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A LONG WAY TO GO FOR CONFLICT OF INTEREST POLICIES AT GERMAN MEDICAL SCHOOLS – A COSS SECTIONAL STUDY AND SURVEY

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ABSTRACT

Objectives: To assess the quantity and evaluate the quality of policies and curricula focussing on conflicts of interests (COI) at medical schools across Germany.

Design: Cross-sectional study, survey of medical schools, standardized web search.

Setting: Medical schools, Germany.

Participants: 38 German medical schools.

Interventions: We collected relevant COI policies and teaching activities by conducting a search of the websites of all 38 German medical schools using standardized keywords for COI policies and teaching. Further, we surveyed all medical schools' dean's offices. Finally, we adapted a scoring system for obtained results with 13 categories based on prior similar studies.

Main outcomes and measures: Presence or absence of COI related policies or teaching at medical school. The secondary outcome was the achieved score on a scale from 0 to 26 with high scores representing restrictive policies and sufficient teaching activities.

Results: We identified relevant policies for one medical school via the web-search. The response rate of the deans' survey was 16 of 38 (42.1%). In total, we identified COI-related policies for 2 of 38 (5.3%) German medical schools, yet no policy was sufficient to address all COI-related categories that were assessed in this study. The maximum score achieved was 12 of 26. 36 (94.7%) schools scored 0. No medical school reported curricular teaching on COI.

Conclusions: Our results indicate a low level of action by medical schools to protect students from undue commercial influence. No participating dean was aware of any curriculum or instruction on COI at the respective school. The German Medical Students Association and international counterparts have called for a stronger focus on COI in the classroom. We conclude that for German medical schools there is still a long way to go.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Institutional Conflicts of Interest (COI) policies and relevant teaching curricula protect medical students from and inform them about undue influence by industry. This study is the first standardised qualitative analysis of medical school COI policies in Germany.
- The cross sectional study compromises both structured web-searches and surveys of deans' offices.
- The conducted survey yielded a response rate of 42%. Despite additional web-searches and seeking experts' advice, teaching activities and policies by non-responding medical schools may have been missed.
- The study focused on COI policies that apply to the specific setting of medical schools. Other state or university wide policies were not included.
- The study design is based on previous studies in other countries and therefore allows for international comparison.

INTRODUCTION

Contacts between pharmaceutical or medical device industry and healthcare professionals have long been a point of discussion, as they may lead to conflicts of interest (COI). According to the widely accepted definition from the Institute of Medicine, COI are circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly

influenced by a secondary interest.[1] In healthcare COI may exist between the physician's commitment to patient care and industry's interest in selling their products. There is mounting evidence indicating an adverse effect of pharmaceutical promotion on physicians' prescribing behaviour.[2] Patients may suffer from the consequences directly due to exposure to unnecessary risks as well as indirectly through a higher financial burden for health care systems.[2] Simultaneously, universities and medical schools in particular are increasingly expected to conduct translational research from "bench to bedside" - a paradigm that includes market commercialization and requires industry collaborations which makes contact with the private sector inevitable. Therefore, COI present challenges towards medical professionalism.[3]

In order to protect independent patient care, professional handling of COI by physicians is essential. It has been argued, that physicians' attitudes towards the pharmaceutical industry and their inclination to be influenced by marketing efforts manifest early during their professional training.[3] A large body of evidence exists showing that medical students themselves are in contact with industrial companies on a regular basis.[3–11] Contacts increase in the course of studies, with more interactions during the clinical part of their studies.[4,12,13] A study by Lieb et al. [7] at eight German medical schools revealed that only 12% of surveyed students had never received a gift or attended a sponsored event. The authors also report that 60% of these students had a promotional gift handed on to them by a physician they worked with, who received the gift by a company beforehand. [7] Professors and other physicians act as role models students base their attitudes and actions on - not only regarding their clinical work, but also regarding interactions with industry and COI. The actions of those role models constitute a "hidden curriculum" and conceptualize what is perceived to be normal.[14] The extent to which teaching faculty in Germany has financial ties to industry actors remains largely unclear. However, such relationships may affect academic and publishing interests, the content faculty chooses to disseminate to medical students and their general professional medical opinions.[15,16] Overall, COI of teaching staff are not commonly disclosed to medical students in Germany.

Previous studies report that 65% of surveyed medical students in Germany felt inadequately prepared for interactions with the pharmaceutical industry.[17] 90% of those students in Germany reported that dealing with industrial marketing practices had never been addressed during their lectures.[17] In another survey, 14.4% of the participating German medical students noted that they attended a lecture or courses dealing with COI; of those classes, however, 90% were optional.[18] Altogether, it remains unclear to what extent German medical schools include COI topics in their curricula. Aside from teaching about industry practices of marketing and promotion, restrictive COI policies at the medical school level have been suggested to increase students' awareness of the consequences of inappropriate marketing practices in the learning environment.[19] Some studies indicate that COI policies at medical schools have a significant impact on prescribing practices by inoculating physicians against persuasive aspects of pharmaceutical promotion.[20–22] In Germany, Lieb et al. found that in 2013 only two medical schools reported having a COI policy.[18] However, none of these schools reporting a policy (TU Dresden and RWTH Aachen) supplied the policies themselves and hence, the content and strength of the policies remain unclear. The objective of this study was to determine whether medical schools in Germany have institutional COI policies in place and to assess the strength of the policies obtained by means of 13 pre-defined criteria including the existence of teaching activities.

METHODS

Our methodology built upon criteria used in earlier studies on COI policies such as the American Medical Students Association (AMSA) scorecard [23], the Canadian scorecard by Shnier et al. [24], and the French conflict of interest ranking by Scheffer et al.[25] A list of the 38 German medical schools was obtained from the website of the German Medical Faculty Association (Medizinischer Fakultätentag).[26] After formal exchange with a member of the German Ethics Council about the nature of this study, which only involves policies at an institutional level rather than patient data or other personal information, it was deemed unnecessary to ask for formal approval from an ethics committee.

Web-based search

Two researchers (LS, MS) independently searched the websites of the respective medical schools (or if non-existent, the websites of the respective universities) using integrated search engines in June 2018 to identify policies related to COI, documents interpreting policies or material published regarding COI in the curriculum. Addresses of the websites searched are listed in the supplementary material. Search terms included "Interessenkonflikt"/"Interessenskonflikt" (conflict of interest), "Industrie" (industry), and "interne Regulierung" (internal regulation) based on previous publications.[25] If a policy was in place, it was recorded together with the latest date of review. Only policies that specified their validity for medical schools were considered relevant for this study. Therefore, policies applying to an entire university or only to a university hospital were excluded. Disagreement about inclusion of the recorded sources was discussed with all authors. Those sources included were later assessed via the methodology previously determined through the scoring criteria in our codebook (as described in 'results', see supplementary material).

Contacting medical schools

In May 2018, we contacted each office of the dean of medicine to inform them about the study through a written letter. The letter gave background information about the study's purpose and outlined the criteria for which we needed documentation. We asked the medical school to send any form of policy (or parts of a policy) relating to the management of COI, as well as information on enforcement of the policy. Furthermore, the letter included the request to provide information on curriculum contents addressing the consequences and management of COI. We did a maximum of three follow-ups for non-responders. We first sent an email in June 2018 reiterating the content of the letter previously sent. We then followed up via email in July 2018 and enclosed two letters of support, one from David Klemperer and one from Barbara Mintzes, co-author of the study which analyzed conflict of interest policies at Canadian medical schools and editor of a widely-used teaching manual on pharma promotion.[27] In August 2018, we followed up by sending the results of the web-based search. Representatives of the dean's offices were given the opportunity to confirm, correct or comment on our web-based findings. In addition to searching the websites and contacting the offices of the deans of medical schools, we sought information via personal contacts and experts in the field. Data cut-off was October 2018. We excluded policies from affiliated teaching hospitals, because they are not under the authority of the dean of the medical school.

Further, we excluded any policies or parts of policies that did not specifically apply to a medical school.

Scoring system

We adapted a scoring system based on criteria used in earlier studies by Scheffer et al. [25] and Shnier et al. [24] in the French and Canadian context respectively, as well as the AMSA Scorecard.[23] The following categories were addressed:

1. Gifts from industry
2. Meals from industry
3. Consulting relationships
4. Industry-funded promotional speaking
5. Educational activities like CME-lectures
6. Participation in industry-funded promotional events
7. Honoraria and scholarships from industry
8. Ghostwriting and honorary authorships
9. Industry Sales Representatives
10. Disclosure of COI
11. Medical school curriculum on COI
12. Extension of policies
13. Enforcement of policies

Subsequently, we graded the results for each category through our scoring system from 0 to 2. Generally, "0" means no policy or a permissive policy, "1" a moderate policy and "2" a restrictive policy. The translated codebook in English, outlining the decision pathway for each category is available as supplementary file to this article. Three reviewers (LH, TW, ST) independently undertook the scoring of the medical schools' policies. All authors then reviewed the scoring. Any disagreement was resolved through discussion and majority vote. We then summed up the scores of all individual categories for each medical school to create a global score, with a range of 0 to 26 points. No weighting of single categories was performed.

RESULTS

Web-based search

The web-based search was conducted to identify publicly available COI policies at German medical schools. The search yielded relevant results for one of the 38 medical schools: an anti-corruption brochure and a third-party funds statute from Charité-Universitätsmedizin Berlin (Figure 1). Additional articles and publications were identified but excluded from analysis, because they either did not relate to predefined criteria or did not specifically apply to the entire medical school. Our web-based search strategy revealed no information on relevant compulsory curricular teaching activities addressing COI. One elective course at Friedrich-Schiller-Universität Jena was identified.

Contacting medical schools

German medical schools were contacted to provide validated insight into existing COI policies. The total response rate was 42.1% (16 of 38). Twelve of the responding medical schools did not send policies. Four medical schools (10.5%) included policies dealing with COI, of which three (an anti-corruption directive and a monetary benefit acceptance policy from the Ludwig-Maximilian-Universität München, a code of practice as well as an anti-corruption directive from the Julius-Maximilians-Universität Würzburg, a compliance brochure, gifts and benefits acceptance policy, and a third-party funds statute from the Friedrich-Schiller-Universität Jena) exclusively applied to university medical centers, not to the respective medical schools, and were therefore excluded from further analysis. One policy met inclusion criteria and comprised an anti-corruption directive issued by the medical school and university medical centre of the Technische Universität Dresden (Figure 1).

Of the 16 replies, 5 medical schools (13.2%) (Universität des Saarlandes, Albert-Ludwigs-Universität Freiburg, Georg-August-Universität Göttingen, Christian-Albrechts-Universität zu Kiel, Universität Witten/Herdecke) responded not having COI policies or that COI were not part of the curriculum. The Universität des Saarlandes stated that there was no separate policy for the medical school, while the Albert-Ludwigs-Universität Freiburg declared not having a COI policy within the medical curriculum, as well as no explicit lectures on COI. In addition, the Christian-Albrechts-Universität zu Kiel reported no existing COI policy within their medical school, neither was the topic taught in the medical curriculum. The reply from the Georg-August-Universität Göttingen stated that basic knowledge about pharmacoeconomics was taught, however, not mentioning corruption and transparency within the medical system. As stated by the Universität Witten/Herdecke, COI management lies with the contracted teaching hospitals. The Friedrich-Alexander-Universität Erlangen-Nürnberg replied that several policies apply within their university; however, no COI policy relevant to this study, issued by the medical school itself is externally available. The Universität Greifswald and the Medizinische Fakultät der Universität Hamburg initially asked for more time to reply, yet did not send material until the end of the data collection period. The Universität Augsburg was still in the process of setting up a medical curriculum, welcoming medical students starting in 2019 and was hence not able to report on COI policies or teaching activities. No further response as to whether a general COI policy existed was received. The Westfälische-Wilhelms-Universität Münster and the Goethe-Universität Frankfurt reported no capacities to take part in our study, while the Justus-Liebig-Universität Gießen actively decided against participating. The Universität Ulm addressed neither COI policies nor curriculum contents in their reply. The remaining medical schools did not respond to any request during the data acquisition period.

Analysis of COI policies

The two included policies were assessed according to a predefined scoring system as set out in our codebook (see supplementary material). Results of each analysis are listed in Table 1.

