development of the hospital reform, it is obvious that no patient representatives were represented in the government commission. It is not surprising that this is reflected in the recommendations. It can and will make sense to focus more on outpatient operations, but it is striking that the issue of travel costs was not considered at all. This would not have happened if there had been patient representation in the commission, because scientists and doctors who are represented in the commission usually do not think about the issue of how a patient gets to hospital in the first place. For me, this shows very well that it leads to blind spots if there is no patient representation in such commissions.

Bartz: From our point of view, the SHI Stabilisation Act is not one that really helps patients. This is not surprising, because its sole purpose is to improve the financial problems of the health insurance funds. There is no rationale why patient care should improve just because less money is given to the pharmaceutical industry. At this point, the patients' wish for the best possible care hits

the wall of economisation. In addition, the law was drafted in a short period of time, was only passed in October 2022 and already came into force on 1 January 2023 - this hits even an industry with well-functioning basic business models extremely hard and will foreseeably lead to negative effects on the provision of therapeutic options.

Please illustrate this with an example.

Bartz: Let's take combination preparations, on which a flat rate of an additional 20 per cent is to be levied in future. Quite apart from the legal justification: That cannot be in the patients' interest. As many combination drugs as possible - even cheaper than single-dose drugs - should be available on the market for them. But which company can afford in the long run to develop preparations that inevitably lead to a sharp drop in revenues? Another example is the reduction of the sales threshold for orphan drugs.

What will that do?

Bartz: It is fatal: it is becoming increasingly difficult to research innovative drugs in Germany and then bring them to market.

This is a narrative that is often heard.

Bartz: Politicians must realise that changes to a set of regulations endanger the planning security of companies on the one hand, and Germany as a research location on the other. You may call this a narrative, but it follows a market economy rationale, the effects of which have been observable for some time. Important location factors for pharmaceutical companies are market and access. If both deteriorate, fewer and fewer studies will be conducted in Germany. This is bad for patients and for those who treat them: The former are deprived of early access to innovative medicines, while research is deprived of funds and know-how.

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Dr. Holger Bartz

Danner: One might assume that the income situation of pharmaceutical companies is not an issue for patients. But it is, because changes in the regulations through the SHI Financial Stabilisation Act will inevitably change the strategies of the companies. We also fear that in some indication areas there will be fewer and fewer reasons to push ahead with the necessary research. The second keyword is step innovations: There are indication areas, such as oncology, where it is easier to show big differences. In others - such as diabetes - the endpoints are usually designed in such a way that it is much more difficult to show large differences. Our position as patient representatives is clear: all patients have a right to an improvement of their situation. Therefore, regulations that set negative incentives to stop investing in certain indications are not in the patients' interest.

Bartz: In principle, the AMNOG has worked for years - leaving aside the details. The basic idea is simple and understandable: Equivalent medicines are paid the same, better medicines are paid better - in various gradations, depending on the degree of evaluation and price negotiation. Of course, a system that is getting on in years needs to be readjusted. But now we are in a situation where we are hardly in a position to predict whether we will get through AMNOG or not with our development programmes that have lasted for years. If there are no consequences this year, then in two or three years at the latest.

Now we have moved a bit far away from patient orientation, even if an adequate supply of innovative medicines is certainly in the interest of patients. What does the pharmaceutical industry have to do with patient orientation, which mainly takes place at the doctor/patient level?

Bartz: We are part of the health care landscape. Our task in this complex health care system is to develop and produce innovative medicines in such a way that they can reach the patient promptly. It is our natural mission and raison d'être to develop innovations based on the needs of patients that interrupt, alleviate or even cure their disease burden as early as possible. Our highest maxim is that what we produce must have the greatest possible benefit for the individual care of patients, but must also be financially viable for the system. In other words: basically, our work is absolutely patient-centred, because we start thinking very early on about how we can use the findings from phase 1 studies to eventually make innovative medicines for the benefit of patients.

