Review of the 33rd Conference of Experts on Implantology

Guidelines and their functions

Once a year, the BDIZ EDI invites dental experts to the Conference of Experts on Implantology on behalf of the Consensus Conference on Implantology. In 2023, the one-day continuing education event was held in Kiel in cooperation with the Schleswig-Holstein Dental Chamber.

The 33rd BDIZ EDI Conference of Experts on Implantology, convened on behalf of the Consensus Conference on Oral Implantology, is held each year with a different dental chamber as a partner.

For more than 30 years, experts on implantology—who provide expert opinions for courts, insurers and other stakeholders—have met once a year for the Conference of Experts on Implantology at the invitation of the BDIZ EDI. Also for more than 30 years, this Conference has also been held as part of the Consensus Conference on Implantology, which brings together specialist societies and professional associations.

The annual meeting serves as a forum for the exchange of information between the experts. One of the topics that the BDIZ EDI included in this year's programme was the topic of guidelines. Christian Berger, President of the BDIZ EDI, and Dr Michael Brandt, representing the hosting Dental Chamber at the Zahnärztehaus ("House of Dentists") in Kiel, welcomed the experts. The event was hosted by Berger and the Chairman of the BDIZ EDI Expert Committee, Dr Stefan Liepe. This article focuses on the various aspects of guidelines and their implications as they developed during the deliberations.

Guidelines are here to help

The first speaker, DDr Markus Tröltzsch (Ansbach), participated via video link. He is a member of the BDIZ EDI Board. As Chair of the Academy of Dentistry and Oral Medicine (APW) of the German Society of Dentistry and Oral Medicine (DGZMK), he is not only familiar with guideline work but has also co-authored some of them. How does knowledge transfer take place today? This was the question that Tröltzsch raised at the beginning of his presentation. Where do I get my know-ledge from? In a structured way? And how do I know that I am not reading the personal opinion of one single author?

In preparation for his presentation, he had asked ChatGPT for the definition of "medical guideline", with a surprising result: "The purpose of guidelines is to give professionals clear recommendations for action—according to the current state of knowledge and the best available evidence," the large language model had replied. But according to Tröltzsch, this is precisely what guidelines are not supposed to be, even though they are sometimes misinterpreted by practitioners—that guidelines limit the scope for action. "We want to give recommendations for action!" The aim of a good guideline is to critically examine options for action and to indicate where evidence exists—and where it does not.

In Germany, the Association of the Scientific Medical Societies (AWMF) is responsible for guidelines in all areas of medicine and dentistry. According to Tröltzsch, it would be useful to agree on a guideline

format, a procedure—similar to the four-star system for hotels (S1, S2 and S3). The AWMF defines guidelines as follows: systematically developed statements, current state of knowledge and systematic review and appraisal of evidence, clear recommendations for action and decision corridors (from which deviation is possible or sometimes even necessary).

One important point, Tröltzsch felt, is the disclosure of conflicts of interest, which are weighted by the AWMF. "This is where it gets critical: the person you want to be the author of a guideline is, after all, the person who should know something about the subject matter. And, of course, since we cannot do certain things at all without the industry providing us with the material, there are often financial links. At some point, it becomes difficult to find suitable authors."

Tröltzsch sees another dilemma in the guideline development process itself. The prevailing methodological background is very important. This is also crucial for assessing the range of possible actions: "Is my guideline strong or weak on evidence? We have to accept that there are limits to the level of evidence that can be attained for certain areas of dental practice." He gave the example of bisphosphonate therapy and dental management. The recommendation for antibiotic treatment was based on only one study with fewer than 60 participants—which is not very strong evidence. "However, since we know beyond doubt that the genesis of drug-induced osteonecrosis of the jaw is primarily due to bacterial infection, it would be madness to treat it without antibiotics."

If you search for guidelines, you will find 56 hits for dental implants, Tröltzsch pointed out. "And I think a lot of practitioners ask themselves, how am I going to read 56 guidelines?" But there is no need to, he said. The AWMF guidelines are written in such a way that the relevant knowledge can be quickly extracted with just a few mouse clicks. "We just have to know where and how to look."

