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# Criteria to Assess Independence in Continuing Medical Education (CME): Independence through Competence and Transparency

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## ABSTRACT

Marburger Bund is the largest doctors' union in Europe representing about 125,000 salaried doctors in Germany and fights for fair working conditions, appropriate salaries, quality in training, and improvements in the work-life balance. Following a decision of 127<sup>th</sup> Marburger Bund General Assembly 2015, criteria should be developed to be applied by participants to assess independence in planning and delivery of individual CME activities. This position paper describes the role of

- methodological and medical competence
- generation and use of data (evidence)
- independent sources of information
- independence of faculty in CME
- language in medical education
- conduct of independent CME, and
- independence of (passive) physician participants in CME

Measures are defined by which independence in CME may be achieved and how this may change the process of CME delivery.

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## KEYWORDS

CME; independence;  
transparency; competence

## Preamble

Lifelong learning for physicians (often referred to as “continuing medical education”) plays a crucial role in maintaining and adapting the quality of medical decisions in an ever-changing environment in which evidence-based medicine needs to accommodate the preferences of the patient and the structure of the health-care system in Germany.

Independence in medical decision-making is **the** crucial prerequisite for our medical identity and credibility and therefore has always been an integral part of the regulations by which the profession is governed [1,2], and has more recently also been addressed in various initiatives of scientific associations and other organisations (e.g.) [3–6].

However, they are not explicit about which medical decisions have to be considered as unduly influenced by economic interests and how this should be avoided in an evidence-based manner.

Marburger Bund has always argued against the dominance of economic determinants in medical decision-making processes, and this expressly includes continuing medical education [7].

Although this document will focus on physician–physician interaction in CME and thus expert training [8,9], it will also present a comprehensive description of the status quo with regard to commercial influences on CME as well as Marburger Bund’s demands for independence in CME.

Suggestions to active and passive participants about how this should translate into the practice of CME should help to support the measures taken by German Medical Association and the Chambers of Physicians in recent years. This refers back to the decision taken by 127<sup>th</sup> Marburger Bund General Assembly [10], by which development of criteria for assessment of independence in CME was to be initiated.

## Background

The “freedom from economic interests”, as demanded by the medical profession [2], in principle refers to all persons or institutions that might have an interest in influencing the healthcare system and in particular physicians’ decision-making behaviour. But in reality, the focus is mostly on relationships between doctors

and the pharmaceutical and/or medical device industry, which exist on many levels (e.g. research, health care, etc.) whether or not intentional.

At the same time, a substantial part of CME takes place under conditions that aim to be (or must be) economically balanced, such as specialist congresses, CME in specialist journals, or on the Internet.

It is not uncommon for industry to be the guarantor of profitability through sponsorship. But even then, care has to be taken to ensure that the primacy of “freedom of CME content from economic interests” is preserved.

With this paper Marburger Bund aims to provide participants with clear and practicable criteria to be used to determine whether independence can be assumed both in the announcement and delivery of individual CME activities. However, the paper will also demonstrate current limitations for such an undertaking and delineate the resulting political demands.

In the following, we will take a position on the following topics under the overarching aspect of “freedom from economic interests”:

- Methodological and medical competence
- Generation and use of data (evidence)
- Independent sources of information
- Independence of faculty in CME
- Language in medical education
- Conduct of independent CME
- Independence of (passive) physician participants in CME

### **Independence through Methodological and Medical Competence**

The ability critically to assess methodology underlying generation of knowledge relevant to medical decision-making is one of the basic requirements for the adequate handling of evidence in such decision-making. However methodological and clinical skills are not regularly coordinated with each other during undergraduate medical training. Thus, the German Science Council has just recently demanded that “the scientific foundation of undergraduate medical training should be implemented in the Medical Licensure Act by defining the teaching of the scientific methodological basis of medicine as an equally important educational objective in medical studies.” [11]

In view of this situation, Marburger Bund demands the consistent and comprehensive integration of methodologically orientated courses into medical studies. This should be accomplished as early and

longitudinally as possible to facilitate further consolidation of knowledge in the clinical part of undergraduate training [12].

