BUNDESÄRZTEKAMMER

## Bekanntmachungen

**On the recommendation of the Scientific Advisory Board, the Executive Board of the German Medical Association adopted at its meeting on 25 September 2015:**

### Statement on the

# "Standardisation proposals regarding healthcare services from the physicians point of view"

## Foreword

Standards regulate the safety of medical devices and technical operations for diagnostic and therapeutic procedures. But standardisation efforts have now also set their sights on services in the healthcare sector. Healthcare services must, however, categorically be regarded as complex interventions. Accordingly, quality assurance of medical activities rests both internationally and nationally upon the state-of-the-art in medical science and technology and thus on the principle of evidence-based medicine and guidelines. The primary intentions behind this are to protect patients, provide assurance for the physicians treating them and to ensure high-quality healthcare, bearing in mind the individual physician-patient relationship and the therapeutic discretion of the physician.

In recognition of these basic principles of medical practice, the Treaty on the Functioning of the European Union (TFEU) stipulates, with good reason, the protection of each Member State's responsibility for defining its own health policy and for the organisation and delivery of its health services and medical care. However, despite the fact that these responsibilities are explicitly acknowledged under European law, both individual representatives of so-called "interested parties" and the European Commission are increasing their efforts to regulate healthcare services by means of technical standardisation. The current negotiations regarding the proposed free trade agreement (TTIP) also raise fears that its purview could include and regulate healthcare services, thus subjecting them to standardisation.

Through numerous initiatives, the German Medical Association has already expressed that the standardisation of healthcare services at the national, European and international level should be firmly rejected. However, given that there had been no scientific study of this topic to date, the Executive Board of the German Medical Association commissioned its Scientific Advisory Board to examine the methodological foundations, as well as the implications of standardisation in the health sector from a scientific medical point of view. Based on the understanding that patients and the progression of their diseases are neither standardised nor capable of being standardised, it was especially important in this case to bring out the basic principles for individualised state-of-the-art medical care.

The statement at hand clearly illustrates the divergent objectives and conceptual differences between the drafting of guidelines, on the one hand, and standards on the other. At the same time, it becomes clear that standards are not an appropriate regulatory tool for the field of healthcare services and, in particular, for the work inherent to the practice of medicine, since, in this field, information or specifications must be interpreted and evaluated on an individual basis.

To do justice to this complex issue and take into account a variety of perspectives, the Working Group was staffed with an interdisciplinary team, in cooperation with the Association of the Scientific Medical Societies in Germany. In sometimes controversial, but always constructive discussions, members and guests of the Working Group carefully formulated the statement and recommended it to the Executive Board of the German Medical Association for a decision. For this we would like to take this opportunity to sincerely thank all parties involved.

The unabridged version of the statement presents a profound analysis of this subject matter. The abridged version offers a supplementary compact treatment of this argument. The hope is also to make the standardisation efforts of the European Commission widely known and, in particular, to alert policy makers at the national as well as the European level to questions and problems associated with the standardisation of healthcare services. With this in mind, the Executive Board of the German Medical Association reached a decision to translate the statement into English. The stated goal of these efforts is to ensure that standardisation is introduced in a way that is nuanced and appropriate going forward and thus bring to an end the inappropriate attempt to standardise healthcare services.

Prof. Dr. med.
Frank Ulrich Montgomery
Präsident der Bundesärztekammer
und des Deutschen Ärztetages

Prof. Dr. med. Dr. h. c. Peter C. Scriba
Vorsitzender des
Wissenschaftlichen Beirats
der Bundesärztekammer

Prof. Dr. phil. Robert Jütte
Federführender des Arbeitskreises

## Preamble

The primary objective of standardisation is the methodical, collaborative achievement of uniformity of tangible and intangible goods. The task of physicians is to preserve life, protect and restore health, alleviate suffering, support the dying and participate in the preservation of the natural foundations of life with regard for their importance for human health. By practicing medicine any exercise of the profession is understood by which medical knowledge can be used or used among other things. Practicing medicine thus requires the necessary professional qualifications and compliance with the accepted state of medical knowledge.

Against this background the present statement of the Scientific Advisory Board of the German Medical Association calls attention to the questions of what constitutes individualised state-of-the-art medical care, where might standardisation be reasonable from the point of view of physicians and patients (see chapter


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1), and in which areas do other methods grounded in evidence based medicine have to be applied in order to ensure high-quality medical care that is targeted at individual cases. Thereby, the different conceptual features become the focus of attention in the development of standards, on the one hand, and clinical practice guidelines on the other (see chapter 2). Among other things it is essential for a discussion of standardisation proposals in medicine that regulations regarding healthcare services are exempt from the Treaties of the European Union regarding enhanced cooperation (see chapter 3).

Healthcare services must be regarded as fundamentally complex interventions. Accordingly, internationally as well as nationally, quality assurance relies on the principle of evidence based medicine and on clinical practice guidelines. Directives are not examined more closely in this statement. The primary objective of clinical practice guidelines is to safeguard medical care, always based on the current state of the art. The recommendatory nature of clinical practice guidelines takes into account, on the one hand, the physician's duty to treat patients according to the accepted state of medical knowledge as well as, on the other hand, the patients' right of self-determination when medical procedures are to be administered. Accordingly, quality assurance and health care based on evidence based clinical practice guidelines are established by law in Germany.

In contrast, attempts to subject healthcare services to standardisation are foreign to their nature. This is evident in the standard EN 16372 "Aesthetic surgery services" enacted in the middle of the year 2014 by the European Committee for Standardisation (Comité Européen de Normalisation, CEN).