The speaker concluded a guideline reflects the current state of knowledge—from expert consensus to meta-analysis.

Prof. Johann Müller from Munich criticised the guidelines.

Prof. Thomas Ratajczak presented the potential dangers of guidelines.

In addition, it provides specific recommendations for action, but these are graded. "We cannot escape liability by following a guideline, nor is liability triggered by disregarding a guideline." Markus Tröltzsch admits that it is not easy to keep track of all the existing guidelines. For him personally, guidelines generally provide valuable support. He suggested that reviewers or guideline experts should help colleagues adopt and apply the guideline.

Guidelines in the spotlight: Criticism of the CMD splint therapy guideline

Prof. Johannes Müller, Expert on Implantology and President of the European Dental Association (EDA) illustrated the risks that can be associated with guidelines, using functional therapy as an example. At the 2022 Bavarian Dentists' Congress, the German Society for Functional Diagnostics and Therapy (DGFTD) had presented its new scientific statement on CMD therapy—which completely contradicted its own guideline issued just six years earlier. According to Müller, the new guideline is currently being developed under the auspices of the DGZMK and DGFTD and has "enormous potential to change dentistry in the long term"—in a negative way, he believes.

Müller quotes the main message of the new guideline as follows: Internationally, occlusion has long ceased to play a role in craniomandibular dysfunction (CMD). For this and for other reasons, Müller con-

Prof. Ulrich M. Gassner discussed the EU Medical Device Regulation.

Dr Kai Voss, Vice President of the hosting Schleswig-Holstein, Dental Chamber, spoke on the problem of interpreting radiographs.

The hosts: Dr Stefan Liepe and Christian Berger from the BDIZ EDI and Dr Michael Brandt, President of the Schleswig-Holstein Dental Chamber (from left). In the background: The first speaker of the conference, DDr Markus Tröltzsch, joined in by video link.

siders the DGFTD guideline currently under development worthy of criticism. His list of criticisms is extensive: He cannot understand the justification for a new S2k guideline on splint therapy that states that too little evidence is available, especially since the S2k guideline on dental instrumental functional analysis and jaw relationship determination (AWMF: 083-017) was published only recently, in 2022.

The guardrails of the new guideline, now in its third reading: many "shall" instead of "should" provisions; literature references that did not match the topic. Müller suspects that this has to do with political issues. The majority of authors came from the TMD (temporomandibular dysfunction) field. "So occlusion does not play a role", he suspects. "Anything causally related to occlusion is not covered in the guideline. Literature on TMD is simply transferred to CMD, which means that we will only treat symptomatically." Not only has the literature been misquoted, but the clinical evidence has been completely omitted, and the members of the group involved in writing the guideline have been selected, in part, on inadequate grounds.

With this guideline, he concluded, it will not be possible to maintain the level of quality that has been achieved in Germany over decades.

The potential dangers of guidelines

Prof. Thomas Ratajczak, BDIZ EDI legal counsel, believes that the biggest problem with guidelines is that they often have less to do with science than with personal vanity. For Ratajczak, control by practitioners would be a minimum requirement for acceptance—especially in dentistry. He believes it to be inappropriate for guideline authors to cite their own studies as relevant literature for the guideline—there are examples of this in dentistry as well. He reported that two years ago his law firm halted an S3 dental guideline that had already been adopted. "The fact that it is at all possible to stop something like this by the mere threat of a lawsuit, after a mere evaluation of the guideline report, is significant," he said.

The intriguing question is how to seriously assess whether validated medical evidence has been incorporated into the guideline? In the case of the aforementioned S3 guideline, 42 studies were reviewed, the majority of which were deemed irrelevant. "Dentists are not used to scientifically dissecting a guideline."

According to a 2017 study that examined dentists' daily guideline practice, Ratajczak said, participants rated the cognitive integration performance of external knowledge as having little practical relevance. "How many of our clients in liability cases do you think do not even know the relevant guidelines that are being put forward by patient advocates?" His experience specifically includes expert witnesses. "Time and time again we have cases where even the expert witness does not know the guideline, and it is only in the patient advocate's response to the expert's opinion that a guideline is finally cited that the expert witness did not mention and had to admit he did not even know."