Marburger Bund also supports the view of the German Science Council that “teaching scientific competences is of functional importance for quality of care, because future doctors are more than ever dependent on the ability to think and act scientifically and in an evidence-based way in view of the rapid scientific and technological advances in medicine.” [11]

Currently it must be assumed that the majority of participants in CME do not have the necessary methodological competence in judging evidence.

### **In This Context, Marburger Bund Defines as an Assessment Criterion**

*Speakers/authors actively integrate relevant methodological aspects into their presentation.*

### **Independence in Generation and Use of Data (Evidence)**

Clinical research, especially in the field of new pharmaceuticals, is currently dominated by industry-funded studies: In addition to industry-funded pre-licensure research, about 80% of all patients included in head-to-head comparative trials are included in industry-funded studies [13], in which doctors play only a minor role in decisions on study design and conduct as well as data storage and use [14].

Data collected as part of the “early benefit assessment” according to the (German) Pharmaceuticals Market Reorganisation Act (AMNOG) also show that only about 30%–50% of the data generated in clinical studies (related to the medication under review) is made publicly available through channels like congresses or scientific journals [15]. This problem is further aggravated by the finding that only about 50% of all completed clinical studies are published, and the publication rate of studies carried out independently by physicians or academic institutions is no better [16,17].

It should also be kept in mind that in the case of industry-sponsored studies, companies may reserve the right to decide on what to publish, but that independent CME nevertheless requires full availability of all evidence related to a certain topic. Furthermore, all subsequent analyses (e.g. systematic reviews, meta-analyses, CME, etc.) conducted by independent institutions (e.g. Cochrane Collaboration) have the caveat in their statements that previously unpublished data could potentially change the picture significantly.

Complete documentation of unwanted side effects of drugs and medical devices is limited due to the fact that, in contrast to drug approval, there is no equivalent framework for mandatory in-depth documentation of adverse clinical events. Marburger Bund regards the complete transparency of all data collected on a clinical problem with use of scientific methodology as a crucial prerequisite for maintaining the trust of the medical profession in one of the most important areas for the development and maintenance of competence.

### In This Context, Marburger Bund Demands

- (1) In all projects aiming to generate data with (potential) relevance to patient care, and in particular in clinical trials, physicians and/or academic institutions should have the final say in deciding on outcomes and conduct of data collection, as well as storage and further use of data. All physicians involved in such activities should be as independent as possible. However, Marburger Bund is well aware of the fact that the high expectations associated with analysis of “big data” represent another obstacle to implementation of this demand.
- (2) For Marburger Bund, the publication of clinical trial results is governed by the conscientious professional practice of physicians as laid down in the medical professional code. It therefore urges all colleagues involved in such studies to fulfil their professional duties appropriately and for the benefit of their patients and to make all the results of their research publicly available in a timely manner. In this context, Marburger Bund considers as a minimum standard the presentation of the clinical data in the databases of the regulatory authorities in due time after the completion of the study [18].
- (3) Evaluation of clinical studies, which have grown exponentially in number in recent years, and the methodological assessment of their evidence strength, have become increasingly complex. Both exceed the time resources and abilities of the individual physician, as well as that of hospital departments. On the other hand, using study data is indispensable for shared decision-making in the treatment of our patients. Marburger Bund therefore calls on the federal government to decree that all citizens will have the opportunity to have access to the Cochrane Library free of charge [19].
- (4) Marburger Bund continues to urge the federal government to take appropriate measures to strengthen patient protection against adverse

drug reactions (ADR), for example by introducing reporting requirements. Treatment decisions are always based on a risk-benefit assessment. While a proven benefit is generally the basis for the approval of pharmaceuticals, the full extent of ADR only becomes apparent when drugs are used under long-term conditions and/or in patient groups not covered by the approval studies. In contrast to drug approval, there is no equivalent set of rules for ADR that prescribes documentation of clinical data as needed. The pharmaceutical industry must therefore be urged to meet its obligations to publish outcomes data from completed clinical trials in due time in the European Medicines Agency (EMA) database.

Marburger Bund also supports the goals of EU Regulation 2017/745, which aims to improve the long-term safety of medical devices.

Marburger Bund puts emphasis on the fact that for all medical colleagues, there is an obligation under the medical professional code to report adverse drug effects [20].