The present statement is intended to complement other statements that have already been published (see selection of references at the end of the statement) by examining the problem of standardisation of healthcare services pursued at the European level predominantly from a scientific medical point of view. With this the protagonists at the national and European level are provided with additional supporting arguments regarding the evaluation of attempts at standardisation in the public health sector.

## 1. Introduction

Medicine is more than a science; this is not just a truism but may also be regarded as an established fact by now. Thus additional methods are used in medicine compared to the exact sciences, for example qualitative studies (see here among others the Guiding Principles on Health Policy of the Medical Community, "Ulm Document", 2008, p. 4). According to a definition by Klaus Dietrich Bock, medicine is "an applied and performative science, choosing methods and theories used in other sciences, such as chemistry, physics, biology, psychology and social sciences, with respect to their usefulness for diagnosing, treating and preventing diseases. Such methods and theories chosen are then modified and rules are developed empirically for their application in medical research and practice." Thus modern medicine is based both on scientific knowledge and on elements belonging to the humanities, employing science-based methods in the service of the patient and viewing the human being as a bio-psycho-sociocultural being. For this reason, in particular ethical issues must also be considered.

Practicing medicine is a combination of science and the art of healing and, according to Klaus Dieter Bock, consists of four components: (1) one based on manual or technical skills, (2) one based on theories, (3) one based on experience and (4) one relating to the patient, making use of the three components mentioned above. In the latter component he includes making an individual diagnosis as well as drawing up an individualised treatment plan, making recourse to medical expertise. As the "Ulm paper" puts it, "For this, therapeutic freedom is of fundamental, high importance for patients and physicians. Any physician is responsible for his therapy. Together with the patient he decides on the degree to which he will incorporate in his treatment the results of evidence based clinical practice guidelines. External interference in the therapeutic freedom, such as schematic standardisation, will only have a destructive impact on the relationship of trust between the patient and the physician." (Ulm paper, 2008, p. 5).

Practicing medicine is not to be equated with other personal services. The patient is someone suffering and requesting help. He is seeking out the physician with highly private concerns, quite frequently even with life-and-death questions and therefore touching on existential fears. This kind of therapy and attention requires a special kind of relationship of trust which is not reflected likewise in service standards. It also requires decision making processes that take individual patients' needs into consideration as a constitutive element. Service standards do not similarly provide the necessary scope of action adapted to the individual patient although there is certainly the "uno-actu principle" in service economics. This refers to services for which it is absolutely necessary for the provider and the consumer to work together. This also applies to the practicing of medicine which is possible only with the patient present. According to Philipp Herder-Dorneich and Werner Kötz, the direct interaction of provider and consumer, especially in the case of medical services, results in "considerable personal, spatial and sometimes also temporal preferences. This means that a provider cannot be replaced easily by another because an important role is played here by subjective factors such as sympathy and antipathy, a particular relationship of trust and the like". These subjective factors prevail on both sides in the relationship between physician and patient.

In the field of direct patient care, standardisation of healthcare services would therefore be a new approach and would lead to replacing gradually or completely the individuality of patient and physician by abstract expertise. However, the latter's applicability in turn depends on the question what kind of knowledge was entered into this system in the first place. As Christoph Rehm says, "Only by evaluating again the diagnostic 'suggestions' of an expert system with regard to their degree of reality and validity in view of the specific sick person does the physician's indispensable task of judgement recommence. It is indispensable because the therapy or at least the determination of a therapy is to be derived from the diagnosis and is the physician's task."

### 1.1 Individualised Medicine

Physicians have an individual-specific task covering diagnosis as well as therapy, prevention and follow-up care. When medical literature refers to individualised medicine today usually a distinction is made between a more person-oriented and a more technically oriented variant. According to Bircher and Wehkamp, "Person-oriented medicine primarily relies on medical knowledge and skill for diagnosis and therapy, whereas technically oriented medicine predominantly offers the services of the highly developed areas of laboratory diagnostics, medical imaging and surgical interventions." Both kinds of individualised

medicine have their merits; and, as surveys have shown, patients want both of them. Among others, an international survey[1] involving over 10,000 patients suffering from rheumatoid arthritis has shown that patients profit from individualised therapy plans. According to this, those patients who had drawn up a therapy plan together with their physician assessed their present state of health markedly more positively than those who had not. Patients with such a plan answered an inquiry into their state of health twice as frequently with "hopeful" (27 % vs. 13 %) and "confident" (41 % vs. 21 %) than those patients without an individualised therapy plan. Another study of women with breast cancer[2] could also point out the fact that the persons affected expect from their therapist personalised, specialised and modern (based on the current state of the art) therapy, assistance and support during their illness.

Individualised diagnostics and therapy are oriented towards the following assumptions. In particular, they assume that

- the circumstances of each patient in regard to aetiology, the course of disease and recovery and prognosis, respectively, are distinctly individual,
- the participation of the patient in the process of recovery is indispensable,
- there is a special, trusting and personal relationship between physician and patient which influences adherence, and
- diagnostics and therapy must always be a decision addressed to an individual person.

In spite of the observation that today's patients demand individualised treatment more vehemently than in the past, we must still bear in mind the risk of a "pattern therapy" which has already been pointed out 100 years ago by Ernst Schweninger (1850–1924), the personal physician of Bismarck.

## 1.2 Evidence Based Medicine as the Base of Recommendations in Medicine

In modern medicine, recommendations should be based on scientific investigations (external evidence) and be given by taking into account the physicians' clinical expertise (internal evidence). The patients' point of view must always be integrated as the third component of a recommendation. In pursuing this objective, patient-oriented outcome parameters are meanwhile increasingly being considered in clinical trials.

