Redaktion

"Guardian function with regard to quality and safety"

Karin Maag, who has been an impartial member of the Joint Federal Committee since July 2021, gives a real tour de force through current quality assurance issues in an interview with "Monitor Versorgungsforschung". The topics range from minimum volume regulations, quality indicators such as plan.QI and DeQS, the use of routine and registry data, to the abolition of event-driven controls by the KHVVG. The former Member of the German Parliament and, as such, health policy spokesperson for the CDU/CSU parliamentary group, emphasises several times and very decisively: "We will continue to fulfil our watchdog function for patient safety."



In the title interview: Karin Maag, impartial member of the Joint Federal Committee

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>> Ms Maag, one of the currently much-discussed issues is the Hospital Care Improvement Act (KHVVG), which was approved by the Bundesrat in November 2024 and readjusted at the instigation of the federal states, with new service groups and Level 1i hospitals being mentioned here. The GKV-Spitzenverband (National Association of Statutory Health Insurance Funds) in particular is concerned about quality criteria, which – according to a view often expressed in the media – could be watered down too much. One of the goals of the hospital reform that came into force on 1 January 2025 is precisely to further develop quality, at least in the hospitals remaining after a restructuring phase. What can the G-BA do to ensure that the quality criteria are not watered down but are actually taken into account?

From our point of view, we will of course continue to exercise our watchdog function with regard to quality and patient safety throughout the entire healthcare system. The legislator has not relieved us of this responsibility through the hospital reform. In addition, we were pleased to see that, for example, part of our structural guidelines will be adopted in the future system of service groups as a result of the reform. It remains to be seen how the reform will develop in coordination between the federal and state governments.

***"Minimum volumes remain one of our most important instruments for* quality assurance."**

But what can the G-BA do?

The G-BA continues to be legally mandated to set minimum requirements for structural, process and outcome quality, provided that this does not conflict with the quality criteria of the service groups. I don't think that will happen.

The minimum requirements specified by the G-BA in its structural guidelines ensure the quality of the respective specific services provided in hospitals; they are based on the best possible evidence and are legally binding. In contrast, the quality criteria associated with the service groups are neither geared towards particularly risky procedures nor are they based on evidence. They follow a different system, as they bundle services according to hospital planning standards. They will therefore also be guided by the principle of economic efficiency in accordance with Section 12 of the German Social Code, Book V (SGB V), and are intended to lead to a concentration of care structures. Minimum requirements as part of the service groups are often confused with minimum volumes. However, despite the similarity in name, these are completely different instruments. We therefore continue to fulfil our watchdog function for patient safety. As mandated by the legislator, we will continue to work together with our two scientific institutes, the Institute for Quality and Efficiency in Health Care (IQWiG) and the Institute for Quality and Transparency in Health Care (IQTIG), to ensure that evidence-based quality is upheld in our healthcare system.

Do you see any danger from new political plans or a lack of enforcement?

I do not see the Federal Ministry of Health, parliamentary groups or individual members of the Bundestag questioning the tasks assigned to the G-BA by law.

There are three federal states that are taking legal action against the minimum volumes. This is an attack on a key quality assurance instrument because the states feel that their regulatory authority is being impeded.

Minimum volumes remain one of our most important instruments for quality assurance. This is a matter of routine, which the G-BA requires for plannable and particularly difficult, complex operations and procedures. The lawsuit is expected to be directed against the Federal Republic of Germany, not against the G-BA. I do not know exactly what the lawsuit is about, as neither the Federal Chancellery nor the Federal Ministry of Health nor we have received a statement of claim yet. I am only aware of press

statements in which, for example, the Minister of Health of Schleswig-Holstein explains that she does not actually want to attack the instrument of minimum volumes as such, but only has problems with a certain minimum volume.

Let us guess: premature babies.

Exactly. She is concerned about the minimum volume regulation for severely underweight premature babies. It is precisely this minimum volume that is considered indispensable in medical circles. I refer to the statements of all professional associations in the field of perinatal care. They expressly support this minimum volume and have reacted to the lawsuit with absolute incomprehension. This minimum volume protects the lives of a particularly vulnerable group. In this respect, I am very confident that the Federal Constitutional Court will take a similar view.

The KHVVG means that the federal states are losing the quality indicators (plan. QI) that are relevant to their planning as a control instrument. Do the data from the G-BA quality indicators (such as DeQS) offer real added value for the federal states' hospital planning, or is more needed?