### In This Context, Marburger Bund Further Defines as Assessment Criteria

- (1) *In their presentations, speakers/authors point out which role doctors have played in the collection and use of data.*
- (2) *Speakers/authors actively integrate the results of additional analyses by independent providers (e.g. meta-analyses, systematic reviews, e.g. the Cochrane Collaboration) into their presentations on a regular basis.*

### Independent Sources of Information

Current data suggest that only a minority of accredited CME events is sponsored [21].

Nevertheless, organisers of important opinion-forming events, e.g. congresses, still receive substantial funding from industry. The same applies to the dependency of many print and digital media on their advertising clients or on the income from reprint orders.

Independent offers (non-sponsored) exist for face-to-face events as well as print and digital media, but may be limited in reach (e.g. CME activities organised by the Chambers of Physicians). In addition, other independent sources of information such as the Cochrane Collaboration, (which is subsidised by the German Government), the Institute for Quality and

Efficiency in Health Care (IQWiG), and the Drug Commission of the German Medical Association (AkdÄ), among others, provide indispensable contributions to medical decision making. Critical to the success of such independent providers, however, is the decision of the medical profession regularly to use their offers.

### In This Context, Marburger Bund Demands

- (1) The German Medical Association should urgently define the scope and content of the disclosure of institutional conflicts of interest, to be presented by providers, as required by the (Model) CME Code [22].
- (2) The German Federal Government should take action to ensure free access to the Cochrane Library for medical professionals (see above), and also that the EMA provides the results of its activities in a timely manner, clearly structured, technically easy to use, and in clinically relevant wording for the purpose of CME. This also applies to institutions such as the IQWiG, the Cochrane Collaboration and the AkdÄ [23].

### In This Context, Marburger Bund Further Defines as Assessment Criteria

- (1) *CME providers disclose their financial structure to the participants as part of their institutional declaration of interests.*
- (2) *The information from independent providers is regularly and actively integrated into presentations by speakers/authors (see above).*

### Independence of Faculty in CME

Since CME is ideally a physician-to-physician interaction [8,9], the role of the speaker/author is of special importance. They must not only provide transfer of information, but at the same time they must also make suggestions for the critical evaluation of the available evidence and give evidence-based recommendations. The latter can include third party recommendations (e.g. guidelines), but can also be based on subjective expertise (“expert opinions”). In all these actions they are under professional legal obligation and bear undivided responsibility for practising their profession conscientiously [1].

At times when, for example,

- the large majority of treatment studies are financed by industry [13] and the economisation

of medicine forces doctors more and more into economic discussions [24], contacts between doctors and industry and thus also to sponsors of CME occur on a regular basis and are to a large extent unavoidable;

- almost all areas of social life are subject to the concept of competition (and this does not exclude medical research), non-financial interests (e.g. professional career) also substantially gain in importance.

There may often be unresolved conflicts of interest, when organisers of CME are faced with the situation that independent speakers/authors (in the sense of complete freedom of interests) who nevertheless have the required level of expertise, are not available. In this context, creating the highest level of transparency is most important to provide the participant with the accompanying information that he or she absolutely needs for his or her overall assessment. On the other hand, there is still ample opportunity for organisers of CME to implement current recommendations on how to manage conflict of interests, i.e. to minimise third party influence on medical opinion forming (25, e.g. 26).

The opinion of medical experts is becoming increasingly important in the context of medicine, in particular

- in relation to patient care,
- as part of CME and
- for decisions made by the German Joint Committee (G-BA).

For the majority of everyday problems in healthcare, there are often no recommendations available which are based on results from randomised studies, but only on the evidence level of so-called expert opinion. In recent years, guideline authors have increasingly made use of non-evidence-based recommendations [27,28] in order to increase the clinical relevance of the guideline. These recommendations are usually given as so-called expert opinions and are often associated with high grade recommendations. “Expert opinions” therefore also play a major role in the context of CME. However, there is currently no agreed definition of a “medical expert”. Thus, regarding decisions made by the G-BA, there has recently been a critical stance on dealing with “expert knowledge” [29,30].

### In This Context, Marburger Bund Demands

- (1) There is an urgent need to provide a binding definition of the formal and professional

requirements to be fulfilled by a “medical expert”. For this purpose, the medical profession should agree on a transparent process, and a procedure must be defined by doctors to achieve this. Institutions including expert opinions in their decision-making processes should make public based on which criteria experts have been selected and to which extent they have taken influence on their decisions.