Standardisation of healthcare services is usually the opposite of a physician's genuine medical activity which consists both in the art of making a diagnosis and in the drawing up of a personalised therapy plan. A patient is regarded as a case belonging to a collective of "uniformly" sick persons for whom the standard in question (e. g. in the field of aesthetic surgery) has been developed. Such an approach is ultimately based on a purely human biological and stochastically oriented science which abstracts from and therefore widely ignores a physician's experiential knowledge as well as the circumstances of the patient. One of the "fathers" of evidence based medicine (EBM), David L. Sackett, has cautioned against this: "Evidence based medicine is not 'cookbook' medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus whether it should be applied. Clinicians who fear top down cookbooks will find the advocates of evidence based medicine joining them at the barricades." This is why evidence based clinical practice guidelines that have become increasingly mature and differentiated over the past years are also to be understood as a diagnostic and treatment corridor that takes into account the individual circumstances and the physician's assessment.

## 1.3 Increasing Demand for Quality in Medical Care

Undoubtedly, there is an increasing and justified demand for quality in medical care. For this, provisions are made and implemented to measure quality in various areas. Directives, guidelines, recommendations, treatment pathways, norms[3] and standards are intended to serve this approach.

As far as quality management is done according to KTQ[4] or ISO standards, the term standard refers to the practice of quality management. Overall, the certification of a hospital according to ISO standards includes the adherence to a system of regulations for quality management, describing the in-house standards of the hospital, but does not involve standardisation of practicing medicine.

Contrary to the subsidiarity principle in regard to healthcare services in the EU (see chapter 3), attempts are being made to implement standardisation under the guise of "quality standards", e. g. in the context of the "cross border patient health care". This approach carries the danger of connecting "standardisation" with the terms "quality management" and "quality standards". Thus there is the risk of not perceiving clearly that standardisation ultimately determines which measures in the physician-patient relationship are controlled externally and in what way.

## 1.4 Sectors in Medicine Where Standardisation Has Proved of Value

Standardisation resulting from unification of diverse procedures or requirements of a product in a formalised process is reasonable in medicine and promotes patient safety and quality of health services, provided that this concerns medical-technical services such as laboratory medicine or procedures in the production of medical devices, sterilisation procedures and requirements of medical-technical equipment and of air conditioning systems, among other things. The uniformity of the procedures to determine laboratory values which is achieved by standardisation makes a comparison of laboratory values possible even if they were determined in different laboratories. In this context standardisation can contribute to patient safety. However, the interpretation of the laboratory values is based on competence and depends on the

[1] AbbVie Deutschland GmbH & Co. KG. Press information „Mehr Aufklärung und engere Zusammenarbeit von Arzt und Patient nötig", Madrid 2013.
[2] Kreienberg R, Möbus V, Jonat W, Kühn T: Mammakarzinom interdisziplinär. 4th ed. Springer Verlag, Berlin, Heidelberg, New York 2010, p. 265
[3] This term refers to a well-defined approach which admittedly does not meet the demands made on a standard. However, the term "norm" is used simultaneously also in the way of the Anglo-American scientific literature, i.e. synonymously with "standard".
[4] Certification procedures of the Cooperation for Transparency and Quality in Healthcare [*Kooperation für Transparenz und Qualität im Gesundheitswesen*].

physician, his experiential knowledge and the reference to the specific patient; thus it inherently defies standardisation. This example illustrates well the possibilities and limitations of standardisation: The strong points of standards are their abstract universal specifications, whereas their limits are reached every time information or specifications have to be interpreted and assessed individually.

Standardisation is also a prerequisite for obtaining meaningful epidemiological analyses from data generated in the context of routine diagnostics. For example, data generated with the help of standardised procedures allow statements on the development of anti-microbial resistance in Europe and are incorporated in the corresponding publications of the European Centre for Disease Prevention and Control (ECDC). Standardisation is also indispensable in the context of fighting the spread of epidemics up to pandemics because uniform protocols for isolation of a pathogen and its characterisation are an essential prerequisite for a good data base, thus permitting to make reliable epidemiologic analyses.

## 1.5 The Terms: Clinical Practice Guideline, Standard, Standardisation

Scientific clinical practice guidelines are systematically developed decision making aids concerning appropriate procedures for specific diagnostic and therapeutic problems. Physicians are given some leeway for decision making and a "corridor of action" which can also be deviated from in justified individual cases. They provide the critical appraisal of the best evidence available in the form of a clinical recommendation that has been differently verified and therefore weighted. It is prepared by a multidisciplinary group of experts according to a predefined procedure, making transparent any potential conflict of interest. The results are published with a predefined expiration of the validity (AWMF Guidance Manual and Rules for Guideline Development). The development process is documented in a guideline report.

Standards lay down technical or quality-related specifications. Their content is based on the verified results of science, technology and experience and takes into account economic circumstances. They represent private technical regulations with a recommendatory nature[5] that must be observed, at first voluntarily, in regard of goods, production processes or services. However, standards can lose their voluntariness and become binding, in particular by going into legal effect.

It is the objective of the standard to unify different procedural methods and the requirements for a product[6], respectively. This facilitates the exchangeability of industrial products as well as compliance with certain safety and quality standards that are laid down centrally. Standards are developed in a formalised process by private organisations such as the German Institute for Standardisation (Deutsches Institut für Normung, DIN) or the European Committee for Standardisation (Comité Européen de Normalisation, CEN). Standardisation shall take into account scientific findings, experience as well as technical feasibility. The result of standardisation or rather the process of standardisation is the standard. It is the objective of a standard to unify procedures; therefore an exact description of the procedure is a constituent part of a standard. A standard contains neither consulted references nor its assessment derived from the strength of evidence. At the European level an additional objective of standardisation is to promote the exchange of goods and services and to reduce trade barriers. The elaborations prepared by these private national or European institutions are regarded as voluntary recommendations after they have been adopted by all countries involved. Thereafter the standards are made available by the above-mentioned institutions or organisations against reimbursement of expenses.