Danner: Ultimately, it's about improving care. To do this, we need good active substances in sufficient quantities - keyword supply bottlenecks - and as broad a selection of alternatives as possible to open up treatment corridors. But we also need an understanding that endpoints such as mortality, overall survival and prolongation of life are important, but that the improvement of quality of life must not take a back seat. In the past two decades, an extremely elaborate methodology has been developed to objectively represent this absolutely patient-relevant endpoint. However, the concept of quality of life has so far been based on an aggregated patient-reported outcome. Now we have to manage to focus more on the specific patient-reported outcome. It is worthwhile for companies to continue thinking in this direction, because they can then lead new drug candidates to beneficial innovations even more from the patient perspective.

Bartz: You mentioned the different levels of patient participation before. I see the pharmaceutical industry at all levels: On the macro level, we are committed to the further development of the health care system and the political framework in the interest of patients. At the meso level, we work with all stakeholders as best we can, including of course patient organisations. At the micro level, however, we are limited in Germany to exchanges with the medical profession, as we are not allowed to communicate directly with the patient community. What we do, however, is to provide the medical profession with the best possible study data and training materials about our products, as well as materials that they can use to support the health literacy of their patients.

However, I still miss the patient's perspective. I did an interview with the congress president of the 22nd DKVF for the last issue of „Monitor Versorgungsforschung". In it, Professor Dr. Geraedts calls for a structured recording of the patient's point of view in order to be able to represent real care: a kind of care cohort in Germany, which already existed in the past with the Bertelsmann Health Mo-

nitor. What do you think of this?

Danner: That is definitely an interesting idea, if it is possible to represent the wishes, experiences and needs of the population by surveying a representative group. However, I'm afraid that the needs of patients are very complex on the one hand and very heterogeneous on the other. In addition, there is the regional and local situation, whereby the care structures and also the availability and qualification of the practitioners are very different. Therefore, I doubt whether one can adequately describe this complexity with such a cohort. Although it would be absolutely desirable to consistently research the image of the patient's point of view and to implement the resulting results on underuse and misuse in the further development of our health care system.

Bartz: From my point of view, a cohort of care in Germany would be a really useful tool for presenting relevant parts of care from the patient's point of view. Apart from smaller studies, this has been a black box so far. If it were possible to use such a data set to better understand an extremely important part of the reality of health care, it would be possible to identify levers that could be used to better design our health care system from the patient's point of view. However, such data only show the current situation and gaps in the system, new possibilities are not described. That is then again the task of health services research. If this is done, there must also be regulations and mechanisms that ensure that the possibilities for improvement are also introduced into the system.

Danner: You can think even bigger in terms of a future-oriented vision. At some point we will have a national data room that could also help detect gaps in the system. In addition, pay-for-performance contracts could be used to observe the effects in the health care system over a longer period of time and create an even better background of knowledge. The crux of the matter is that we do not yet have this infrastructure available.

Bartz: Pay-for-performance models abound in other European countries. They create the most solid data that can be obtained, because clinical data have to be collected in order to secure reimbursement. It would be an interesting idea to include this data in an overall data model. There is really a lot of potential in this, which in the end saves a lot of money for the system and also helps to provide better care for each individual person.



Dr. Holger Bartz

is Medical Director and Managing Director of Janssen Germany. As Medical Director and Managing Director, Holger Bartz has been responsible for the medical and scientific activities in all therapeutic areas of Janssen Germany since June 2022. He held a similar position at Janssen Austria from 2020 to 2022. He started his career at Johnson & Johnson in 2016 as Therapeutic Areas Director Immunology & Infectious Diseases & Vaccines. In this position, he managed various successful market launches. A medical doctor by training, Holger Bartz has worked as a paediatrician and is a specialist in medical microbiology. He also holds an MBA in General Management.

At the beginning of our conversation, we looked back up to 20 years. What will patient orientation look like in 2033?