The plan. QI instrument was intended to enable the federal states to better take into account the quality of care provided by individual hospitals in their planning decisions . However, the instrument was never really accepted by the federal states. Only seven or eight federal states even asked to see the results. This meant that the associated G-BA guideline could not fulfil its purpose. The G-BA also repealed this guideline because we were unable to establish universally applicable, evidence-based quality standards for the different departmental structures of hospitals in Germany, for example. The quality indicators used in data-based quality assurance must be considered separately. The relevant guideline here, the Data-Based Cross-Institutional Quality Assurance Guideline (DeQS-RL), enables comparison between service providers, but is not an instrument that was created for hospital planning.

***"In my view, the hospital reform, which is still not in its final form, does not necessarily represent an* improvement in quality."**

Isn't the elimination of plan. QI a major step backwards?

Planning authority lies with the federal states. In my opinion, the federal legislature lacks the regulatory competence to set quality standards for hospital planning in the federal states. However, I believe that abandoning this procedure is harmless for the reasons mentioned above.

What about the use of routine data to measure location-based care beyond pure case numbers?

We are in the process of revising the DeQS guideline on several levels in order to make data-supported quality assurance more efficient and effective. This means that we are reviewing every procedure, for example, revising the quality indicators, making them more targeted and reducing the overall documentation effort. In addition, we are making greater use of other instruments, such as routine data from health insurance funds or results from patient surveys.

What about registry data?

In future, the DeQS guideline will also work with registry data, e.g. from cancer registries. The IQTIG has developed the use of registry data in principle, but no procedure has been finalised yet.

Could you give us an example?

The QS Prostate Cancer procedure will be the first to incorporate cancer registry data. We expect a decision on this to be made this year.

What experience have you had with the use of health insurance data so far?

Data that is documented anyway for the billing of medical services to a health insurance fund has the advantage that it does not cause any additional work for the institutions, i.e. it enables leaner procedures for service providers and, overall, a bettercost-benefit ratio. The use of social data also allows follow-up stays and procedures to be taken into account, regardless of whether they took place in the same or a different hospital. However, a final evaluation of the use of health insurance fund data is still pending and will probably be available by mid-2026. In general, we expect this to provide a much more comprehensive picture.

Hospital reform is often perceived as a purely cost-cutting measure. How can you convey to the public that your work is an improvement in quality?

I would like to distinguish between hospital reform and the quality assurance tasks assigned to the G-BA. In my view, hospital reform in its current, still not final form does not necessarily improve quality. The original goal was certainly to improve quality at the same time, among other things through structural reform. However, as I said, the legislator also has economic efficiency issues in mind. The G-BA, on the other hand, has a legal mandate to define such requirements so that patients receive high-quality, evidence-based care that is in line with the latest scientific findings, not only in hospitals but also in doctors' and dentists' practices, for example.

The service groups explicitly cite cost-effectiveness as a driver in the law (Section 12 of the German Social Code, Book V).

It is true that the minimum provision figures for the service groups are a result of the economic efficiency requirement pursuant to Section 12 SGB V. However, economic efficiency is not a criterion that we have to meet in the G-BA's quality assurance. We focus on evidence-based quality requirements. Incidentally, in an initial proposal for a methodology for minimum provision figures in the service groups, the IQWiG expressly emphasised that quality must be more important than economic efficiency.

One critical point of the KHVVG is the abolition of event-driven controls (Section 137 (3) SGB V). How can the G-BA ensure that quality deficiencies continue to be detected?

I will say this very clearly and once again: we will continue to exercise and uphold our watchdog function. We will continue to work on our issues, such as the DeQS or MD-QK guidelines, which regulate quality controls by the Medical Service. The legislator has not taken this competence away from us, even if there may be grey areas. However, I am determined to maintain our regulatory framework in line with our legal mandate to ensure

quality and patient safety nationwide, as long as no one expressly prohibits us from doing so.

On the subject of random checks instead of individual case checks for billing: what are the prerequisites for this to work?

Actually, the legislator provides for random sampling as a regulatory instrument for the G-BA. However, we must justify a full survey.

In the hospital sector, the political aim of switching to random sampling is to finally end the "arms race" between the coding departments of hospitals and the audit departments of health insurance funds. However, this is less of a G-BA issue and more a matter of billing audits. Our quality assurance random sampling has other reasons.