Table 1: Overview of strength of COI policies included in analysis

	Strength of policy			
Medical school	**No/ permissive (0)**	**moderate (1)**	**restrictive (2)**	**total**
TU Dresden				**12**
	Participation in promotional events	Gifts from industry	Honoraria and scholarships from	

			pharmaceutical industry	
	Education activities like CME-lectures	Meals from industry	Disclosure	
	Ghostwriting and honorary authorships	Consulting relationships	Extension of policy	
	Industry Sales Representatives	Industry-funded speaking relationships	Enforcement of policy	
	Medical school curriculum on COI			
Charité Universitätsmedizin Berlin				**4**
	Meals from industry	Consulting relationships	Gifts from industry	
	Participation in promotional events	Extension of policy		
	Education activities like CME-lectures			
	Industry-funded speaking relationships/speakers' bureaus			
	Ghostwriting and honorary authorships			
	Industry Sales Representatives			
	Disclosure			
	Medical school curriculum on COI			
	Enforcement of policy			
	Honoraria and scholarships from pharmaceutical industry			

With 12 out of 26 points, the Technische Universität Dresden achieved the highest score. Charité Universitätsmedizin Berlin scored 4 points in total. All other medical schools did not supply a valid COI policy and had no retrievable information on COI policies on their websites according to inclusion criteria (Figure 1).

We did not acquire any information about obligatory teaching activities on COI through web-based search or the deans' survey. However, through personal contacts and seeking advice from experts, we received information on courses that cover COI at 3 medical schools (7.9%): Charité Universitätsmedizin Berlin, Universität Mainz and Universität Leipzig. These teaching activities are either lectures in which COI is discussed (Universität Leipzig, Universität Mainz, Charité Universitätsmedizin Berlin) or elective courses that students can choose within their curriculum (Charité Universitätsmedizin Berlin, Universität Mainz).

DISCUSSION

Statement of principal findings

In this cross sectional study and survey of German medical schools we found that only two German medical schools (5.3%) have policies relating to COI in place. Moreover, none of these policies sufficiently covered the broad spectrum of evaluated categories with relevance to COI, nor did they focus explicitly on medical education. The maximum score achieved was 12 of 26. 36 (94.7%) schools scored 0 and no medical school reported curricular teaching on COI. These results indicate little effort by German medical schools to address the issue of COI in medical education.

Strengths and limitations of the study

In total, 16 out of 38 medical schools responded to our letter and emails and therefore COI teaching activities and policies by non-responding medical schools may have been missed.

To address this issue we conducted a systematic web-search, which in general supported the results of the survey. The policy identified for Charité Universitätsmedizin Berlin was evaluated without response from the dean's office to validate the document retrieved online. The web-search was performed with few predefined search terms using integrated search engines on the websites of medical schools, thus limiting potentially retrievable documents. Consequently, the results of this study might underestimate the number of COI policies and teaching activities that are publicly available. However, scarce results among the 16 medicals schools participating in the survey as well as from the web-search indicate that too few German medical schools adopted policies on conflicts of interests.

Medical schools don't exist in a vacuum and further COI policies may exist at a university-wide level or at university medical centres. We argue that the consequences of COI in medicine potentially harm patient health and are therefore even more critical compared to COI that might occur in other fields. Thus, medical schools require more restrictive COI policies than other departments within a university. Teaching physicians are predominantly also employed by a university medical centre which might issue COI policies not specifically applying to medical school. However, these policies are aimed at COI of physicians working in patient care and lack specific regulations that apply to the teaching environment of medical students.

Strengths and limitations in relation to other studies, discussing important differences in results

Comparable studies were conducted in the United States, Canada, Australia and France, allowing for an international comparison of our results.[23–25,28] In general, North American medical schools tackle the issue of COI in medical education more proactively. In Canada 16 of 17 medical schools had some form of COI policy in place in 2013 [24] and in 2014, 136/160 US medical schools reported an existing policy on COI.[23] The Australian study found that 7 medical schools out of 20 had a COI policy.[28] The French study exposed similar results as our own data. They found no formal COI policy at any of the 37 French medical schools and only scattered COI teaching activities. Their response rate of 8.1% may be indicative of the low interest in the topic by medical schools at this time. The publication of these results led to increased media attention [29] and ultimately the French deans' conference adopted a nation-wide COI policy.[30]

The best performing policy in our study was an anti-corruption directive issued by the Technische Universität Dresden that included four restrictive and four moderate elements related to different scoring categories. Yet we were unable to retrieve this policy from the medical school's website during the performed web-search. Prior studies excluded non-public policies from analysis, since an inaccessible, not widely circulated policy is unlikely to have a relevant impact and may go unrecognized by academic staff.[24,28] In an earlier study two German medical schools were reported to have a policy on COI.[18] Our research could only verify one of those COI policy equivalents at TU Dresden. RWTH Aachen reported a policy in 2014 but did not reply to our study, nor was a policy identified on the school's website. Despite six medical schools committed to the development of a COI policy in 2014 [18], our results indicate that no policy has been published since. We furthermore did not receive any information about teaching on COI through the deans' survey. This is in contrast to the survey by Lieb et al.[18] In their study, deans from seven medical schools reported COI teaching activities (Universität Bonn, Universität Erlangen-Nürnberg, Universität des Saarlandes (Homburg), Universität Gießen, Universität Göttingen, Universität Frankfurt, Universität Köln).

From these medical schools, only the dean's office of Universität Göttingen commented on COI teaching and declared that their curriculum included basic education on pharmacoeconomics but did not explicitly cover COI related aspects like transparency or corruption.

Implications for medical schools and policymakers

Education and policies on COI have been suggested to sensitise medical students against undue influence by industry.[4,20–22] Medical students themselves increasingly demand stronger COI regulations, disclosure of teaching faculty's COI and courses on COI. The German Medical Students' Association (bvmd e.V.) adopted a position paper on the independence of education in 2013.[31] In May 2019 the European Medical Students Association (EMSA) passed a policy titled "Conflicts of Interest in Medical Education Settings"[32] and the International Medical Students' Association (IFMSA) followed in August 2019 with a policy called "Integrity and transparency in medical education".[33] These actions are indicative of broader student interest in policy change.

We found COI teaching activity at German medical schools, if existent, to be an initiative by singular faculty members rather than a structured component of the curriculum. The scarce efforts to include COI in teaching are all the more surprising, since the German National Competence-Based Learning Objectives for Undergraduate Medical Education (NKLM) include COI (without specifically naming them) in chapter 11.1.1.2.[34] Moreover, the IMPP (Institute for medical and pharmaceutical examination questions) that develops national exams for medical students in Germany introduced an item directly referring to COI in its latest edition published in November 2019. Recently, a randomized controlled trial showed that a structured and integrated curriculum on COI and risk communication leads to a large and sustainable increase in risk communication performance among German medical students.[35] Taking the mounting evidence, broad student engagement and changing requirements into consideration, German medical schools are under pressure to adopt structured COI curricula and policies.

Unanswered questions and future research

In the US, the regular AMSA scorecard assessed COI policies at U.S. medical schools and contributed to a constant improvement in policies since its initiation in 2007.[23] Regular evaluation of the development of policies and curricula addressing COI might also be useful in Germany to incentivise and monitor progress towards better COI education at medical schools.

Surely, policy development is a dynamic process and some schools signalled willingness to introduce teaching activities and considered COI policies after we contacted them. This, however, was also the case in previous studies.[18] Yet, our work indicates that little action was taken since then.

Future research should further assess the impact of stringent policies during medical training on prescribing behaviour, and ultimately evaluate other patient relevant outcomes.

Conclusion

In contrast to other parts of the world, such as North America, German medical schools barely regulate students' contact with pharmaceutical companies or teach about impacts of conflicts of interest. Several organizations[38,39] and increasingly students themselves are demanding a cultural change in the medical profession starting with independent, unbiased medical

education.[31–33] COI policies at medical schools have been shown to positively impact prescribing and practise.[20–22] Medical schools in Germany have a key responsibility to protect students from undue influence and enable them to critically appraise information to achieve the best possible patient care. Although national learning objectives include teaching on COI, German medical schools do too little and have a long way to go.

LEGENDS

Figure 1: Flowchart of included COI policies

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AUTHOR CONTRIBUTIONS

P.G., Z.F., L.U.H, L.S., M.S., S.T., T.W. and D.K. designed the study. P.G., Z.F., S.G., L.U.H., L.S., M.S, S.T., T.W. conducted the survey. M.S. and L.S performed the web-based search. P.G., L.U.H., S.T., T.W. evaluated obtained results. P.G. and L.U.H. wrote the manuscript. All authors reviewed the manuscript.

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COMPETING INTEREST STATEMENT

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no financial support from any organisation for the submitted work; SG previously consulted for Universities Allied for Essential Medicines (UAEM) Europe e.V.; all other authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

DETAILS OF ETHICAL APPROVAL, PATIENT AND PUBLIC INVOLVEMENT STATEMENT

After formal exchange with a member of the German Ethics Council about the nature of this study, which only involves policies at an institutional level rather than patient data or other personal information, it was deemed unnecessary to ask for formal approval from an ethics committee. Neither patients nor public were involved in conceptualizing or conducting this study.

DATA SHARING STATEMENT

Data from web-searches will be made available upon request.

TRANSPARENCY DECALRATION

The lead author and manuscript guarantor PG affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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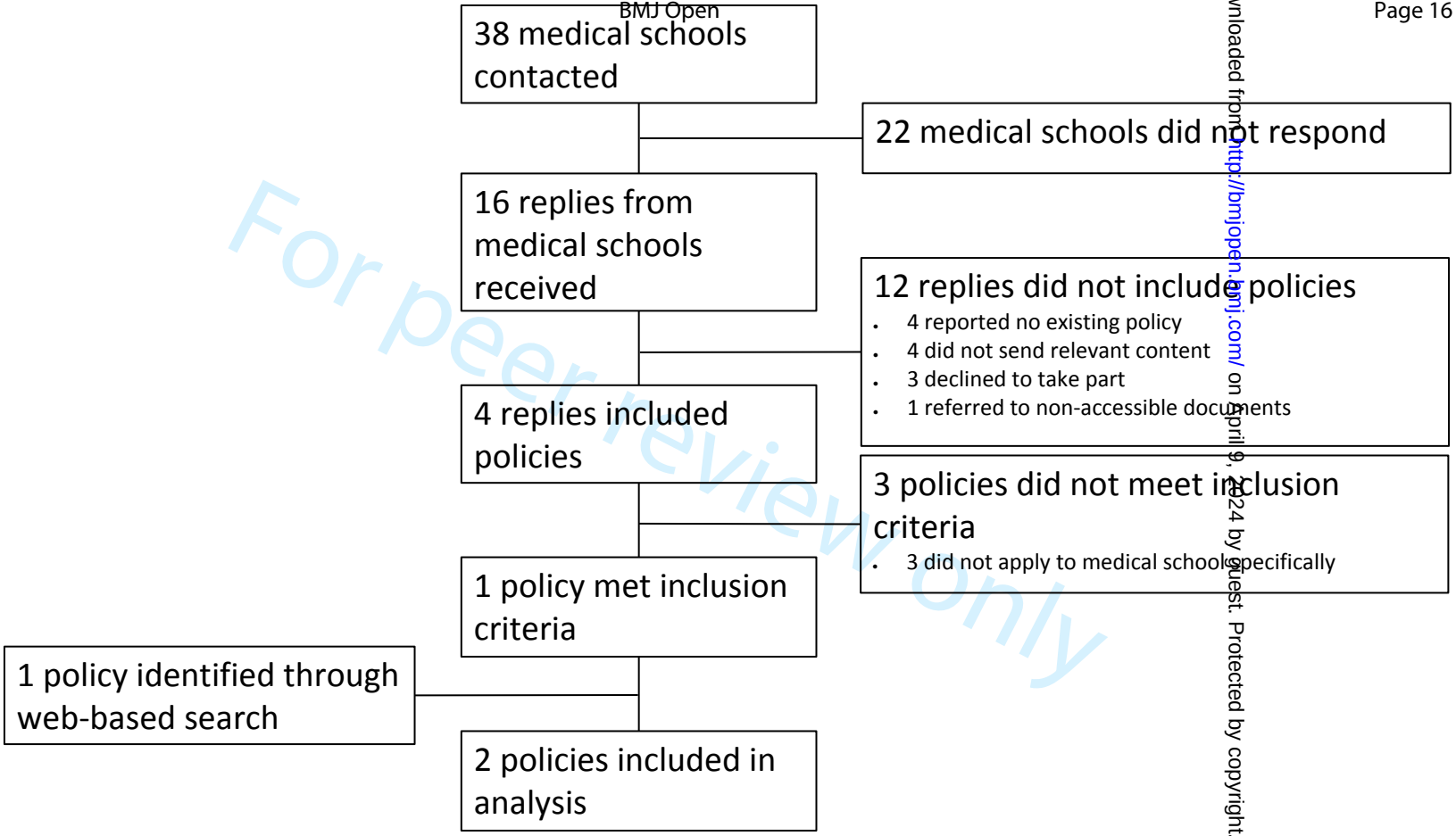