So what is the significance of guidelines? Systematically developed, but not relevant in the sense of being legally binding? In Ratajczak's experience, the guidelines absolutely do have legal relevance for the courts. "If experts base their testimony on guidelines, the courts are more likely to follow their reasoning."

Practitioners are expected to research whether a relevant guideline exists at all and to be able to analyse it critically. This involves looking at the relevant studies in the guideline and in the literature, and considering whether the strength of the recommendation is plausible. Then they would have to answer the question whether they may, or must, follow the guideline and they would have to document his decision. "This is what we expect to happen when we put guidelines out into the world."

The problem of interpreting radiographs

Dr Kai Voss, Vice President of the hosting Schleswig-Holstein Dental Chamber, has been involved in the field of quality assurance for over 30 years, both on behalf of the association and on various committees of the German Dental Association. He is also a member of an advisory committee for the Federal Ministry for the Environment and the state authorities on radiation protection. In his lecture, he addressed the issue of misinterpretation of radiographs by experts, which he believes can be very conflictual. He presented various expert opinions and examples of what can be "interpreted" in radiographs. Expert review of radiographs is a description, not a diagnosis, he clarified, which is not always obvious. It makes sense to describe to the court what there is to see. He cited projection geometry and misinterpretation due to artefacts as one of the problem areas. However, Voss made it clear that the pillars of assessment are the patient's history and clinical findings; imaging only comes into play when "the hands and the eyes and the brain are used together". "We should not offer assessments unless they aren't somehow provable and verifiable by additional diagnostic parameters."

The Mecklenburg-Vorpommern Dental Chamber shows interest in the BDIZ EDI expert conference: BDIZ EDI President Christian Berger, President of the Chamber (left), Stefanie Tiede (second from left) and Dr Gunnar Letzner, Chairman of the Board of the State Dental Association (second from right), with colleagues from Schleswig-Holstein.

The "Notified Bodies" bottleneck and the MDR

Prof. Ulrich M. Gassner (Augsburg), a lawyer and the founding director of the Research Centre for E-Health Law (FMPR) at the University of Augsburg, spoke about the EU Medical Device Regulation (MDR), which has been in force for six years. In 2019, the BDIZ EDI had commissioned the law firm of Ratajczak & Partners to conduct a survey on the expectations of the dental industry.

The results were published in *BDIZ EDI konkret 2/2020* and confirmed Gassner's assessment, which he had already predicted in 2017. "The MDR was accompanied by an explosion in the number of rules we are subjected to." He cited the disappearance of products from the market as an example from the survey at the time. In fact, many medium-sized dental manufacturers have given up because the bureaucracy and its costs have increased immensely. The "streamlining" of the product portfolio has also been evident since 2019, he said. The entry into force of the MDR has been postponed twice, ostensibly because of the COVID-19 pandemic, but actually because of a lack of notified bodies.

"We are talking about regulatory overkill," Gassner confirmed, especially at a time when manufacturers of innovative products often have to give up early. He cited the case of the Munich paediatrician who had travelled to Brussels to meet EU Commission President von der Leyen because stents for infant cardiac surgery were no longer available; the manufacturer had discontinued this line of business.

Gassner himself and representatives of the Baden-Württemberg state government had travelled to Brussels and found a Commission that seemed willing to talk. The concrete response from Brussels was to set up a task force of mission and inventory products to exert a "sub-legislative" controlling influence. In a position paper addressed to the Notified Bodies responsible for CE certification, urging them to be more flexible. "There is something to be gained from exerting pressure", Gassner admitted. The transition period for existing products will be extended; this also applies to implants.

Dr Stefan Liepe concluded the one-day Conference of Experts on Implantology—not without looking ahead to the 34th conference, which will be held in Dresden in 2024 in cooperation with the Dental Chamber of Saxony.

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