In particular because of the methodology used in developing the two systems of regulations there is a risk of contradiction between a guideline and a standard. This is because the group consensus on a wording agreed upon represents the essential basis for the recommendation in the case of a standard, whereas in the case of a guideline a systematic appraisal of the literature (external evidence) combined with clinicians' experiential knowledge present in the group developing the guideline (internal evidence) forms the basis of the recommendation.

### 1.5.1 Excursion: Legal Effects of Clinical Practice Guidelines and Standards

Standards in terms of the above definition are not inherently binding. However, they become legally relevant in particular when they are referred to, e. g. in contracts, in legislation by the legislative body or in the interpretation of vague legal terms. Therefore a standard or a guideline might sometimes be referred to when interpreting for example the vague legal term "due diligence".

A clinical practice guideline is not inherently binding either. Clinical practice guidelines, in particular S3 treatment guidelines, reflect the state of medical knowledge at a specific point in time. It does not follow that they represent the norm under liability law in each case. However, they "have – depending on the quality of method – to a greater or lesser degree indicative importance for the required medical standard and thus for the assessment of the required diligence in the concrete case. Their adherence indicates a dutiful conduct."[7] Nevertheless, a guideline does not replace an examination by experts on a case-by-case basis, in particular not in a liability action.

There is more recent case law with regard to the clinical practice guidelines' importance under liability law; among other things it is oriented towards the notion that guidelines help define a standard in a liability process but may not indiscriminately be equated with it.[8] Thus clinical practice guidelines do not determine constitutively the required standard. They are for information purposes only and do not represent a binding direction for action for the attending physician.[9]

## 2. Differences in Concept, Intention and Methodology between Standards and Clinical Practice Guidelines

The fundamental differences in concept between standards and clinical practice guidelines are reflected already in their internationally applicable definitions (see insert).

[5] German Federal Court of Justice (BGH), Neue Juristische Wochenschrift (NJW) 1998, 2814 (2815); NJW 2007, 2983 (2985)

[6] Excerpt from the statutes of DIN: "The results of DIN's work serve to advance innovation, safety and communication among industry, research organizations, the public sector and society as a whole, and to support quality assurance, rationalization, occupational health and safety, and environmental and consumer protection." Available at: http://www.din.de/blob/66170/8bb71770582cb181130e4250d5c08dc2/din-satzung-en-data.pdf

[7] Deutsch/Spickhoff, Medizinrecht, 7th ed., margin number 372 and further reference

[8] BGH, decision of March 28, 2008, file no.: VI ZR 57/07; BGH, judgement of April 15, 2014, file no.: VI ZR 382/12

[9] Higher Regional Court (OLG) Saxony-Anhalt, judgement of July 11, 2006, file no.: 1 U 1/06

A standard is

a **normative document, developed according to consensus procedures,** [...] that provides requirements, specifications, guidelines or characteristics **that can be used consistently** [...]

International Organization for Standardisation (ISO). What is a standard? (available at: http://www.iso.org/iso/home/standards.htm)

Guidelines are

**systematically developed** statements **to assist** physicians and, if necessary, other healthcare professionals and patients with **decisions** about appropriate health care in specific clinical circumstances [...] [...] **recommendations** [...] that are **informed by a systematic review of evidence** and an assessment of the benefits and harms of alternative care options.

Institute of Medicine (2011). Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press

In addition, the existing systems of regulations for developing clinical practice guidelines, on the one hand, and for developing standards on the other show also substantial differences, despite some similarities with regard to relevant aspects and requirements.

The following statements are based in particular on the systems of regulations valid and relevant, respectively, for standardisation activities and guideline work (DIN 820-Series of Standards by the German Institute for Standardisation and the system of regulations "Clinical Practice Guidelines" by the Association of the Scientific Medical Societies (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF).

### 2.1.1 Area of Application

| Standards | Clinical Practice Guidelines |
|---|---|
| Preferably international | Preferably national – but also international – taking into account specific features of the system. |

Basically, a standard enacted at the CEN level (EN standard) is valid in all of the CEN member countries. Minimum standards are defined in part by establishing service standards. National standards deviating from EN standards are to be withdrawn. As a rule, an EN standard must be published as a national standard by the German Institute for Standardisation (DIN-EN standard) within six months.

To apply EN standards in the particular sector of practicing medicine/providing healthcare services is fundamentally questionable in view of the individual care for patients. Internationally valid standards defining minimum standards for healthcare services do not lead to better healthcare in countries such as Germany where, as a rule, high quality standards in the medical sector are guaranteed as a result of statutory regulations, ordinances, guidelines etc. Instead they carry the danger of a reduction in quality, on the one hand, and increased legal uncertainty on the other. Moreover the application of standards for medical services is not possible or only possible to a limited extent in these countries because often (as is the case in Germany) the laws, ordinances, statutes etc. regulating the sector of medical services take precedence over the application of standards. Accordingly, the EN standard 16372 on Aesthetic Surgery Services that was adopted in the middle of the year 2014 contains numerous regulations that may not be applied in Germany due to overriding statutory regulations, ordinances/statutes etc.