List of websites searched

Medical school	Websites searched
RWTH Aachen	https://medizin.rwth-aachen.de/
Universität Augsburg	https://www.med.uni-augsburg.de/ https://www.uni-augsburg.de/de/
Charité – Universitätsmedizin Berlin	https://www.charite.de/ https://www.fu-berlin.de/ https://www.hu-berlin.de/de
Ruhr-Universität Bochum	http://www.medizin.ruhr-uni-bochum.de/ https://www.ruhr-uni-bochum.de/de
Rheinischen Friedrich-Wilhelms-Universität Bonn	http://ukb.uni-bonn.de/42256BC8002AF3E7/direct/home https://www.uni-bonn.de/
Medizinische Fakultät Carl Gustav Carus der Technischen Universität Dresden	https://tu-dresden.de/med https://tu-dresden.de/
Universität Duisburg-Essen	https://www.uni-due.de/med/ https://www.uni-due.de/
Heinrich-Heine-Universität Düsseldorf	http://www.medizin.hhu.de/ https://www.uni-duesseldorf.de/home/startseite.html
Friedrich-Alexander-Universität Erlangen-Nürnberg	https://www.med.fau.de/ https://www.fau.de/
Goethe-Universität Frankfurt	http://www.uni-frankfurt.de/54233767/fachbereich http://www.uni-frankfurt.de/de?locale=de
Albert-Ludwigs-Universität Freiburg	http://www.med.uni-freiburg.de/de http://www.uni-freiburg.de/
Justus-Liebig-Universität Gießen	https://www.uni-giessen.de/fbz/fb11 https://www.uni-giessen.de/index.html
Georg-August-Universität Göttingen	https://www.med.uni-goettingen.de/index_de.php http://www.uni-goettingen.de/
Universitätsmedizin Greifswald	https://www.medizin.uni-greifswald.de/de/home/ https://www.uni-greifswald.de/
Martin-Luther-Universität Halle-Wittenberg	https://www.medfak.uni-halle.de/ https://www.uni-halle.de/
Universität Hamburg	https://www.uke.de/organisationsstruktur/medizinische-fakult%C3%A4t/index.html https://www.uke.de/index.html https://www.uni-hamburg.de/
Medizinische Hochschule Hannover	https://www.mh-hannover.de/
Ruprecht-Karls-Universität Heidelberg	http://www.medizinische-fakultaet-hd.uni-heidelberg.de/ https://www.uni-heidelberg.de/de

Universität des Saarlandes (Homburg)	http://www.uniklinikum-saarland.de/de/ https://www.uni-saarland.de/nc/startseite.html
Friedrich-Schiller-Universität Jena	https://www.uniklinikum-jena.de/ https://www.uni-jena.de/
Christian-Albrechts-Universität zu Kiel	http://www.medizin.uni-kiel.de/de http://www.uni-kiel.de/de/
Universität zu Köln	http://medfak.uni-koeln.de/ http://uni-koeln.de/
Universität Leipzig	https://www.uniklinikum-leipzig.de/ https://www.uni-leipzig.de/
Universität zu Lübeck	https://www.uni-luebeck.de/index.php?id=897 https://www.uni-luebeck.de/universitaet/universitaet.html
Otto-von-Guericke-Universität Magdeburg	http://www.uni-magdeburg.de/ http://www.med.uni-magdeburg.de/
Johannes-Gutenberg-Universität Mainz	http://www.um-mainz.de https://www.uni-mainz.de/
Medizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg	https://www.umm.uni-heidelberg.de/home/
Philipps-Universität Marburg	https://www.uni-marburg.de/de/fb20 https://www.uni-marburg.de/de
Ludwig-Maximilians-Universität München	https://www.med.uni-muenchen.de/index.html https://www.uni-muenchen.de/index.html
Technischen Universität München	http://www.med.tum.de/de/die-fakult%C3%A4t-f%C3%BCr-medizin/ https://www.tum.de/
Westfälischen Wilhelms-Universität Münster	https://www.medizin.uni-muenster.de/fakultaet/start/ https://www.uni-muenster.de/de/
Carl von Ossietzky Universität Oldenburg	https://uol.de/medizin/ https://uol.de/
Universität Regensburg	https://www.uni-regensburg.de/medizin/fakultaet/ https://www.uni-regensburg.de/
Universitätsmedizin Rostock	https://www.med.uni-rostock.de/ https://www.uni-rostock.de/
Eberhard Karls Universität Tübingen	https://www.medizin.uni-tuebingen.de/de/ https://uni-tuebingen.de/
Universität Ulm	https://fakultaet.medizin.uni-ulm.de/ https://www.uni-ulm.de/
Universität Witten/Herdecke	https://www.uni-wh.de/gesundheit/department-fuer-humanmedizin/#profil https://www.uni-wh.de/
Julius-Maximilians-Universität Würzburg	https://www.med.uni-wuerzburg.de/startseite/ https://www.uni-wuerzburg.de/startseite/

Conflict of Interest Policies at German medical schools – A long way to go

Codebook

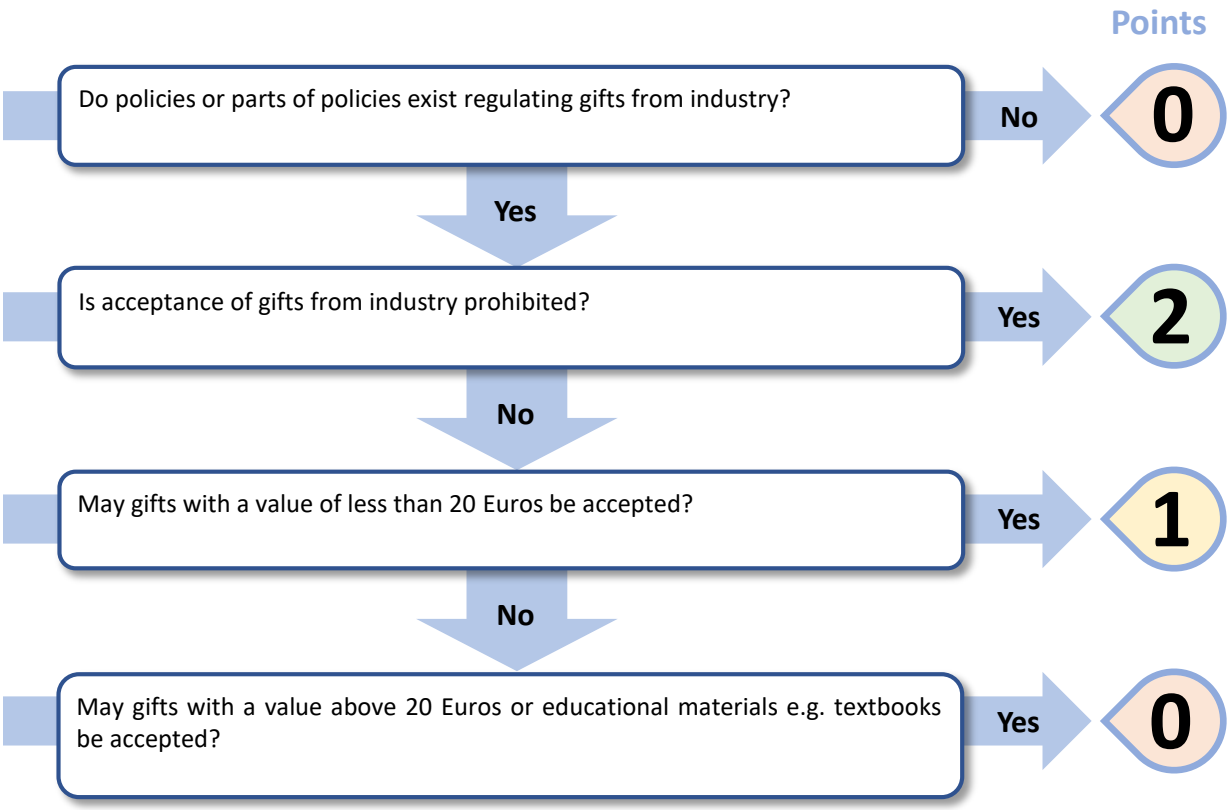
Version January 2018*

Working Group Conflicts of Interest
Universities Allied for Essential Medicines Europe

*Official Codebook in German

Table of contents

1. Gifts from industry

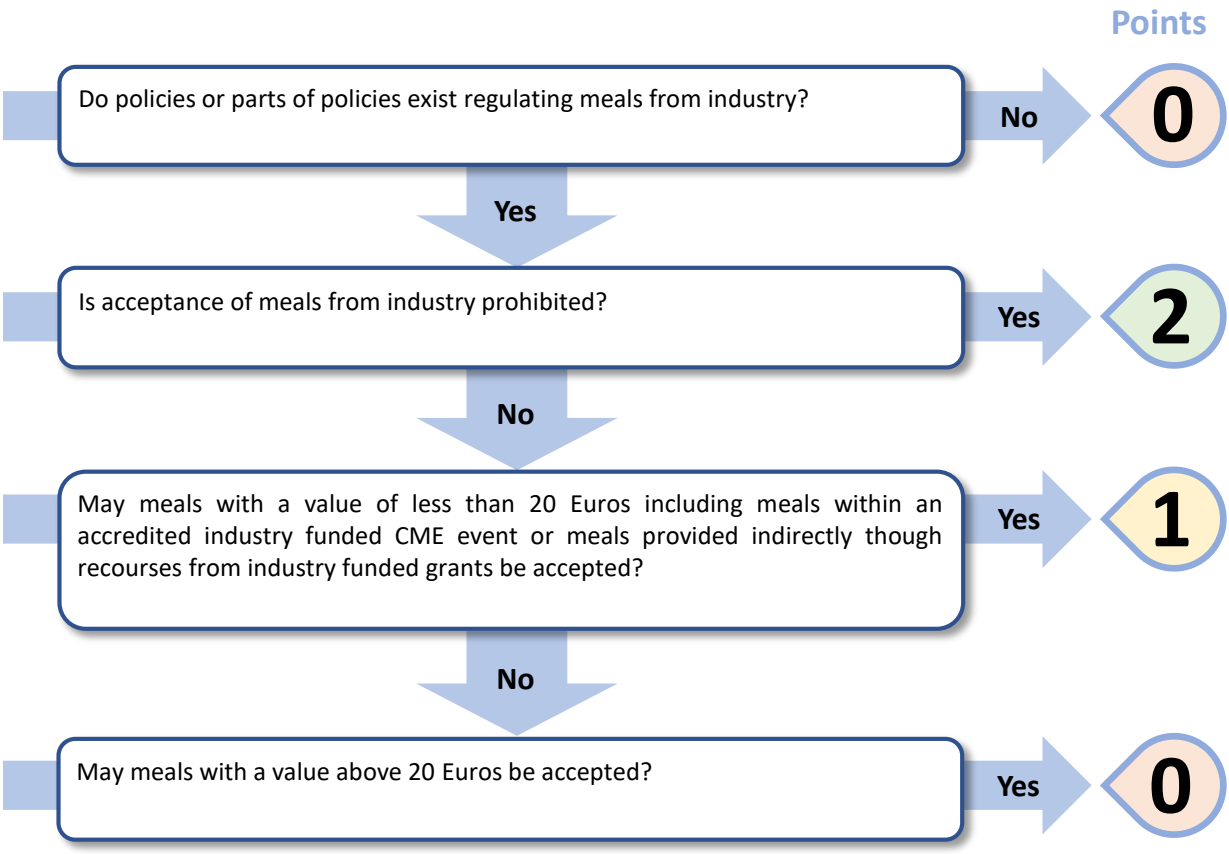


Definition:
Every object or service that is provided free of charge is considered to be a gift with the exception of meals (see criterion 2).

Notes:
Qualification for 2 points:

- Examples for prohibited gifts from industry:
  - Educational gifts to students or medical schools, e.g. textbooks, articles or online subscriptions. Policies that allow educational gifts score 0 points regardless of the recipient (individual person or institution) and also if the identity of the donor is not disclosed on or in the gift.
- Examples for permitted gifts from industry:
  - Gifts primarily addressing patients e.g. posters explaining a procedure or showing an anatomic model.
  - Small gifts like conference bags or bottles of water.