- (2) Sponsored CME is subject to several non-coordinated legal regulations, i.e. professional, competition, social, tax, labour, and collective bargaining law. In the application of regulations to partners, attempts are increasingly made to act at the expense of the freedom of medical information. However, complete availability of all relevant data for decision-making in diagnostics and treatment to improve patient health is just as indispensable as their critical weighting in collegial dialogue. Marburger Bund therefore condemns all endeavours and measures which (could) lead to any restrictions (due to primarily economically motivated reasons). This includes
  - withholding of clinical studies with a neutral or negative outcome by the sponsors,
  - all attempts of hospital owners to influence which CME activity may be pursued by their employees,
  - information organised by manufacturers and presented to specially selected groups of doctors,
  - the influence of sponsors on the selection of speakers/authors, CME content, etc.
- (3) Furthermore, Marburger Bund calls on all involved medical professional parties to develop a concept under the leadership of the German Medical Association which, based on primacy of independence of medical information and an unrestricted exchange of medical information, provides a detailed description of the possibilities and limitations of third-party financial support of CME [31,32].

### **In This Context, Marburger Bund Further Defines as Assessment Criteria**

- (1) *Speakers/authors disclose their financial as well as non-financial interests to participants in a comprehensive, timely and sustainable manner (this can currently best be achieved through a consensual publication on the internet).*
- (2) *Organisers of CME have a defined, publicly accessible framework of rules for management of conflicts of interest.*

### **Language in Medical Education**

Language is the crucial tool for conveying and interpreting medical information and thus also the essential means for manipulating opinions and decisions.

To date, the language used by various stakeholders active in this area (e.g. scientific societies, methodologists, legislators) has developed in an uncoordinated manner (e.g. 33-35) and currently does not allow a harmonised translation of different levels of evidence into clinical practice recommendations, which is particularly true for clinical decision-making on the background of moderate to weak levels of evidence. This often results in largely diverse perceptions by CME participants to recommendations about their practice of medicine and thus represents considerable potential for manipulation [36,37] in selection of patients for diagnostic and/or treatment procedures.

Achieving a harmonised approach to language in medicine has further been hampered because for the majority of problems in everyday medical practice, only data of poor quality or even no data from clinical studies are available. However, this on the other hand does not diminish the need for clinical decisions on the background of uncertainty. The irrefutable need for timely clinical decisions and the general human desire for causality [38] have promoted a language that induces in physicians similar levels of certainty in decision-making, based on weak or non-existent evidence, as for unambiguous findings from randomised studies. As examples, high level recommendations based on expert opinion may be quoted as well as the often-encountered claim that something has been “demonstrated” in a subgroup analysis.

### **In This Context, Marburger Bund Further Defines as Assessment Criteria**

*Speakers/authors of independent CME*

- (1) *use language that clearly and unambiguously separates causal findings from other data;*
- (2) *separate the description of the level of evidence from giving a clinical practice recommendation;*
- (3) *clearly delineate which factors (beyond level of evidence) have been taken into account in the development of clinical practice recommendations, and whether there is an underlying hierarchical structure (e.g. prioritisation of improvements in prognosis over decreases in morbidity etc.) (see also “Summary” below).*

## Conduct of Independent CME

Marburger Bund principally regards CME as workplace activity. However, many CME activities take place out of working hours and not at the workplace.

It is thus also important to ensure, that under these conditions, CME activities will be perceived as independent and solely professionally motivated. In this regard, Marburger Bund refers to a decision of the European Court of Justice, which has ruled that the presentation of a “product” must convey an unambiguous impression at first glance [39], and would like to see this principle fully applied also in CME.

### In This Context, Marburger Bund Demands

- (1) CME is an integral part of physicians’ professional practice. It is an element of quality assurance in medicine.
- (2) All physicians should have equal access to CME, in particular irrespective of their level of training, function, or professional position.
- (3) CME should be considered as part of physicians’ work performance. It should primarily take place during working hours. Doctors should have the opportunity to practice CME at the workplace (e.g. via the Internet).
- (4) Cost of CME should be covered by the employer.