In comparison, according to the principle "Evidence-Based Decision Making: Global Evidence, Local Decisions", clinical practice guidelines shall be examined on principle with regard to their adaptability in differently structured healthcare systems and, if necessary, be adapted. This has already been the case with the European clinical practice guidelines that were developed by different expert groups.

### 2.1.2 Objectives and Purpose

| Standards | Clinical Practice Guidelines |
|---|---|
| Formulation of requirements on the usual, technically proper course of action and the expediency of the services, respectively. (conformity) | Formulation of recommendations and decision making aids for physicians and patients regarding the diagnostic and therapeutic procedure in individual cases. (individuality) |

Norms serve the setting of uniform standards that shall show as few deviations as possible in their application. According to DIN EN 45020, a service standard is a norm establishing requirements to be met by a service in order to safeguard the expediency of the service. Application of (DIN-EN-ISO) standards is indeed essentially on a voluntary basis, but by becoming incorporated in stipulations (e. g. service contracts) or by quoting standards in legal references their application may become mandatory (see DIN SPEC 77226 "Interfaces between service legislation and standards – Guidelines for standardisation").

By definition, clinical practice guidelines are merely decision making aids. They represent a broad evidence based knowledge base the applicability of which must always be considered in individual situations. Regarding legal issues a guideline thus cannot replace an examination by experts on a case-by-case basis.[10] This is in line with the patients' right of self-determination in the administration of medical procedures and ensures medical services based on participatory decision making.

### 2.1.3 Development Prompted by

| Standards | Clinical Practice Guidelines |
|---|---|
| Requirements of the market; core criterion: economic benefit. | Room for improvement in patient care, information needs; core criteria: Optimisation of patient care, knowledge transfer, quality assurance. |

The crucial factor for developing a standard is its market relevance which means a benefit associated with the standard for the stakeholders involved (e. g. companies and consumers/patients).

In contrast, the development of clinical practice guidelines is initiated following the determination of room for improvement in patient care and/or when there is need for knowledge transfer in the case of innovations. It takes into account the interests of patients and the general public.

[10] BGH, decision of March 28, 2008, file no.: VI ZR 57/07; BGH, judgement of April 15, 2014, file no.: VI ZR 382/12

### 2.1.4 Representativeness, Involvement of Stakeholders

| Standards | Clinical Practice Guidelines |
|---|---|
| Stakeholders, including industry, shall be represented in reasonable proportion to each other. | The involvement of all stakeholders shall be ensured; direct participation of industry is not permitted. |

The development or rather assistance in developing of national and international standards is carried out by the working committees of the standards committees of the national institutes for standardisation (in Germany the DIN). The standards committees as well as the working committees are formed by the so-called stakeholders. These include in particular the companies, organisations, experts and consumer groups that are affected by the standard in question.

The respective standards working committees themselves determine their precise composition. The stakeholders' involvement happens more or less randomly which is inherent in the system. Thus there is a risk of manipulation. In comparison, the composition of the clinical practice guidelines groups must follow explicitly the principle of representativeness in regard to the target groups and key affected groups, respectively. Implementation is not left to these groups alone; instead, representatives of the target users (groups of professionals who are to implement the recommendations) and of the targeted group of patients (persons for whom the guidelines are intended and to whom they shall apply) are involved in the development of guidelines at an early stage. In addition, it is recommended to involve independent experts in methods and facilitators, respectively. In contrast to standardisation proposals, direct participation of industry representatives in guideline work is explicitly prohibited due to possible conflicts of interest.

### 2.1.5 Contents Are Based on

| Standards | Clinical Practice Guidelines |
|---|---|
| Current state of the art of science and technology. | Evidence base: independent systematic literature search, selection and appraisal. |

Standards should be based on verified results of science, technology and experience and be aimed at promoting optimum benefits for society. For this, no systematic procedure is prescribed.

In contrast, clinical practice guidelines should be based on the systematic processing of the best knowledge available from controlled clinical trials and on the experience of experts and patients.

### 2.1.6 Decision making Process

| Standards | Clinical Practice Guidelines |
|---|---|
| Use of unspecified methods for achieving consensus.<br>No provision for expressing dissent. | Use of methods for achieving consensus that are (demonstrably) suitable for avoiding bias.<br>Declaration of the strength of consensus and of reasonable dissent, both in terms of individual details and as a whole. |

The stakeholders together perform by consensus the unification of goods including intangible ones (e. g. services) that is aimed at by standardisation. No details are given on the manner of the process to achieve consensus. The term "consensus" is defined as follows in the DIN EN 45020: "General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments." Consensus need not necessarily imply unanimity in this context; however, dissenting opinions are not published.

In contrast, in developing clinical practice guidelines clear and strictly formalised consensus processes are used that are suitable for avoiding bias due to particular interests or group dynamic processes; their suitability has been demonstrated empirically. There is no pressure for universal agreement. Ultimately, the strength of consensus (number of agreeing vs. number of voting participants) as well as scientifically justified dissent are presented and published. In case a scientific publication is intended in a scientific journal, it will be subjected to another independent review.

### 2.1.7 Transparency

| Standards | Clinical Practice Guidelines |
|---|---|
| Poor<br>The process of developing a standard is only transparent to the public to a limited extent (during each of the temporary opportunities to comment). | High<br>The process of developing a guideline is made publicly available (e. g. by "Clinical Practice Guideline Reports"). |

The concrete process of developing a standard is generally not transparent to the interested public – or only to a limited extent – because of the confidentiality applied on the work of standards committees. The deliberations of the standards committees are not open to the public; and the stakeholders and relevant parties involved in developing the standard in question are not disclosed.