2. Meals from industry

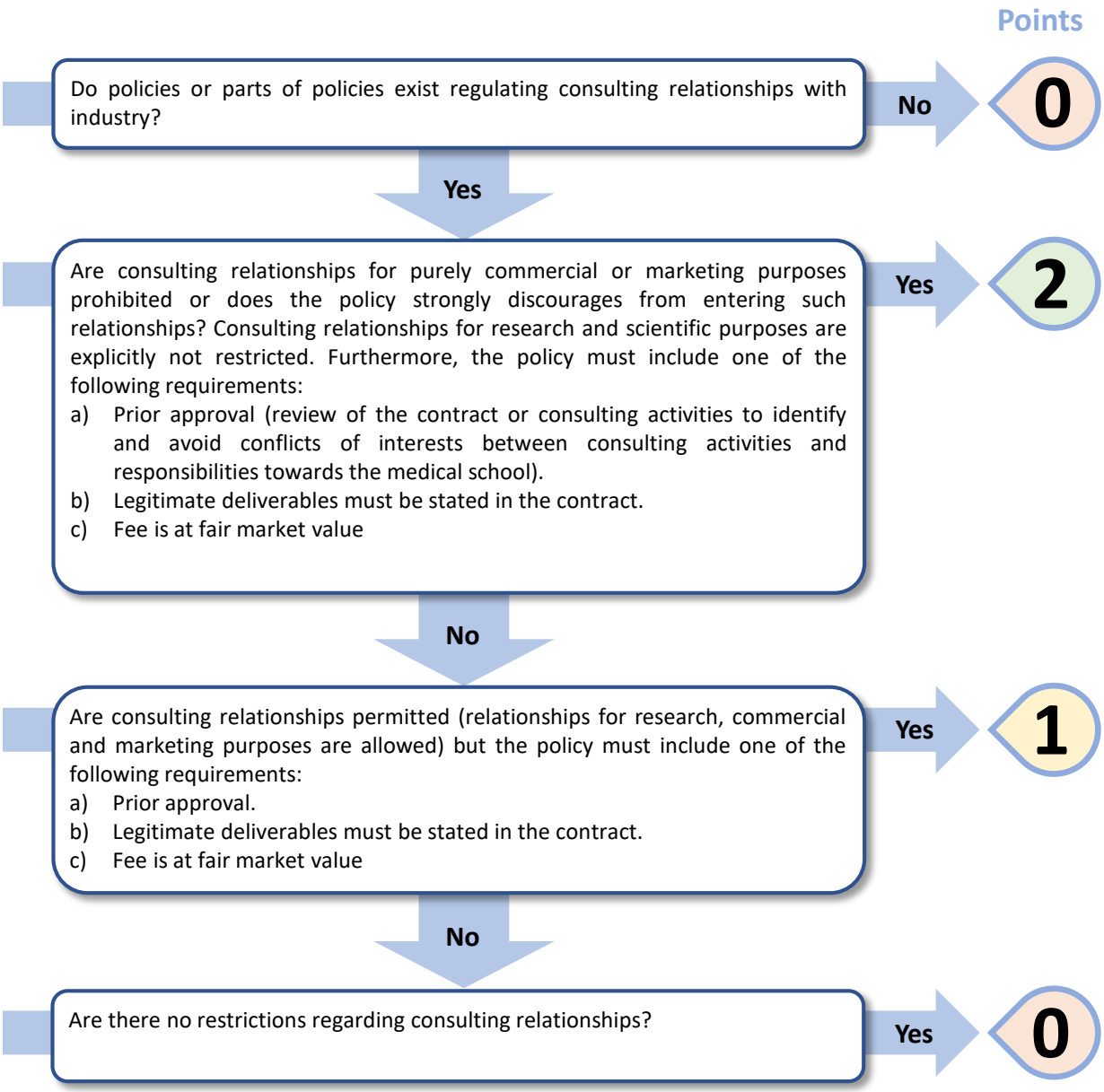


Definition:
This criterium considers meals during CME and non-CME events as well as meals provided on and off campus.

Notes:
Qualification for 2 points:

- Examples for **prohibited** meals form industry:
  - Every industry sponsored meal on campus.
  - Industry sponsored meals during promotional events off campus (e.g. dinner with promotional presentation).
  - Meals in the course of industry-sponsored CME events if not paid by a non-industry party such as medial societies, organizing departments or through participation fees.
- Examples for **permitted** meals form industry:
  - Industry sponsored meals during large academic events such as annual meetings of medical societies if the meals are provided to every participant.
  - Industry sponsored meals which are part of an approved research contract.
  - Meals that are anonymously provided by more than one industrial sponsor.

3. Consulting relationships



Note: please continue on page 6

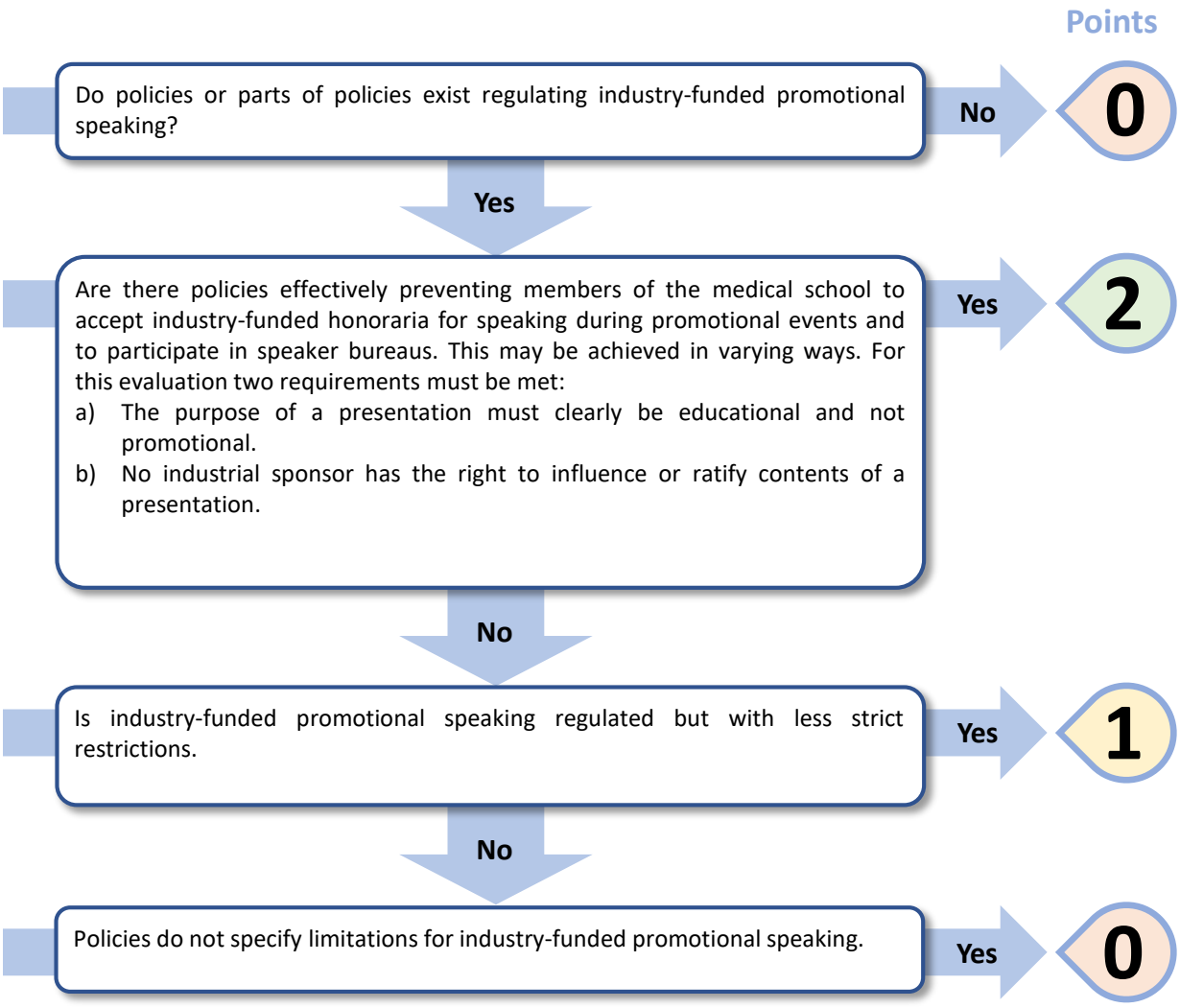
3. Consulting relationships

Notes:
Within this study consulting relationships are evaluated separately from industry-funded promotional speaking. Some Institutions regard theses speaking relationships as part of consulting. In this case the part of a policy that addresses speaking relationships is not relevant for this criterion but will be evaluated within criterion 4.

Qualification for 2 points:

- **Permitted** consulting relationships:
  - A policy does not have to state explicitly that consulting relationships are prohibited but should include terms like “for scientific purposes”.
  - Some scientific consulting relationship might include marketing components (e.g. if a scientist is involved in the development of a new surgical instrument and helps the manufacturer to create contents to advertise for the tool’s properties). These consulting relationships are acceptable within a model policy as the core of the consultation is scientific in nature.
- **Prohibited** consulting relationships:
  - Consulting with the sole aim to help marketing a commercial product without scientific background (e.g. consulting with regard to different channels of advertisement and their effective use).

4. Industry-funded promotional speaking



Notes:

This section does not refer to accredited CME events. In German and English language different terms are linked to industry-funded promotional speaking such as “speaker bureaus”, “promotional talks”, peer-to-peer education or “lunch and learn” in English and “Lunch-Symposium” or “Satelliten-Symposium” in German. Some policies include limitations for compensation and reimbursement. Yet, criteria a) and b) must be met to score 2 points.

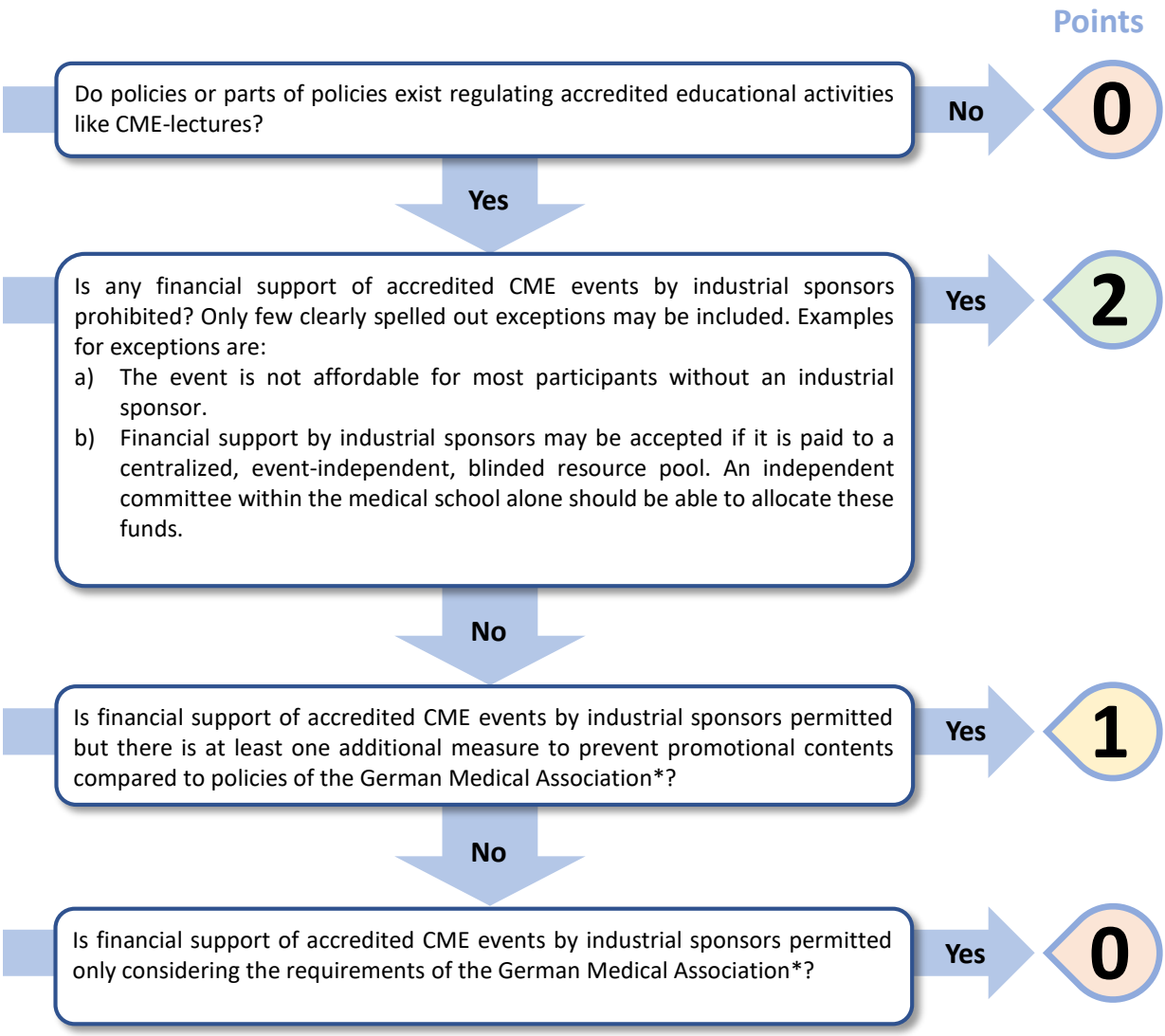
Qualification for 2 Points:

- Industry-funded speaking has to be purely educational without promotional aspects. To address this requirement policies may include terms like “scientific”, “objective” or “independent”. Within this study policies with such terms will be regarded as sufficient to prevent promotional speaking and therefore qualify for 2 points.