Marburger Bund fully supports the position of the German Medical Association that doctors should be entirely free in choosing the what (content), how (format), and when (date) of CME. Marburger Bund considers this as the best way to react flexibly and in a problem-orientated way to challenges in everyday health care. In this regard Marburger Bund criticises the increase in obligatory CME activities (as enacted by regulators as part of disease management programmes) which counteracts the freedom of choice in CME.

- (5) Medical information is more often being offered digitally and at the workplace, and is therefore becoming increasingly important for point-of-care decisions. Concepts as to whether and how this type of electronically-based education (“micro-e-learning”) could be integrated into individual concepts and into current accreditation systems of the Chambers should be developed.
- (6) Independence (in particular from commercial interests) of content and judgements in CME should be defined and managed entirely by the

medical profession as laid down in the (Model) Professional Code (of the German Medical Association). Relevant recommendations in this regard are available [40]. Legislative measures (as in the “Physicians Payment Sunshine Act” in the USA) may be supportive of these efforts, but cannot replace them. Thus, Marburger Bund currently sees no need for additional legal regulations (in Germany) with its well-functioning system of physicians’ self-regulation. All professional organisations should put even more effort into further developing criteria for the independence of CME [41].

### In This Context, Marburger Bund Further Defines as an Assessment Criterion

*In all planning, announcement, delivery and follow-up evaluation, physician as well as non-physician providers, speakers, authors, chairpersons, course directors and moderators avoid any appearance that a CME activity could not be completely independent and exclusively professionally motivated.*

### Independence of (Passive) Physician Participants in CME

Though not having top priority in current discussions on independence in CME, it can probably be assumed as self-evident that passive participants also have interests, which may impact on their perceptions and conclusions in CME. This might at least in part explain, e.g. the high subjective variability demonstrated in studies on the perception of guideline recommendations [32].

Since there are currently no tools available feasibly to disclose the interests of passive participants in CME, there is a lack of knowledge to what extent the perception of CME or strength of practice recommendations might have been influenced by the interests of participants.

### In This Context, Marburger Bund Further Defines as an Assessment Criterion

*If doctors participating in continuing medical education do not remain anonymous (e.g. in the form of contributing to the discussion), they commit to the same principles that apply to speakers and authors. At face-to-face events, the declaration of interest is made verbally; in the case of continuing medical education in digital or print media, in writing (e.g. in a letter-to-the-editor).*

## Summary and Practical Conclusions

Physicians have committed always to select the most reliable diagnosis and treatment for their patients. However, the chain from generation of data (evidence) to evaluation of clinical relevance and finally to clinical practice recommendations is subject to powerful and often economically motivated interests in an increasingly competitive environment.

Issues relevant to this process, but outside the realm of physicians and their professional organisations have been brought to the attention of policymakers by Marburger Bund.

In recent decades an increasingly sophisticated and globally accepted methodological approach has been developed for generation and evaluation of evidence. However, translation of evidence into language, resulting in unambiguous practice recommendations, is still pending.

Compared to other potentially influential factors (such as the influence of various “medical schools”) currently the verbal presentation of medical findings probably shows the highest potential for manipulation to further economic and other interests. On the other hand, analysis of the current proposals for translation of evidence into practice recommendations for decision-making demonstrates, that it is probably unrealistic to find a solution based solely on differences in wording, which would result in easily understandable language, universally perceived as unambiguous.

Thus, notwithstanding further efforts to clarify linguistic issues, additional supportive measures in delivery of CME have to be taken, which aim to provide participants in CME with an objective overview of the exponentially increasing available evidence and enable them to make their own balanced judgements.

### This Results in the following Suggestions for the Practice of CME

- (1) *2. Problem-orientated systematic presentation of the structure of evidence in appropriate language*
  - (2) *Comprehensive disclosure of interests of all persons and institutions directly and indirectly involved in a CME activity.*
- This can only be achieved through regular integration of aggregated information (e.g. systematic reviews, meta-analyses) from independent sources.
  - Since, based on methodological considerations, in general only results from **randomised studies** can be used for clinical decisions based on **causal**

relations (e.g. in treatment), existing evidence should always be presented in a hierarchical structure, which starts with presentation of results from randomised trials. However, since randomisation per se does not always guarantee a sufficiently high quality of evidence, instruments for evaluating the quality of evidence in randomised studies have been developed. Of these the approach developed by the GRADE group is currently the methodologically most mature, most widely used, and preserves the professional autonomy of physicians by following a fully transparent procedure. GRADE’s assessment approach also provides the participants with tools to check, for the individual CME activity, whether presenters are trying adequately to judge the quality of the evidence. GRADE divides the quality of evidence from **randomised studies** into high, medium, low and very low quality (= trustworthiness), and this wording can directly be adopted for CME.