In contrast, the presence of a guideline report is obligatory for each clinical practice guideline. Thus the development process becomes reproducible and optimum transparency is provided. The persons involved in the development are identified, and their conflicts of interest are disclosed and the way of how these are handled.

### 2.1.8 Editorial Independence

| Standards | Clinical Practice Guidelines |
|---|---|
| No regulation of how conflicts of interest are handled.<br>Third parties not precluded from exerting financial influence. | Regulated and transparent way of dealing with conflicts of interest.<br>Influence by third parties via financial means ruled out. |

Conflicts of interest are inherent in the system when developing a standard because representatives of industry, for example, are involved in setting a standard. In addition, all stakeholders are directly drawn upon by the DIN for funding the offices of the standards committees. This is to be done primarily through subsidies. A contribution is collected from those stakeholders involved in standards committees who grant no or insufficient subsidies.

Government grants are each earmarked (for individual standardisation proposals). The DIN finances around three-quarters of its budget by its own earnings, essentially by royalties from selling standards but also by membership fees (5 %).

When financing guideline proposals, attention is paid to the safeguarding of editorial independence. Usually financing is done by fees paid by the professional associations involved, by organisations that are non-profit associations themselves as well as partly by independent foundations or public sponsors that are not guided by economic interests. Direct financing by industry, e. g. in the case of clinical practice guidelines regarding drugs, is precluded. All representatives of the affected professional circles and the public concerned are involved directly and indirectly in developing guidelines, e. g. by expert hearings, which makes a reconciliation of interests possible.

Clinical practice guidelines that contain conflicts of interest with regard to financing are not incorporated in the AWMF register, for example. Neither are those where the conflicts of interest of some participants lack transparency. Financing by sales does not apply because guidelines are freely available in the interest of the public (see 2.1.9).

### 2.1.9 Accessibility

| Standards | Clinical Practice Guidelines |
|---|---|
| Limited, because fee required – only accessible for free in a few places for display. | Unrestricted access on the Internet free of charge. |

Standards and draft standards must be purchased (see comments on this under running no. 2.1.8 [Editorial Independence]). In addition, it is possible to inspect DIN standards and draft standards for free (neither print-out nor digital copies possible) only in 116 (as of 2015) places for display of DIN standards (www.beuth.de/de/rubrik/auslegestellen).

After prior registration it is also temporarily possible to inspect draft standards versions free of charge for the purpose of commenting on the respective draft version (www.beuth.de/de/rubrik/auslegestellen). Here, too, it is prohibited to make a hard copy or a digital copy of the inspected documents.

Usually guidelines are available on the Internet free of charge together with any associated documents (e. g. long version, short version, guideline report, evidence report and patients' version).

## 2.2 Comparative Overview

| | | Standards | Clinical Practice Guidelines |
|---|---|---|---|
| 1. | Area of application | Preferably international | Preferably national – but also international – taking into account specific features of the system. |
| 2. | Objectives and purpose | Formulation of requirements on the usual, technically proper course of action and the expediency of the services, respectively. (conformity) | Formulation of recommendations and decision making aids for physicians and patients regarding the diagnostic and therapeutic procedure in individual cases. (individuality) |
| 3. | Development prompted by | Requirements of the market; core criterion: economic benefit. | Room for improvement in patient care, information needs; core criteria: Optimisation of patient care, knowledge transfer, quality assurance. |
| 4. | Representativeness, involvement of stakeholders | Stakeholders, including industry, shall be represented in reasonable proportion to each other. | The involvement of all stakeholders shall be ensured; direct participation of industry is not permitted. |
| 5. | Contents are based on | Current state of the art of science and technology. | Evidence base: independent systematic literature search, selection and appraisal. |
| 6. | Decision making process | Use of unspecified methods for achieving consensus. No provision for expressing dissent. | Use of methods for achieving consensus that are (demonstrably) suitable for avoiding bias. Declaration of the strength of consensus and of reasonable dissent, both in terms of individual details and as a whole. |
| 7. | Transparency | Poor The process of developing a standard is only transparent to the public to a limited extent (during each of the temporary opportunities to comment). | High The process of developing a guideline is made publicly available (e. g. by "Clinical Practice Guideline Reports"). |
| 8. | Editorial independence | No regulation of how conflicts of interest are handled. Third parties not precluded from exerting financial influence. | Regulated and transparent way of dealing with conflicts of interest. Influence by third parties via financial means ruled out. |
| 9. | Accessibility | Limited, because fee required – only accessible for free in a few places for display. | Unrestricted access on the Internet free of charge. |

## 3. Basic Questions of Legitimacy – Interventions in Concerns of Corporate Self-governance

The European standard "Aesthetic Surgery Services" that has already been referred to in the beginning defines requirements for the practice of aesthetic surgery. This applies to services in aesthetic surgery. The European standard in question gives recommendations on the general conditions regarding standardisation and other matters. This includes the ethical framework and general principles according to which clinical services are provided by all general practitioners as well as other physicians specialised in the field of aesthetic surgery. These recommendations apply before, during and after the procedure. Among other things, reconstructive surgery procedures are excluded from the scope of this standard. Therefore it is a case of a standardisation process driven by interests, with the purpose of defining limits and thus for the benefit of one professional group.

Incidentally, in the healthcare services sector there is no legal loophole which would have to be filled by an European standard, because the laws, regulations and other statutory provisions of the member state where the patient will be treated are valid. Furthermore, it is not the purpose of the association CEN to develop a standard, for instance for the aesthetic surgery sector, because there are no "barriers to trade" that would have to be removed. Measures to increase patient safety do not fall within the competence of CEN.