Qualification for 1 point:

- Policies that discourage from industry-funded promotional speaking qualify for 1 point. For 2 points policies must prohibit industry-funded promotional speaking.

5. Accredited educational activities like CME-lectures



Note: please continue on page 9

5. Accredited educational activities like CME-lectures

Notes:

Qualification for 2 points:

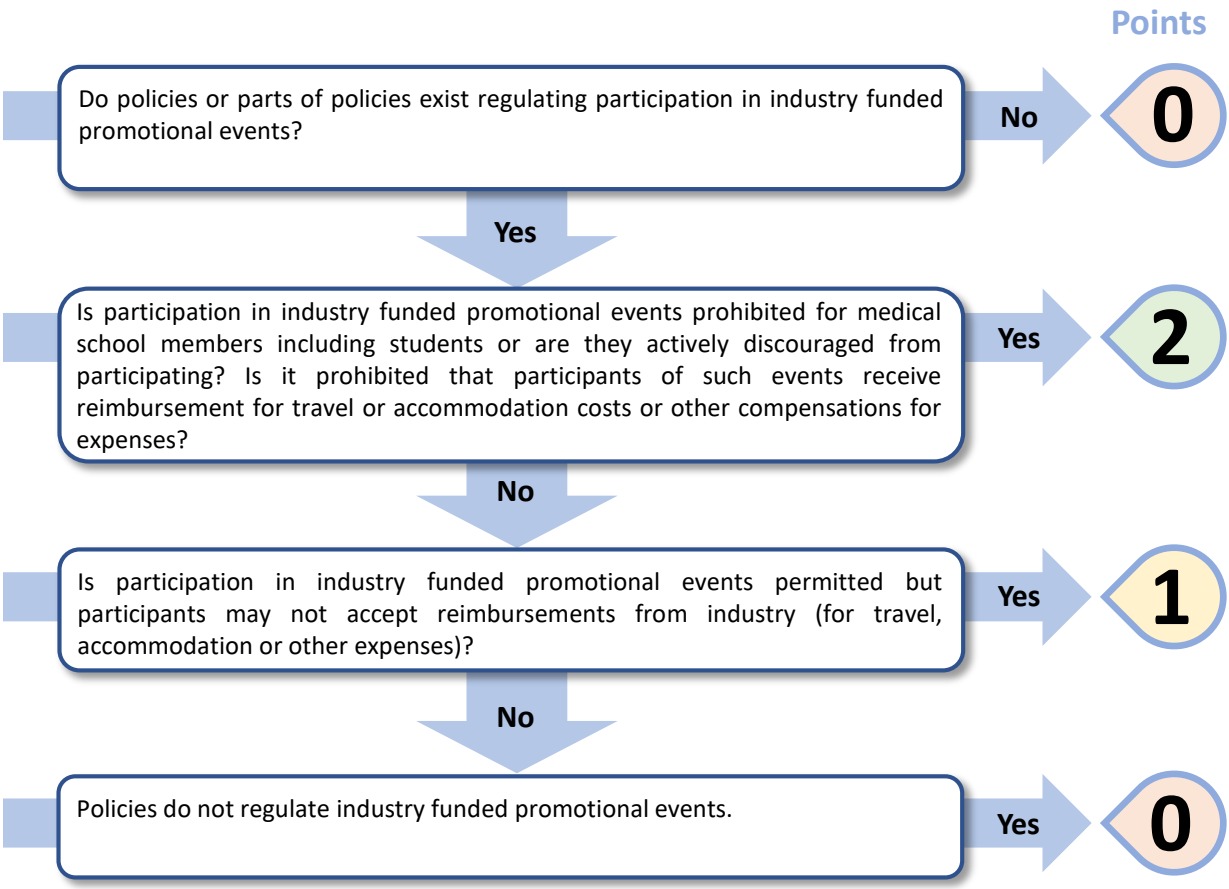
- **Prohibited** financial support for CME events by industrial sponsors:
  - The sponsor determines content or topic of the event or chooses a specific department as recipient of the financial support.
- **Permitted** financial support for CME events by industrial sponsors:
  - Industrial sponsors pay financial support to a blinded, independent resource pool that allocates funds without influence by the sponsors.
  - Support for educational or method training, that is unavailable for the institution without the collaboration with an industrial sponsor.

Qualification for 1 point:

- **Permitted** financial support for CME events by industrial sponsors:
  - Financial support by industrial sponsors according to the recommendations of the German Medical Association (Bundesärztekammer) and one additional measure to strengthen the educational character of an CME event. Examples of such measures are:
    - More then one sponsor has to fund the event.
    - Financial support has to be managed by a central CME office within the medical school and not by the department or the persons organizing the event.
    - Participants themselves have to cover some of the costs (e.g. meals, registration, …).

*[https://www.aerztekammer-berlin.de/10arzt/25_Aerztl_Fb/30_Downloads/10_EmpfehlBAEKFobi.pdf, accessed January 29, 2020]

6. Participation in industry funded promotional events



Notes:

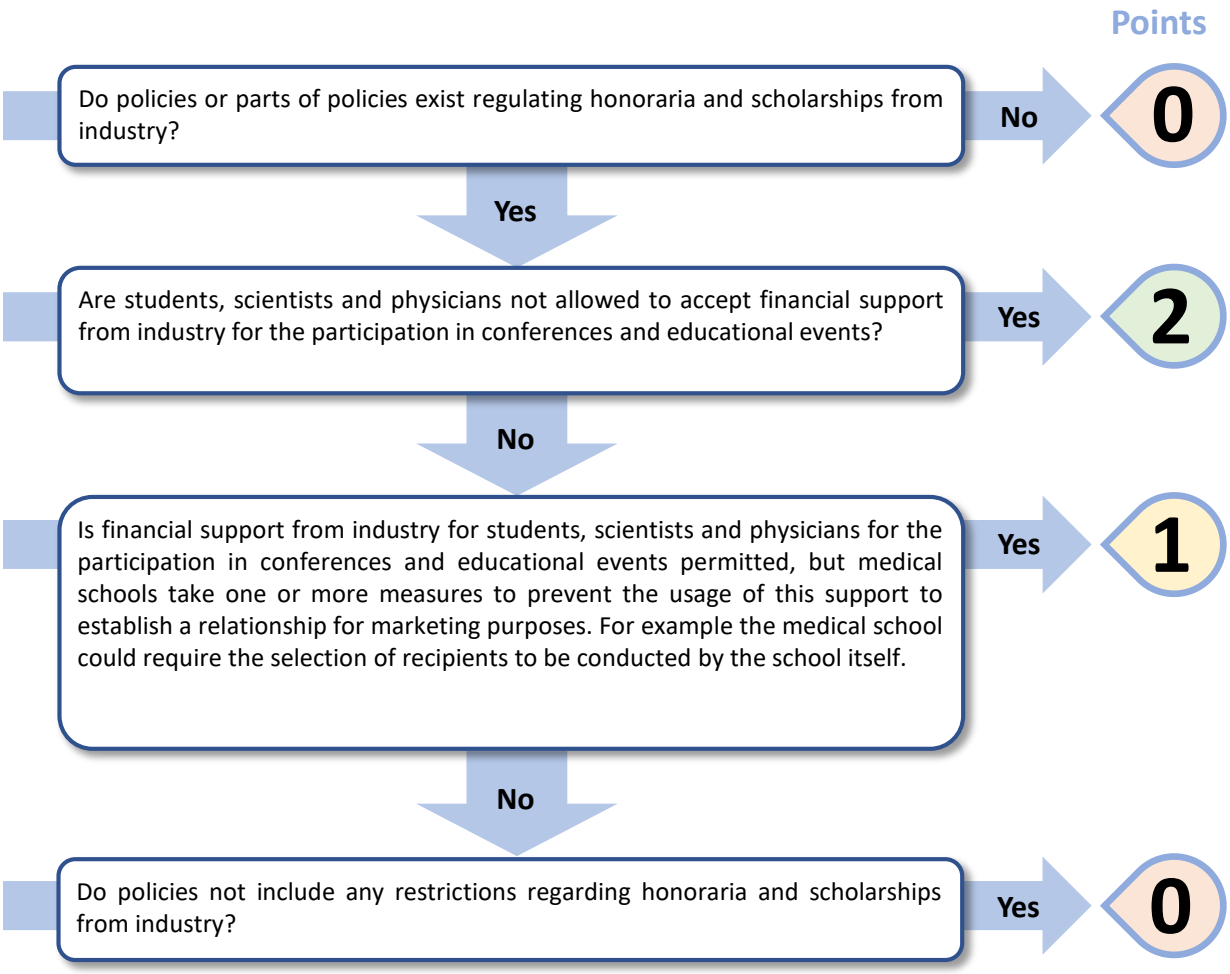
Qualification for 2 points:

- The policy has to prevent or actively discourage medical school members including students from participating in non-accredited CME events that are hosted by industry (this excludes annual meetings of scientific and medical societies, if they offer accredited educational events next to an industry-sponsored program)
- This criterion does not cover events where medical school members are invited as speakers. (See 4. Industry-funded promotional speaking)

Qualification for 1 point :

- Policies permitting the participation in industry funded events which are advertised as “promoting evidence-based medical practice” or “based on scientific research” do not prohibit participation in promotional events and therefore score “1” point.
- If the police encourages individuals to critically evaluate the scientific character of an industry-funded event, the policy does not actively discourage from participating in industry funded promotional events and therefore scores “1” point.

7. Honoraria and scholarships from industry

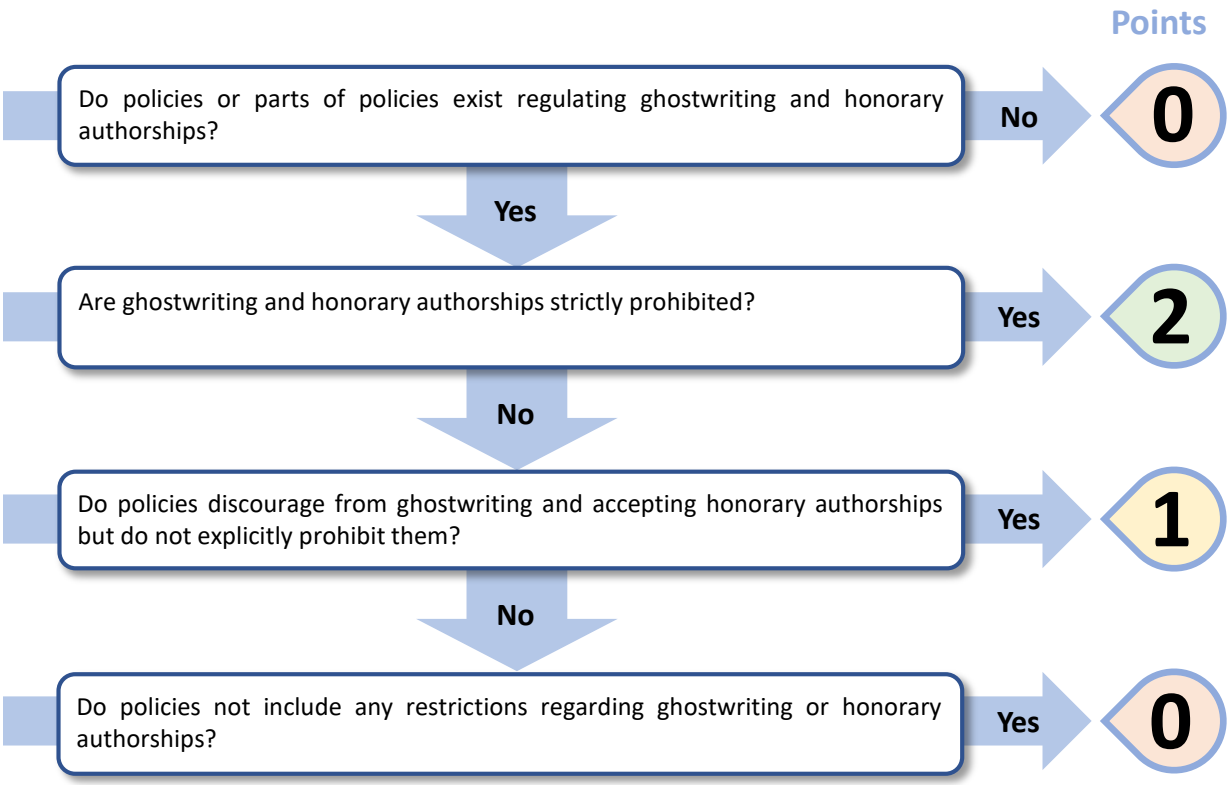


Definition:
This criterion refers to financial support from industry for travel costs and attendance fees for scientific conferences and educational events.