Structured dialogue is intended to bring about quality improvements, but often mathematical anomalies are not identified as genuine quality problems. How can this be improved?

We have commissioned the IQTIG to develop appropriate proposals. A purely mathematical anomaly does not automatically mean that there is a quality problem. There is a wide gap between a mathematical anomaly and the identification of a genuine quality deficit. The so-called statement procedure is used to check whether there is actually a quality deficit.

Please give an example.

Let's take a femur fracture: the indicator requires surgery within 24 hours. However, if a patient also has a heart attack, for example, as a lawyer, I would consider it medically correct not to operate on the hip immediately, but to prevent a life-threatening situation. In purely mathematical terms, the "delayed" operation appears as a conspicuous result in the measurements, i.e. as an "error". However, it is not a "real" deficit, but good medicine. This differentiation can only be clarified in a structured dialogue among experts. As far as I can see, this process is working very well and is extremely cooperative.

What are the obstacles to using G-BA structural data for healthcare research?

None. All that is required is to submit an application for secondary data use to the IQTIG, which is usually reviewed and approved quickly . We currently process about two applications per meeting in the subcommittee.

Karin Maag



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has been an impartial member of the Joint Federal Committee since July 2021. From 2009 to 2021, she was a member of the German Bundestag, and from 2017 onwards, she was the health policy spokesperson for the CDU/CSU parliamentary group in the Bundestag. From 2007 to 2009, the lawyer was a senior civil servant in the state parliament of Baden-Württemberg, and before that she was city director of the state capital Stuttgart and head of the mayor's office.

And what about the research data centre?

As is well known, it is located at the Federal Institute for Drugs and Medical Devices. This is also an interesting data pool for the G-BA, which we would like to make more extensive use of. Direct access would probably require discussions with the legislature.

Regarding patient participation: patient representatives currently have no voting rights in the G-BA. Should this be expanded to increase acceptance?

Patient representatives make active and, above all, qualified use of their current right to submit motions and participate in consultations. However, any change to participation rights is a matter for the legislator. We are open to this, as long as majority decisions in the plenary session remain possible. Personally, I would find it acceptable if patient representatives – similar to impartial members – could use their vote to postpone a decision, for example, to discuss controversial details again. Full voting rights would arouse the envy of many other institutions. Currently, only the partners of the joint self-governing body that finance and support the G-BA have voting rights in the G-BA.

How do you incorporate the patients' perspective into the guidelines?

As I said, the patient representatives already have the right to submit motions, which they exercise, and they are consulted on every guideline. Take the patient survey, for example. As a tool for data-based quality assurance, it is aimed at all patients in the care process and is being

gradually expanded, including in quality assurance procedures for cardiac catheters and outpatient psychotherapy. Our aim is always to incorporate the patients' perspective on their treatment into quality assurance. They should not only be informed about treatment risks in a legally correct manner.

Where do you see the greatest challenge in quality standards for new cross-sector forms of care?

Quality assurance is usually designed to be comparative within a sector. Across sectors, attribution and risk adjustment become more difficult. We must now focus primarily on outpatient treatments – keyword: outpatientisation. Regardless of whether a service is provided in a hospital, on an outpatient basis or by a registered cardiologist – such as transcatheter aortic valve implantation (TAVI) – quality assurance requires the same quality standards across sectors.

What would you like to see in healthcare research?

Off the top of my head: we need first-class medical guidelines with a high degree of consensus from the scientific community. This makes it easier for us to incorporate legally compliant quality requirements into our guidelines or to further develop offerings such as disease management programmes (DMPs).

Finally, let's turn to the topic of primary care and emergency care, which should be considered together.

Absolutely. Emergency care and primary care direct inpatients and outpatients to the appropriate level in the healthcare system and should therefore use the same tools. In emergency care, for example, we have the SmED software, which stands for structured medical initial assessment in Germany. Through targeted and structured questions, it enables a well-founded initial medical assessment of emergencies arriving at the hospital. However, it is important that primary care does not start using other tools in the future that are not compatible. Uniform guidelines are needed in Germany, which the G-BA can develop or has already developed. I refer to the guideline on initial assessment in emergency care, which has been available for two years but which the BMG had legally objected to. In addition, patients could also be given digital access – ideally via an app or by telephone (whether 116117 or 112). In future, these areas must be considered, planned and financed together. We must no longer tick boxes one by one, but must consider and integrate the systems and structures of healthcare provision.

Thank you very much for talking to us, Ms Maag.

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