Such standards are merely in the nature of recommendations and therefore have no direct legally binding effect. Standards may not infringe upon national laws and regulations. They may become binding through the national legislative and regulatory authority by referring to them in laws, regulations and administrative provisions or through contracts in which compliance with them was agreed. This legally binding effect is the declared goal of CEN: "In addition, many standards are developed to support European legislation. 'Reference to standards' within a legislative text is viewed as a more effective means of ensuring that products meet the essential health and safety requirements of legislation than the writing of detailed laws. This allows both processes to support each other, without causing a slowdown"[11]. The consequences of a legally binding effect of standards are presented as follows, with regard to European as well as national legal aspects.

### 3.1 European Legal Aspects

(a) Standardisation of healthcare services will be in breach of article 168(7) of the Treaty on the Functioning of the European Union (TFUV; Vertrag über die Arbeitsweise der Europäischen Union, AEUV), provided it becomes legally binding. This provision clarifies that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them." The practicing of medicine as well as all systems of regulations concerning the physician's medical activity fall under the management of the health care sector and are thus subject to the responsibility of the member states. Standardisation of the healthcare services results in interfering with the rights of the member states to carry out the organisation of public health care and medical care under their own responsibility. This applies in particular to the determination of the professional qualification of members of the health care professions, but also to the definition of ethical requirements and the rules of professional conduct. Accordingly, healthcare services are excluded from the scope of application of the Directive on Services 2006/123/EG (see also on this [b]). Accordingly, the so-called Directive on the Application of Patients' Rights 2011/24/EU refrains from regulating continuing education, ethical requirements and rules of professional conduct. Among other things, it focusses instead on the provision of information and on questions of reimbursement (see for this [c]). Accordingly, the Directive on the Recognition of Professional Qualifications 2005/36/EG refrains from attempts at harmonising education, training and continuous professional development at the European level; it is based instead on minimum requirements agreed upon among the member states (see for this [d]).

(b) Corresponding to the allocation of competences according to TFUV, healthcare services are precluded from the scope of application of the Directive on Services 2006/123/EC and are not subject to regulation by the EU. Article 26(5) of the Directive on Services that addresses the development of "voluntary European standards" for the improvement of the quality of service provision is thus not applicable to healthcare services. In this connection it is not a question of whether the respective healthcare service serves to protect and restore health but a question of whether it is a medical practice which is reserved in Germany in particular to physicians legally qualified to practise medicine. The Federal Administrative Court has consistently defined medical practice very broadly as distinct from cosmetic treatment but including cosmetic surgery the performance of which itself does not call for medical knowledge. However, the question of whether the intervention may be undertaken in the individual case does indeed require medical diagnostic knowledge to avoid any health risks posed by the intervention. In this way interventions in healthy persons are certainly also included, with the result that these are not subject to the Directive on Services, either.[12]

(c) Corresponding to the allocation of competences according to TFUV, the so-called Directive on the Application of Patients' Rights 2011/24/EU recognises "common values and principles in the European Union Health Systems" that are "necessary to ensure patients' trust in cross-border healthcare". In spite of some draft versions in the course of the legislative process, however, the Directive on Patients' Rights does not contain stipulations on which standardisation can be based. Instead, the directive 2011/24/EU clarifies in article 4(1)b that "healthcare shall be provided in accordance with: […] standards and guidelines on quality and safety laid down" by the member states.

(d) Corresponding to the allocation of competences according to TFUV, there are also no harmonised stipulations in the Directive on the Recognition of Professional Qualifications 2005/36/EC on the curriculum of the basic medical training and the specialised medical training. The directive is based on a system of coordinated minimum requirements and, on this basis, has established the system of automatic recognition of professional qualifications. Unification by European standards is incompatible with this system.

(e) Although article 10 of the Regulation on European Standardisation (EU) No 1025/2012 authorises the European Commission to request European standardisation organisations to draft European standards for services, according to recital 12 the distribution of competences is to be respected in this connection between the European Union and the member states as laid down in the TFEU, including the rule on competence according to Article 168(7). As illustrated under (a), the respective competence lies with the member states.

(f) CEN itself has recognised the distribution of competences between the European Union and the member states and has made a commitment accordingly in CEN Guide 15: "European standards shall not cover those subjects that clearly belong to the domain of regulation of the Member States, under the principle of subsidiarity, unless this is explicitly supported by the national authority."[13] The question is whether currently CEN feels bound to this commitment.

[11] "Making European Standards", http://www.cencenelec.eu/news/publications/Publications/MakingEuropeanStandards.pdf

[12] see Statement of the German Medical Association in the context of evaluating the Directive on Services – consultation of stakeholders, October 2010, available at: https://circabc.europa.eu/d/d/workspace/SpacesStore/91ffbcb9–6eb6–4c7a-967a-1619acaad119/Fed%20Medical%20Assoc._DE.pdf

[13] CEN Guide 15, Guidance document for the development of service standards: Version dated 2012–02–01, 5.2, page 13, http://boss.cen.eu/ref/CEN_15.pdf

(g) In terms of European harmonisation processes, however, clinical practice guidelines also based on evidence are meanwhile being developed supranationally and adapted at the national level, or national evidence based clinical practice guidelines are raised to the European level and achieve supranational consensus. This helps improve the patients' cross border health care as well as exchange of knowledge and cooperation of the medical community in the different countries themselves. This process is – in contrast to standardisation – the adequate response to the demand for high-quality medical care in the European Union geared to the individual needs of the patient, which also increases patient safety. In contrast, international standardisation of services regularly encounters its limits in defining qualification, compentency and education, because there are a multitude of regulations and legal framework conditions in the respective countries, in particular in regard to the sectors of health, social issues and education.