Given that already four terms are needed to describe the quality of evidence from randomised studies, it is not realistic to expect to differentiate quality of evidence within the inhomogeneous group of **non-randomised studies** by linguistic means only, and at the same time, keep a clear distinction from the wording used for randomised studies. Thus, language needs to be supplemented by procedural means to achieve a clear perception of differences in trustworthiness of evidence in participants. Presenters should therefore always actively point out that the level of certainty is substantially lower than in randomised studies\*. In particular, expert opinions should be considered as adding no certainty (for patients and physicians) to medical decision-making but may be helpful in liability issues without reducing the necessity for thorough justification of the decisions taken, in particular, if entirely based on expert opinion. In addition, the latter should therefore not be issued with high levels of recommendation\*\*. In general, the subjunctive mood of verbs should be used to describe results of non-randomised studies.

- (3) *Speakers/authors disclose the leading criteria for their practice recommendations (i.e. rate the quality of the evidence in the context of patient care), especially if levels of evidence are low.*

In evidence-based medicine, the significance of results from clinical studies for decision-making by physicians in diagnosis and treatment primarily depends on



- the magnitude of the treatment effect

(or of the net benefit taking also unwanted side effects into account) and

- its trustworthiness

(i.e. the certainty that this effect will also be achieved in the individual patient).

In some cases, however, additional factors such as the availability of treatment or cost may also become important.

Discussions about the clinical relevance of evidence are always subjectively influenced and therefore require the highest level of transparency regarding the criteria for opinion forming. In addition to the basic requirement of comprehensive disclosure of financial and non-financial interests, all those actively involved in CME (speakers/authors but also discussants) should therefore openly state, which criteria have determined their judgements.

- (4) *Practice recommendations should plausibly be derived from what has been presented under 2. and 3.*

In recent years, it has become increasingly common not only to describe levels of evidence, but also to provide practice recommendations, e.g. in pocket guidelines. To this end, the GRADE group has issued recommendations for outcomes of *randomised studies*, which range from strongly positive to weakly positive, and then weakly negative to strongly negative. These recommendations are primarily based on the quality of the evidence and the direction of the effect (net benefit vs. net harm), but also consider other factors such as resource consumption.

*Strongly positive* means that there is regularly a high net benefit for the patient.

*Strongly negative* means that a desired positive effect could definitely not be demonstrated, or even a net harm for the patient has regularly to be expected.

*Weakly positive* means that a positive effect cannot regularly be expected.

*Weakly negative* means that a positive effect cannot be expected and it cannot be ruled out that harm to the patient may occur on a regular basis.

Taking also into account outcomes of non-randomised studies, we would like to suggest the following as **practice recommendations**:

**Grade of Recommendation I:** Strongly positive recommendation (according to GRADE)

**Grade of Recommendation II:** Strongly negative recommendation (according to GRADE)

**Recommendation level III:** Weakly positive or weakly negative recommendation (according to GRADE)

**Grade of Recommendation IV:** Results from non-randomised studies, including expert opinion

*Interventions with grade of recommendation I should generally be performed; interventions with grade of recommendation II should generally not be performed.*

*Interventions with grades of recommendation III and IV are subject to the peculiarities of the individual patient-physician relationship to a degree which renders third party recommendations of subordinate value only.*

\*Potential exceptions could be: Observational studies with a) very large effects or b) indicating a dose-response relationship, or c) if all plausible confounders would lead to reduction of the effect size.

\*\*Nonetheless, data from non-randomised studies may also justify clinical decisions, if for a clinical question

- there are no data available from randomised studies or
- results of randomised studies cannot be considered as sufficiently trustworthy due to serious deficiencies in design and/or conduct of a trial.

The latter particularly applies, if

- blinding has been violated in recruitment and/or treatment of patients
- there has been too much loss to follow up
- results are not shown for all endpoints as defined in the study design (“selective outcome reporting”)

This applies to positive (“benefit”) as well as negative (“risk”) effects (and not only for randomised, but also for observational studies).