Notes:
Qualification for 2 points:
- Examples for **prohibited** support by industry:
  - Stipends from industry for the participation of students, scientists and physicians in scientific conferences and educational events. If such support is permitted but the sponsor has no influence on the selection of awardees, the policy qualifies for "1" point.
- Examples for **permitted** support by industry:
  - Competitive, performance-based support exclusively for scientific and medical education. The sponsor has no influence on the selection of recipients and the sponsor remains anonymous.
  - Support for educational events concerning medical devices that were acquired by the institution.

Qualification for 1 point:
- Policies permit financial support by industry, but the sponsor has no influence on the selection of recipients.

8. Ghostwriting und honorary authorships



Notes:

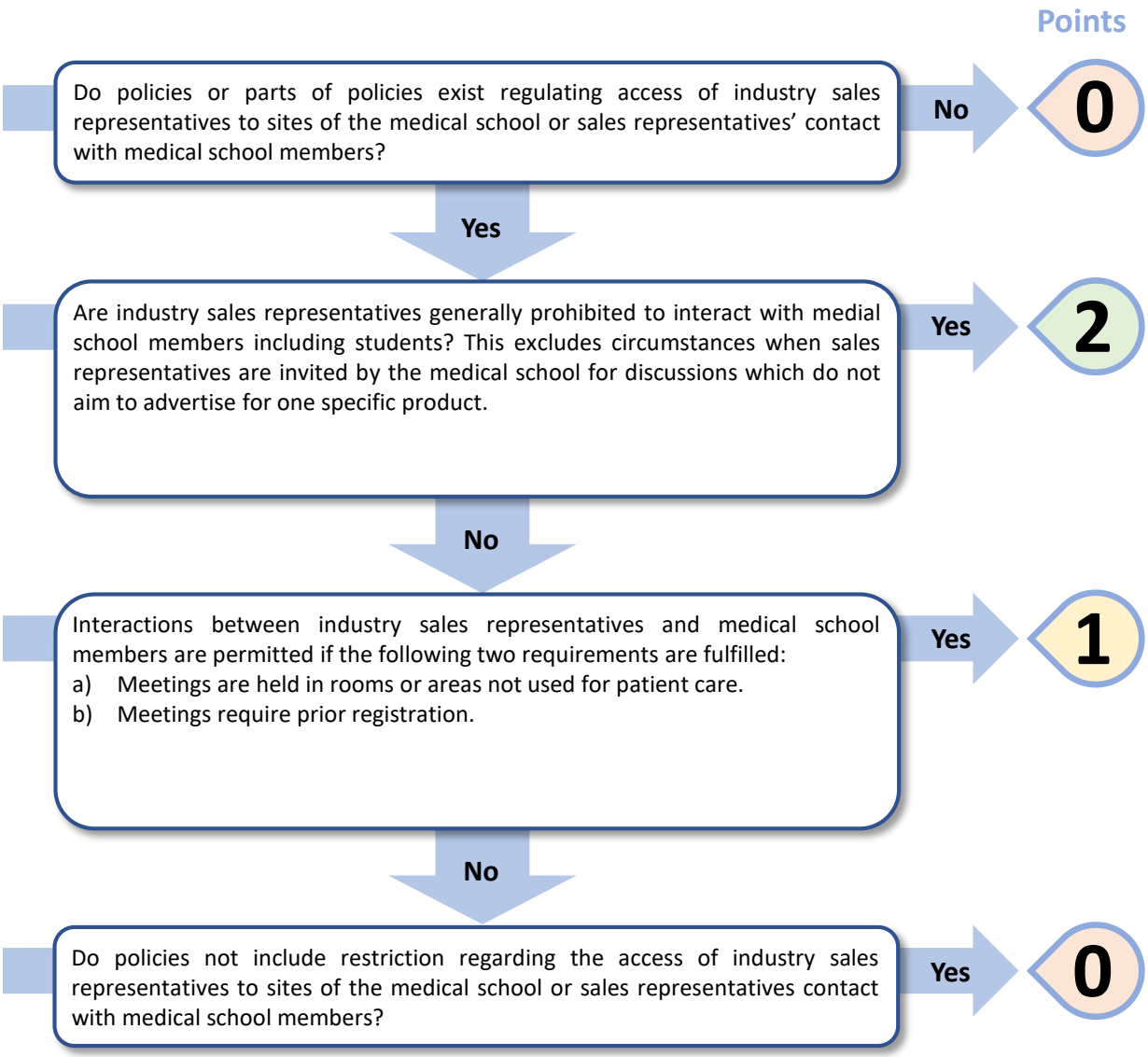
Qualification for 2 points:

- Policies clearly state that ghostwriting and honorary authorships are not permitted or that medical school members have to adhere to the standards of the International Committee of Medical Journal Editors (http://www.icmje.org/).

Qualification for 1 point:

- Policies permit the publication of scientific articles written by industry if this is clearly declared within the article.

9. Industry sales representatives

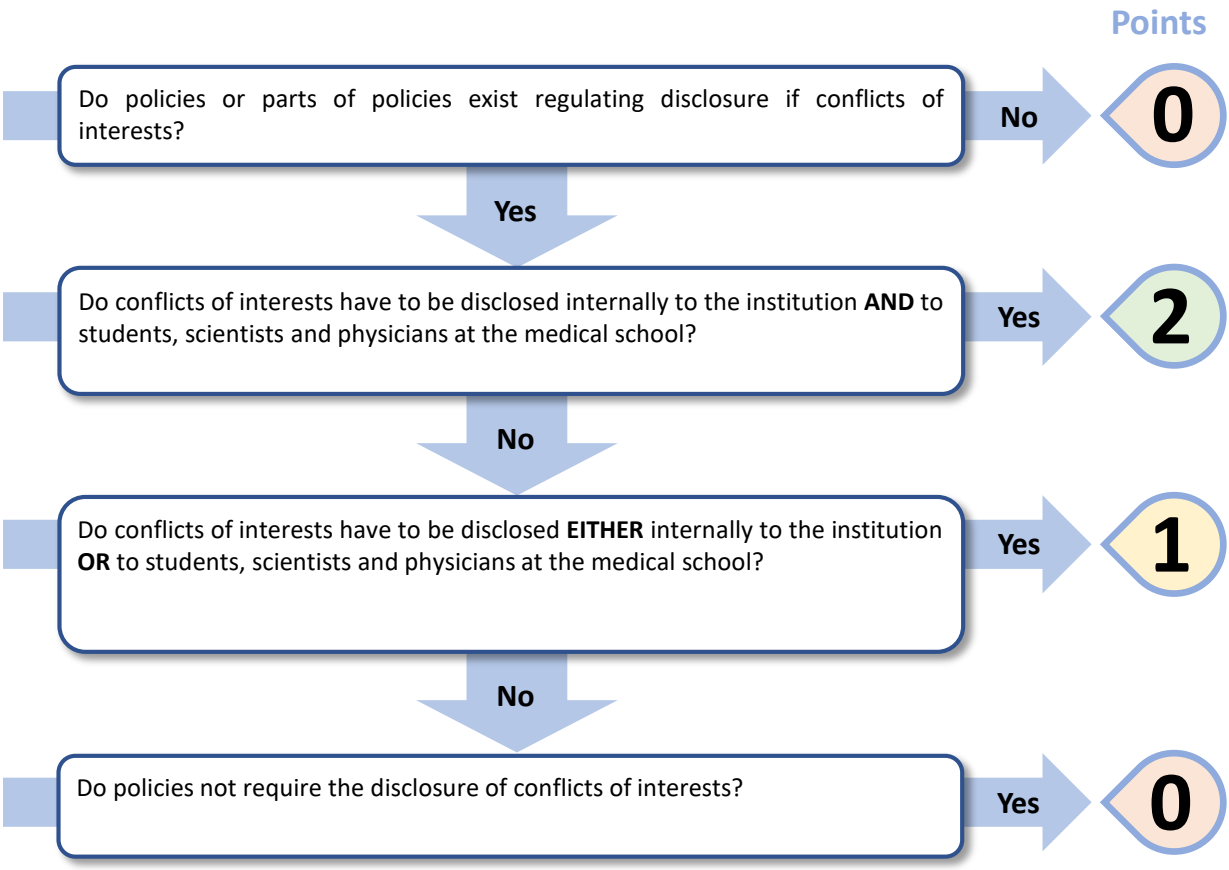


Notes:
Regularly, industry sales representatives are required to wear visible identification. Such policies do not score "2" points because for this analysis identification is not considered being equal to prior registration.

Qualification for 2 points:

- **Permitted** access of industry sales representatives:
  - Policies may permit access of industry sales representatives to committees of purchase or pharmaceutical departments to present information on new products that the institution considers for purchase.
  - Policies may permit access to the medical school and the university medial center to deliver samples as long as these are handed over to a centralized office and no marketing interaction takes place.

10. Disclosure of conflicts of interests



Notes:

"Internal" disclosure:

- Refers to disclosure of conflicts of interests of a medical school member to the institution.

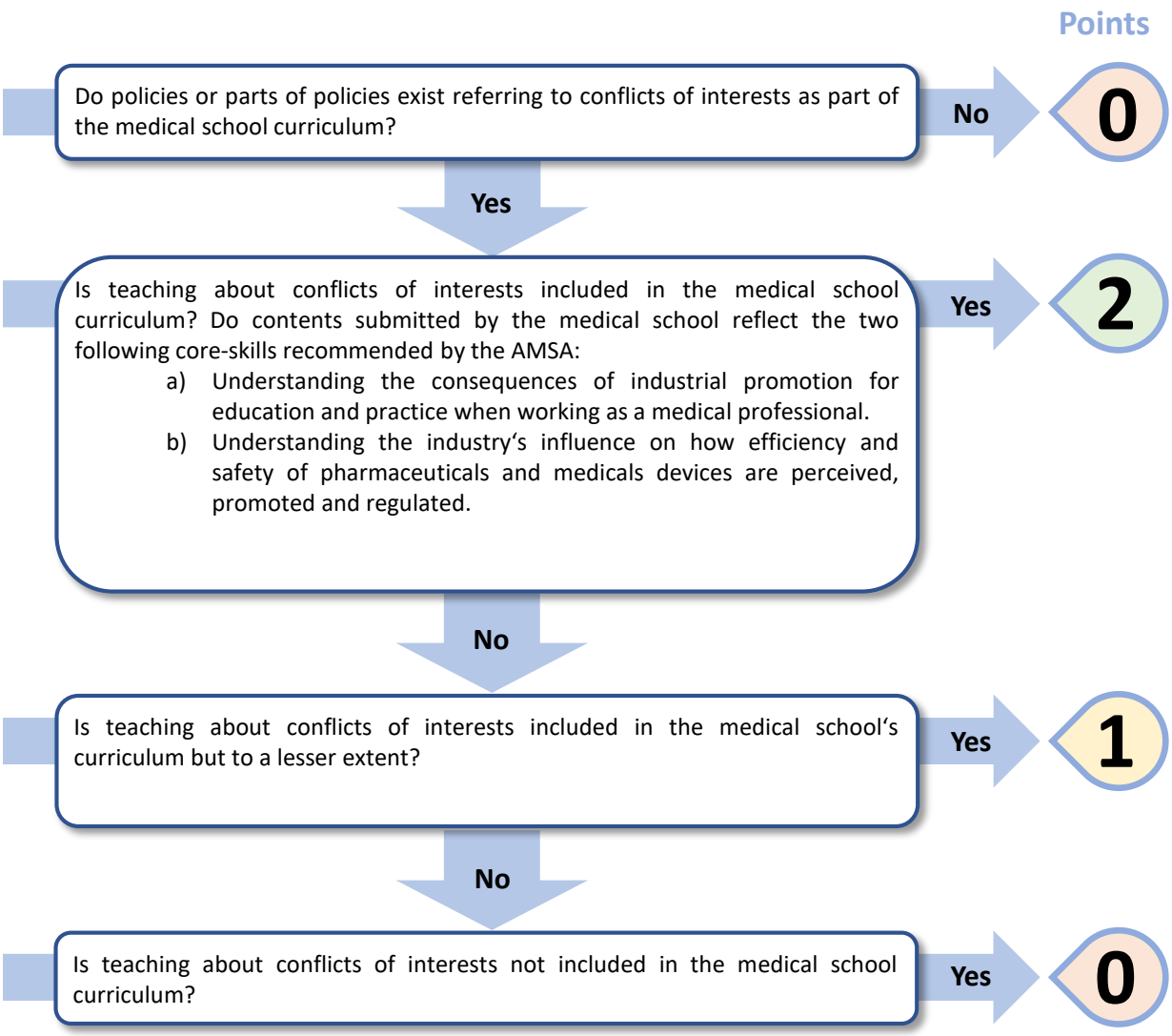
"External" disclosure:

- Disclosure to students, scientists and physicians: Refers to disclosure on slides during presentation or oral disclosure.

General:

- Disclosure of conflicts of interests within a publication is not regarded as relevant "external" disclosure within the medical school in this category.
- Disclosure on a publicly available website is not sufficient to fulfil the requirements for "external" disclosure.

11. Medical school curriculum on conflicts of interests



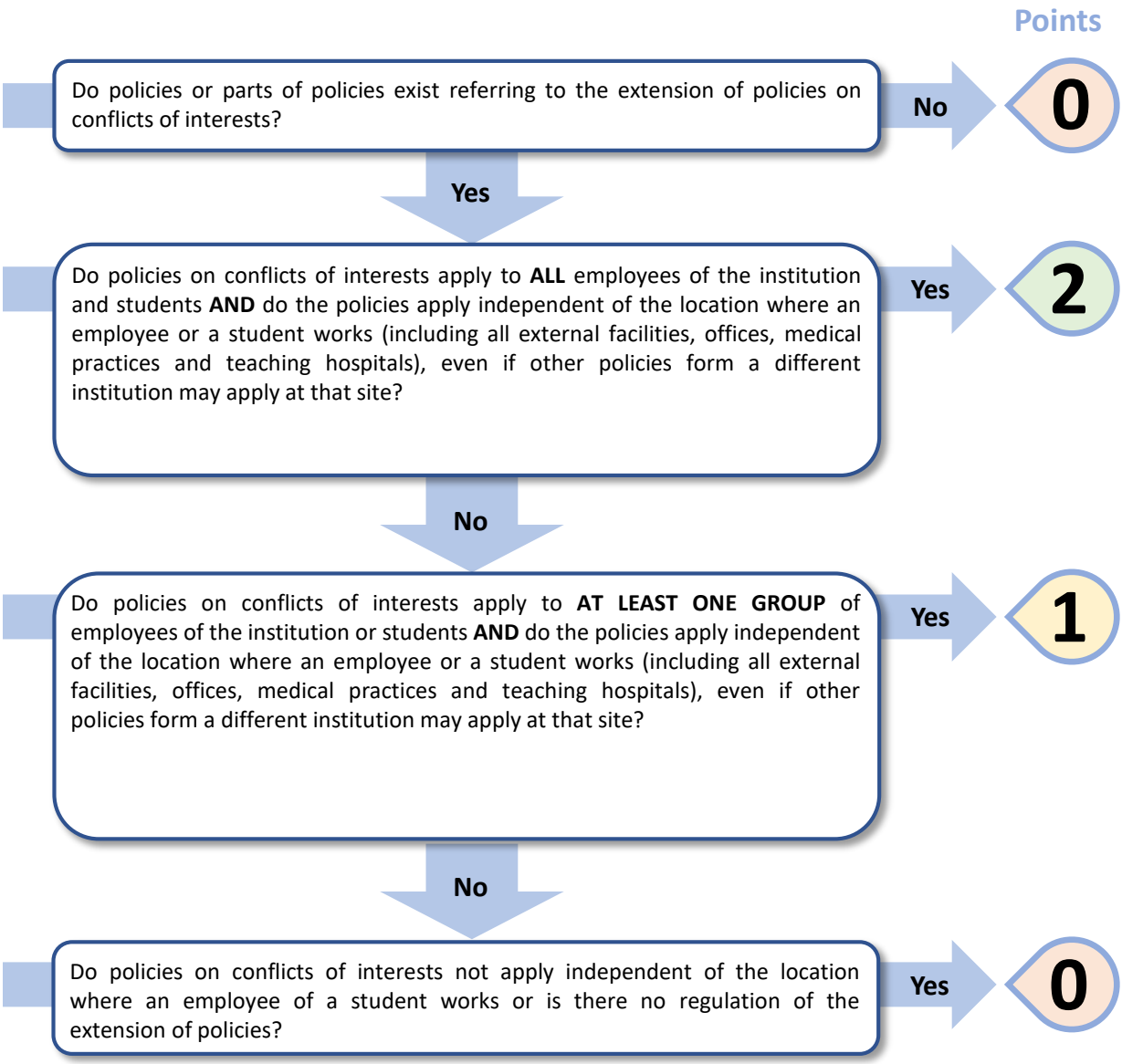
Notes:
Policies explicitly have to apply to medical students.
AMSA: American Medical Student Association

Qualification for 2 points:
Policies have to require a curriculum to include teaching the two above mentioned skills. This may also be reflected indirectly by teaching materials submitted by the medical school. Detailed recommendations of the AMSA for a model curriculum can be accessed here: https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf, accessed January 29, 2020

During the survey, medical schools are asked whether or not their curriculum addresses conflicts of interests. The answer to this question will be considered for this category since most medical schools do not have policies clearly stating on conflicts of interest as obligatory component of the curriculum.

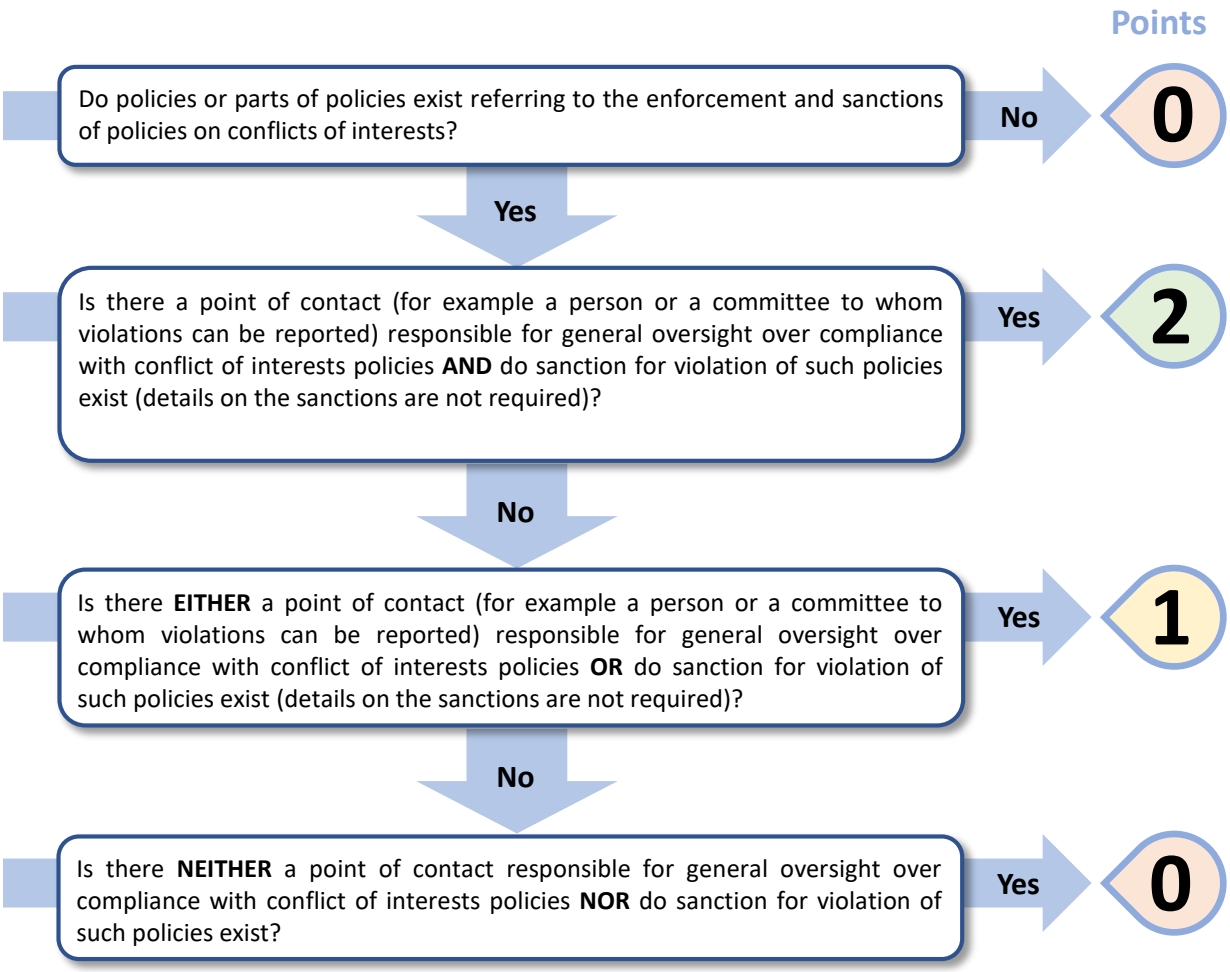
Qualification for 1 point:
Policies requiring regular training about conflicts of interests for scientists, physicians or other non-student medical school members do not qualify for "1" point.

12. Extension of policies



Notes:
A model policy will explicitly state that policies on conflicts of interests apply independent of the location. As an example, at medical schools with policies prohibiting the acceptance of meals sponsored by industry, students would not be allowed to do so also when they work outside of their university medical center e.g. during rotations in their practical year or during internships at hospitals where less strict policies might apply.

13. Enforcement and sanctions of policies



Notes:

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	See:
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Explained
Objectives	3	State specific objectives, including any prespecified hypotheses	Objectives stated.
Methods			
Study design	4	Present key elements of study design early in the paper	Clearly outlined survey, web search
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Dates of web-search and survey given, setting: German medical schools clarified, Responsibilities and mode of data collection clarified.
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	All German medical schools listed as members of Medizinischer Fakultätentag
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	See codebook in supplementary material and method section outlining criteria
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*See codebook*
Bias	9	Describe any efforts to address potential sources of bias	Data extraction and analysis

			was double-coded. We pre-specified analysis criteria within our codebook.
Study size	10	Explain how the study size was arrived at	All medical schools listed as members of Medizinischer Fakultätentag
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	NA
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	See flow diagram
		(b) Give reasons for non-participation at each stage	See flow diagram
		(c) Consider use of a flow diagram	See flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	See results section
Outcome data	15*	Report numbers of outcome events or summary measures	Absolute numbers given
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	See results
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			

Key results	18	Summarise key results with reference to study objectives	See first paragraph
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	See: limitations
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	See paragraph on comparison with other studies.
Generalisability	21	Discuss the generalisability (external validity) of the study results	See paragraph on comparison with other studies.
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No funding

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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QUANTITY AND QUALITY OF CONFLICT OF INTEREST POLICIES AT GERMAN MEDICAL SCHOOLS - A CROSS SECTIONAL STUDY AND SURVEY

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ABSTRACT

Objectives: To assess the quantity and evaluate the quality of policies and curricula focussing on conflicts of interests (COI) at medical schools across Germany.

Design: Cross-sectional study, survey of medical schools, standardized web search.