## 3.2 National Aspects

Regulation of the practice of a profession, including professional duties and continuing education, are reserved to federal state law in Germany. The relevant legal foundation is formed by the different laws on health professionals and on medical associations of the federal states that were adopted by the parliaments of the federal states. The relevant laws authorise the chambers of physicians among other things to pass statutes such as the professional code of conduct or the speciality training regulations. For example, the speciality training regulations govern in particular the manner, the curriculum and the duration of the training and determine specific curriculum contents. In doing so, the chambers of physicians as corporations under public law are subject to the legal supervision of the federal states.

In this respect the standardisation of rules governing professional practice by means of European standards infringes upon the regulatory power reserved to the federal states in Germany that has been "delegated" accordingly to the chambers of physicians. In this way standards would be set in the area of professional practice of health professionals by standardisation committees that have no authority in Germany, have neither the required competence regarding the law governing the profession nor the professional expertise and are also not subject to (federal) supervision, in contrast to the chambers of physicians.

## 4. Conclusion and Outlook

The juxtaposition (see chapter 2) of the differences between clinical practice guidelines, on the one hand, and standards on the other demonstrates that in the field of healthcare services, in particular regarding a physician's genuine medical activity, standards are neither a necessary nor a suitable tool for ensuring or improving the quality of the service provision.

In reference to the unique physician-patient relationship as well as the therapeutic freedom of the physician (see chapter 1) based on evidence based medicine, the CEN does, in fact, emphasise the recommendatory nature of standards. However, deliberately departing from or watering down abstract universal standards leads to the questionable outcome of lending standards in the healthcare services sector the character of clinical practice guidelines. There is no evidence base for such an amalgamation of methods. Therefore, this is not applicable for patient care. Standardisation in this sensitive field leads instead to legal uncertainty and considerable friction with national regulations governing the profession and with liability law, among other things. At the European level, standardisation of healthcare services infringes upon the principle of preserving the autonomy of the member states in charting their healthcare policy as well as in organising public health service and medical care (see chapter 3).

In summary, it should be noted that standardisation should be applied in areas where abstract, universal and more technical provisions are to be developed (see chapter 1.4). In those cases, however, where information or specifications have to be interpreted and evaluated on an individual basis, standardisation is not a suitable regulatory instrument. This is one more reason to strongly object to standardisation in the healthcare services sector.

In contrast, there are promising efforts underway for developing supranational clinical practice guidelines in addition to national clinical practice guideline processes. These efforts should be further strengthened and supported by policy.

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### MEMBERS OF THE WORKING GROUP

Prof. Dr. med. Harald Gollnick
Director of the University Clinic for Dermatology and Venerology of the Otto von Guericke University Magdeburg
Member of Scientific Advisory Board of the German Medical Association

Dr. med. Günther Jonitz
President of the Berlin Chamber of Physicians
Member of the Executive Board of the German Medical Association

Prof. Dr. phil. Robert Jütte (central coordinator)
Director of the Institute for the History of Medicine, Robert Bosch Foundation
Executive Member of the Scientific Advisory Board of the German Medical Association

Prof. Dr. med. Rolf Kreienberg
Former Medical Director of the University Gynaecological Hospital Ulm
President of the AWMF
Executive Member of the Scientific Advisory Board of the German Medical Association

Prof. Dr. med. Reinhard Marre
Former Executive Medical Director of the University Hospital Ulm
Member of the Scientific Advisory Board of the German Medical Association

Prof. Dr. med. Frank Ulrich Montgomery
President of the German Medical Association and of the German Medical Assembly
President of the Hamburg Chamber of Physicians

Executive Prof. Dr. med. Peter Neuhaus
Former Director of the Department for General, Visceral and Transplantation Surgery of the Charité – Universitätsmedizin Berlin
Member of the Scientific Advisory Board of the German Medical Association

Prof. Dr. med. habil. Jan Schulze
President of the Saxon State Chambers of Physicians
Member of the Executive Board of the German Medical Association

Prof. Dr. med. Dr. h. c. Peter C. Scriba
Chairman of the Scientific Advisory Board of the German Medical Association
Former Director of the Inner City Hospital of the Ludwig-Maximilians-University Munich

Prof. Dr. med. Dr. med. dent. Wilfried Wagner
Vice President of the AWMF
Director of the Clinic for Oral and Maxillofacial Surgery of the University Medical Center Mainz

### GUESTS OF THE WORKING GROUP

Diplom-Soziologin Sonja Barth
Personal Aide of the President of the Berlin Chamber of Physicians

Dipl. rer. soc. Manfred Brüggemann
Consultant in the Department Quality Management, Quality Assurance and Patient Safety of the German Medical Association

Alexander Golfier, MBA
Consultant in the Department Quality Management, Quality Assurance and Patient Safety of the German Medical Association

Dr. jur. Marlis Hübner
Head of the Legal Department of the German Medical Association

Ass. jur. Anja Lehmann
Consultant of the Legal Department of the German Medical Association

Annabel Seebohm, LL.M., solicitor
Head of the Brussels Office of the German Medical Association

Ass. jur. Michael Schulte Westenberg
Managing Director of the Saxon State Chambers of Physicians

### EXTERNAL EXPERT

Prof. Dr. med. Ina B. Kopp
Head of the AWMF Institute for the Management of Medical Knowledge
c/o Philipps-Universität Marburg

### MANAGEMENT

Department Science, Research and Ethics
German Medical Association
Herbert-Lewin-Platz 1, 10623 Berlin, Germany
E-Mail: dezernat6@baek.de


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