For decision-making of the individual physician, other factors could also be important, which should therefore be explicitly addressed in CME:

- Clinical trials typically exclude patients with certain clinical characteristics as defined in the study design. This applies, in general, e.g. to patients >75 years of age at study entry, but also to children (and thus affects almost the entire speciality

of paediatrics), and thus, study results may not readily be translated to these patient groups, which nevertheless represent a large part of everyday medical practice (a situation referred to as “indirect”).

- Evidence-based decision-making becomes difficult, if study results from different studies (with similar methodological quality) are inconsistent or even contradictory (classified by the GRADE group as “imprecision”). For one’s own decision-making, as a rule of thumb, the importance of a single finding is all the less, if (meta-analytically considered) the decision would be different depending on whether the true effect is assumed to be at the lower or upper end of the 95% confidence interval.
- It is beyond the capabilities of individual physicians to resolve the problem of publication/reporting bias, i.e. to determine whether and to what extent all completed studies (related to a certain topic) have been published. If funnel plots should be available, they will further clarify the issue and help to determine whether published data tend to overestimate positive (or negative) effects.

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## Disclosure Statement

Declarations of interests can be found under “Supplementary material”.

## References

- [1] (Model) Professional Code for Physicians in Germany, German Medical Association, 2018 Accessed 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/MBO/MBO-AE\\_EN\\_2018.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE_EN_2018.pdf)
- [2] (Model) Regulations on Continuing Medical Education, German Medical Association, 2013 Accessed on 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/International/MFBO\\_2013\\_EN\\_final.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/International/MFBO_2013_EN_final.pdf)
- [3] Schumm-Draeger P-M, Kapitza T, Mann K et al. Rückhalt für ärztliches Handeln (Clinic Code). Dtsch. Ärzteblatt. 2017;114:A2338-40.
- [4] Richter-Kuhlmann E. Mut haben, etwas nicht zu tun (Be courageous not to do something). Dtsch Ärzteblatt. 2015;112:810–811.
- [5] [www.mezis.de](http://www.mezis.de)
- [6] [www.libermed.de](http://www.libermed.de)
- [7] Resolution No. 3, 134th Marburger Bund General Assembly, Berlin, 2018\*
- [8] Grant J Doctors’ changing knowledge, their community of practice and CPD. Cologne Consensus Conference 2013. Accessed 11 June, 2020: <https://vimeo.com/95414848>
- [9] Griebenow R, Campbell C, McMahon G, et al. Roles and responsibilities in the provision of accredited continuing medical education/continuing professional development. J Euro CME. 2017;6. DOI:10.1080/21614083.2017.1314416.
- [10] Resolution No. 26, 127th Marburger Bund General Assembly, Frankfurt 2015\*
- [11] Resolution No. 17, 135th Marburger Bund General Assembly, Münster, 2019\*
- [12] Resolution No. 19, 129th Marburger Bund General Assembly, Hamburg, 2016\*
- [13] Flacco ME, Manzoli L, Boccia S, et al. Head-to-head randomised trials are mostly industry sponsored and almost always favour the industry sponsor. J Clin Epidemiology. 2015;68:811–820.
- [14] Rasmussen K, Bero L, Redberg R, et al. Collaboration between academics and industry in clinical trials: cross sectional study of publications and survey of lead academic authors. BMJ. 2018;363:k3654.
- [15] Köhler M, Haag S, Biester K, et al. Information on new drugs at market entry: retrospective analysis of health technology assessment reports versus regulatory reports, journal publications, and registry reports. BMJ. 2015;350:h796.
- [16] Ross JS, Mulvey GK, Hines EM, et al. Trial publication after registration in ClinicalTrials.gov: a cross-sectional analysis. PLoS Med. 2009;6:e1000144.
- [17] Goldacre B, DeVito NJ, Heneghan C, et al. Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource. BMJ. 2018;362:k3218.
- [18] Resolution Ib-66, 120th German Medical Association General Assembly, Freiburg, 2017, Decision Minutes, p. 232 Accessed on 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll\\_120\\_DAET.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll_120_DAET.pdf)
- [19] Resolution Ib-55, 120th German Medical Association General Assembly, Freiburg, 2017, Decision Minutes, p. 154 Accessed on 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll\\_120\\_DAET.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll_120_DAET.pdf)
- [20] Resolution No. 16, 129th Marburger Bund General Assembly, Hamburg, 2016\*
- [21] Lösche P, Potential for change, Cologne Consensus Conference 2016 Accessed 11 June, 2020: <https://vimeo.com/229917183>