Danner: It is impossible to predict how the two antagonists, digitalisation and data protection, will develop and how this will perhaps at some point open up the possibility of actually developing patient-oriented care. Ultimately, it is always a problem of knowledge to create the best possible care for patients. Otherwise, I am confident that the development process of the last 20 years will progress and that we will take the patient's perspective into account at all levels. This is already the case today in the definition of research work and study designs as well as in the evaluation of endpoints. But the patient perspective should also be taken into account in the development of new care structures. Who should know better how an optimal relationship between outpatient and inpatient care should be designed than the patient:in themselves?

Bartz: We will achieve our goals with regard to consistent patient-centred care much faster and better if we involve patients in all processes earlier. In the next five to ten years, we will all have to work together to ensure that this is actually done.

The bottom line is the concept of value-based care, but the values are mainly determined by the stakeholders - hopefully with the patients' say, but not from the patients' point of view. How do we move from value-based to patient-centred care?

Danner: Ultimately, it is always a matter of setting beneficial targets for the actors in the health care system. For example, initial impulses have already been set with targets for the benefit assessment of medicinal products and medical devices. I now see the need to make the concrete patient orientation clear as a goal for all other actors. But be careful: Patient participation must not be used as a means for all actors in the health care system to behave in a way that is precisely not patient-oriented. This target must apply to all.

Are you on board with this?

Bartz: Value-based healthcare means achieving the best possible outcome, i.e. the maximum health-related value, for those affected with the means available. The former is influenced by how quickly a patient gets to the right doctor and whether the doctor prescribes the right therapy for the individual. If a chronic patient has been

treated incorrectly for more than 20 years, this not only causes suffering and an unnecessarily reduced quality of life. It also costs the health system a lot of money. The right treatment can never be that expensive. However, if the patient:in is treated correctly as early as possible, the costs for the entire system will also decrease. Unfortunately, we apply this perspective far too seldom, because health is always viewed only as a cost factor and never holistically.

Danner: Of course, it is always important that patients get to the best possible place for their care as quickly as possible. When I think of personalised medicine, for example, the right diagnostics also play a very important role, because it is then no longer about the patient as a patient, but about individual predispositions and biomarkers that can contribute to a disease being detected earlier, treated better or possibly not developing at all. What is needed here is a change in meaning and a social consensus that does not accept illness as God-given.

You just mentioned the VBHC formula: Treatment quality divided by treatment costs. The SHI patient wants the best treatment, but does not see the treatment costs.

Danner: That is the requirement in the system of compulsory insurance. I cannot deprive the population of a large part of its income and then withhold care. That's why I react allergically when there is hasty talk of rationing in the SHI system. The strictest possible benefit orientation must therefore lead to the exclusion of superfluous treatments and those that do not have the optimal benefit. However, it is a misunderstanding that patient representatives always want to have everything for everyone. We don't, because we are well aware of the limited resources of the system. We are more concerned with the competition for the best possible care. VBHC is an orientation marker for this, because ultimately patient-centredness must be the benchmark for everything.

So we would have to bring about a cultural change, away from the view of medical costs towards investment in health.

Bartz: That's true. You see this increasingly in medicine. In the classic treatment paths, people started with the cheapest active ingredient for a long time and then slowly escalated instead of immediately using the innovative, usually more expensive active ingredient to stop chronification or erosion processes as far as possible. For some time now, the „hit hard and early" or rather the „hit smart and early" way of thinking has been gaining more and more acceptance in many disciplines. On the one hand, innovative medicines increase treatment costs, but on the other hand they reduce the costs for the consequences of the disease, treatment times and intangible follow-up costs. Unfortunately, such models are rarely calculated. However, I am convinced that this school of thought will prevail in many therapies in terms of patient benefit.

Danner: Which is good if it is evidently proven by proof of benefit. But only then. <<

Mr. Bartz and Mr. Danner, thank you for the interview..

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

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