- [22] Resolution No. 28, 129th Marburger Bund General Assembly, Hamburg, 2016\*
- [23] Resolution Ib-54, 120th German Medical Association General Assembly, Freiburg, 2017, Decision Minutes, p. 133 Accessed on 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll\\_120\\_DAET.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/120.DAET/Beschlussprotokoll_120_DAET.pdf)
- [24] Wehkamp KH, Nägler H. Economisation of patient-related decisions in hospitals. *Dtsch Ärzteblatt*. 2017;114:797–804.
- [25] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. In: Graham R, Mancher M, Miller Wolman D, et al., editors. *Clinical Practice Guidelines We Can Trust*. (US), Washington (DC): National Academies Press; 2011.
- [26] Stöllberger C, Schneider B. Concerns about the ESC heart failure guidelines. *Int J Cardiol*. 2017;228:707–708.
- [27] Fanaroff AC, Califf RM, Windecker S, et al. Levels of Evidence Supporting American College of Cardiology/ American Heart Association and European Society of Cardiology Guidelines, 2008-2018. *JAMA*. 2019;321(11):1069–1080.
- [28] Tricoci P, Allen JM, Kramer JM, et al. Scientific evidence underlying the ACC/AHA clinical practice guidelines. *JAMA*. 2009;301:831–841.
- [29] Bleß HH, de Millas C, Kern B, et al. Auswirkungen von Stellungnahmen der Wissenschaft in der Nutzenbewertung von Arzneimitteln (Effects of scientific statements in the benefit assessment of pharmaceuticals). IGES Institut GmbH, 2016
- [30] Resolution No. 15, 129th Marburger Bund General Assembly, Hamburg, 2016\*
- [31] Resolution No. 26, 123th Marburger Bund General Assembly, Hanover, 2013\*
- [32] Resolution No. 14, 125th Marburger Bund General Assembly, Düsseldorf, 2014\*
- [33] Editors of the Heart Group Journals. Statement on matching language to the type of evidence used in describing observational studies vs. randomised trials. *Eur Heart J*. 2013;34:20–21.
- [34] Balslem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64:401–406.
- [35] Darrow JJ, Avorn J, Kesselheim AS. The FDA Breakthrough-Drug Designation. *N Engl J Med*. 2018;378:1444–1453.
- [36] Nast A, Sporbeck B, Jacobs A, et al. Perception of the binding nature of guideline recommendations. *Dtsch Arztebl Int*. 2013;110:663–668.
- [37] Weberschock T, Dreher A, Follmann M, et al. Bindingness of recommendations in guidelines: survey on Perception among Guideline Developers. *ZEFQ*. 2016;113:1–8.
- [38] Eidemüller D. Das Weltbild der evolutionären Erkenntnistheorie (The worldview of evolutionary epistemology). In: Eidemüller D, editor. *Quanten - Evolution - Geist: eine Abhandlung über Natur, Wissenschaft und Wirklichkeit (A treatise on nature, science and reality)*. Springer, Berlin-Heidelberg; 2017. p. 209–220. DOI:10.1007/978-3-662-49379-3\_10.
- [39] EUCJ ruling on BVV vs Teekanne, accessed 11 February, 2019: <http://curia.europa.eu/juris/document/document.jsf?docid=164721&text=&doclang=EN&pageIndex=0&cid=4457975>
- [40] Recommendations on Continuing Medical Education, German Medical Association, 2015, accessed 11 June, 2020: [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/Fortbildung/BAEK\\_Recommendations\\_on\\_CME.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Fortbildung/BAEK_Recommendations_on_CME.pdf)
- [41] Resolution No. 12, 126th Marburger Bund General Assembly, Berlin, 2014

\*Resolutions of Marburger Bund General Assemblies can be requested from Marburger Bund Germany, Berlin, Germany.