Setting: Medical schools, Germany.

Participants: 38 German medical schools.

Interventions: We collected relevant COI policies including teaching activities by conducting a search of the websites of all 38 German medical schools using standardized keywords for COI policies and teaching. Further, we surveyed all medical schools' dean's offices. Finally, we adapted a scoring system for results we obtained with 13 categories based on prior similar studies.

Main outcomes and measures: Presence or absence of COI related policies including teaching activities at medical school. The secondary outcome was the achieved score on a scale from 0 to 26 with high scores representing restrictive policies and sufficient teaching activities.

Results: We identified relevant policies for one medical school via the web-search. The response rate of the deans' survey was 16 of 38 (42.1%). In total, we identified COI-related policies for 2 of 38 (5.3%) German medical schools, yet no policy was sufficient to address all COI-related categories that were assessed in this study. The maximum score achieved was 12 of 26. 36 (94.7%) schools scored 0. No medical school reported curricular teaching on COI.

Conclusions: Our results indicate a low level of action by medical schools to protect students from undue commercial influence. No participating dean was aware of any curriculum or instruction on COI at the respective school and only 2 schools had policies in place. The German Medical Students Association and international counterparts have called for a stronger focus on COI in the classroom. We conclude that for German medical schools there is still a long way to go.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first standardized qualitative analysis of medical school COI policies in Germany.
- The cross sectional study comprises structured web-searches and surveys of deans' offices.
- The study design is based on previous studies in other countries and therefore allows for international comparison.
- Despite combining multiple approaches of data collection, teaching activities and policies may have been missed.
- Since this study focused on COI policies that apply to the specific setting of medical schools, other state or university wide policies were not included.

INTRODUCTION

Contacts between pharmaceutical or medical device industry and healthcare professionals have long been a point of discussion, as they may lead to conflicts of interest (COI). According to the widely accepted definition from the Institute of Medicine, COI are circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.[1] In healthcare COI may exist between the physician's

commitment to patient care and industry's interest in selling their products. There is mounting evidence indicating an adverse effect of pharmaceutical promotion on physicians' prescribing behaviour.[2] Patients may suffer from the consequences directly due to exposure to unnecessary risks as well as indirectly through a higher financial burden for health care systems.[2] Simultaneously, universities and medical schools in particular are increasingly expected to conduct translational research from "bench to bedside" - a paradigm that includes market commercialization and requires industry collaborations which makes contact with the private sector inevitable. Therefore, COI present challenges towards medical professionalism.[3]

In order to protect independent patient care, professional handling of COI by physicians is essential. It has been argued, that physicians' attitudes towards the pharmaceutical industry and their inclination to be influenced by marketing efforts manifest early during their professional training.[3] A large body of evidence exists showing that medical students themselves are in contact with industrial companies on a regular basis.[3–11] Contacts increase in the course of studies, with more interactions during the clinical part of their studies.[4,12,13] A study by Lieb et al. [7] at eight German medical schools revealed that only 12% of surveyed students had never received a gift or attended a sponsored event. The authors also report that 60% of these students had a promotional gift handed on to them by a physician they worked with, who received the gift by a company beforehand. [7] Professors and other physicians act as role models students base their attitudes and actions on - not only regarding their clinical work, but also regarding interactions with industry and COI. The actions of those role models constitute a "hidden curriculum" and conceptualize what is perceived to be normal.[14] The extent to which teaching faculty in Germany has financial ties to industry actors remains largely unclear. Despite frequent debates, there is currently no German equivalent to the Physician Payments Sunshine Act in the United States of America, where information on payments from industry to physicians is collected, categorized and made publicly available by law.[15] Data reported by CORRECTIV based on voluntary disclosures indicate that physicians, pharmacists and other healthcare professionals together with their respective institutions received a minimum of 562 million euro in 2016 alone.[16] How many of these providers had teaching responsibilities at medical schools is largely unknown. Such relationships may affect academic and publishing interests, the content faculty chooses to disseminate to medical students and their general professional medical opinions.[17,18] Overall, COI of teaching staff are not commonly disclosed to medical students in Germany.

Previous studies report that 65% of surveyed medical students in Germany felt inadequately prepared for interactions with the pharmaceutical industry.[19] 90% of those students in Germany reported that dealing with industrial marketing practices had never been addressed during their lectures.[19] In another survey, 14.4% of the participating German medical students noted that they attended a lecture or courses dealing with COI; of those classes, however, 90% were optional.[20] Altogether, it remains unclear to what extent German medical schools include COI topics in their curricula. Aside from teaching about industry practices of marketing and promotion, restrictive COI policies at the medical school level have been suggested to increase students' awareness of the consequences of inappropriate marketing practices in the learning environment.[21] Some studies indicate that COI policies at medical schools have a significant impact on prescribing practices by inoculating physicians against persuasive aspects of pharmaceutical promotion.[22–24] In Germany, Lieb et al. found that in 2013 only two out of 36 medical schools reported having a COI policy.[20] However,

none of these schools reporting a policy (TU Dresden and RWTH Aachen) supplied the policies themselves and hence, the content and strength of the policies remain unclear. The objective of this study was to determine whether medical schools in Germany have institutional COI policies in place and to assess the strength of the policies obtained by means of 13 pre-defined criteria including the existence of teaching activities.

METHODS

Our methodology built upon criteria used in earlier studies on COI policies such as the American Medical Students Association (AMSA) scorecard [25], the Canadian scorecard by Shnier et al. [26], and the French conflict of interest ranking by Scheffer et al.[27] A list of the 38 German medical schools was obtained from the website of the German Medical Faculty Association (Medizinischer Fakultätentag).[28] After formal exchange with a member of the German Ethics Council about the nature of this study, which only involves policies at an institutional level rather than patient data or other personal information, it was deemed unnecessary to ask for formal approval from an ethics committee.

Patient and Public Involvement

Neither patients nor public were involved in conceptualizing or conducting this study.

Web-based search

Two researchers (LS, MS) independently searched the websites of the respective medical schools (or if non-existent, the websites of the respective universities) using the sites' integrated search engines in June 2018 to identify policies related to COI, documents interpreting policies or material published regarding COI in the curriculum. Addresses of the websites searched are listed in Supplementary File 1. Search terms included "Interessenkonflikt"/"Interessenskonflikt" (conflict of interest), "Industrie" (industry), and "interne Regulierung" (internal regulation) based on previous publications.[27] If a policy was in place, it was recorded together with the latest date of review. Only policies that specified their validity for medical schools were considered relevant for this study. Therefore, policies applying to an entire university or only to a university hospital were excluded. Disagreement about inclusion of the recorded sources was discussed with all authors. Those sources included were later assessed via the methodology previously determined through the scoring criteria in our codebook (as described in 'results', see Supplementary File 2).

Contacting medical schools

In May 2018, we contacted each office of the dean of medicine to inform them about the study through a written letter (see Supplementary Files 3 and 4). The letter gave background information about the study's purpose and outlined the criteria for which we needed documentation. We asked the medical school to send any form of policy (or parts of a policy) relating to the management of COI, as well as information on enforcement of the policy. Furthermore, the letter included the request to provide information on curriculum contents addressing the consequences and management of COI. We did a maximum of three follow-ups for non-responders. We first sent an email in June 2018 reiterating the content of the letter previously sent. We then followed up via email in July 2018 and enclosed two letters of

support, one from David Klemperer and one from Barbara Mintzes, co-author of the study which analyzed conflict of interest policies at Canadian medical schools and editor of a teaching manual on pharma promotion.[29] In August 2018, we followed up by sending the results of the web-based search. Representatives of the dean's offices were given the opportunity to confirm, correct or comment on our web-based findings. In addition to searching the websites and contacting the offices of the deans of medical schools, we sought information via personal contacts and experts in the field. Data cut-off was October 2018. We excluded policies from affiliated teaching hospitals, because they are not under the authority of the dean of the medical school. Further, we excluded any policies or parts of policies that did not specifically apply to a medical school.

Scoring system

We adapted a scoring system based on criteria used in earlier studies by Scheffer et al. [27] and Shnier et al. [26] in the French and Canadian context respectively, as well as the AMSA Scorecard.[25] The following categories were addressed:

1. Gifts from industry
2. Meals from industry
3. Consulting relationships
4. Industry-funded promotional speaking
5. Educational activities like CME-lectures
6. Participation in industry-funded promotional events
7. Honoraria and scholarships from industry
8. Ghostwriting and honorary authorships
9. Industry Sales Representatives
10. Disclosure of COI
11. Medical school curriculum on COI
12. Extension of policies
13. Enforcement of policies

Of note for category 11 "Medical school curriculum on COI": German medical schools are not likely to implement policies that describe COI as an obligatory component of the curriculum. We accounted for this by a) asking schools to provide information on curriculum contents addressing the consequences and management of COI and b) noting curricular teaching activities identified via the web-search. Evidence of curricular teaching was graded as outlined in the codebook, page 15 (see Supplementary File 2).

Subsequently, we graded the results for each category through our scoring system from 0 to 2. Generally, "0" means no policy or a permissive policy, "1" a moderate policy and "2" a restrictive policy. Medical schools with no identified policy or curriculum in both survey and web-search were also rated with a score of 0. The translated codebook in English, outlining the decision pathway for each category is available as Supplementary File 2. Three reviewers (LH, TW, ST) independently undertook the scoring of the medical schools' policies. All authors then reviewed the scoring. Any disagreement was resolved through discussion and majority vote. We then summed up the scores of all individual categories for each medical school to create a global score, with a range of 0 to 26 points. No weighting of single categories was performed.

RESULTS

Web-based search

The web-based search on medical school's websites was conducted to identify publicly available COI policies and evidence for curricular teaching activities addressing COI at German medical schools . The search yielded relevant results for one of the 38 medical schools: an anti-corruption brochure and a third-party funds statute from Charité-Universitätsmedizin Berlin (Figure 1). Additional articles and publications were identified but excluded from analysis, because they either did not relate to predefined criteria or did not specifically apply to the entire medical school. Our web-based search strategy revealed no information on relevant compulsory curricular teaching activities addressing COI that could receive a score (cf. Codebook page 15, Supplementary File 2). Only one non-compulsory elective course at Friedrich-Schiller-Universität Jena was identified.

Contacting medical schools

German medical schools were contacted to provide validated insight into existing COI policies. The total response rate was 42.1% (16 of 38). Twelve of the responding medical schools did not send policies. Four medical schools (10.5%) included policies dealing with COI, of which three (an anti-corruption directive and a monetary benefit acceptance policy from the Ludwig-Maximilian-Universität München, a code of practice as well as an anti-corruption directive from the Julius-Maximilians-Universität Würzburg, a compliance brochure, gifts and benefits acceptance policy, and a third-party funds statute from the Friedrich-Schiller-Universität Jena) exclusively applied to university medical centres, not to the respective medical schools, and were therefore excluded from further analysis. One policy met inclusion criteria and comprised an anti-corruption directive issued by the medical school and university medical centre of the Technische Universität Dresden (Figure 1).

See table 1 for an overview of the answers received from the medical schools.

Table 1: Overview of the answers received from medical schools.

Medical school	Response contained a policy meeting inclusion criteria	If applicable: Response included a statement on curricular teaching activities
Medizinische Fakultät Carl Gustav Carus der Technischen Universität Dresden	yes	n.a.
Universitätsmedizin Greifswald	no	n.a.
Universität Hamburg	no	n.a.
Universität des Saarlandes (Homburg)	no	n.a.
Friedrich-Schiller-Universität Jena	no	n.a.
Ludwig-Maximilians-Universität München	no	n.a.
Westfälischen Wilhelms-Universität Münster	no	n.a.
Universität Witten/Herdecke	no	n.a.
Friedrich-Alexander-Universität Erlangen-Nürnberg	no	n.a.
Goethe-Universität Frankfurt	no	n.a.
Justus-Liebig-Universität Gießen	no	n.a.
Albert-Ludwigs-Universität Freiburg	no	No explicit curricular teaching on COI
Georg-August-Universität Göttingen	no	No explicit curricular teaching on COI

Christian-Albrechts-Universität zu Kiel	no	No explicit curricular teaching on COI
Julius-Maximilians-Universität Würzburg	no	No explicit curricular teaching on COI
Universität Augsburg	no	n.a.
The schools not mentioned in the table did not reply to any of our three emails sent. Those are: Universität Augsburg, RWTH Aachen, Charité – Universitätsmedizin Berlin, Ruhr-Universität Bochum, Rheinischen Friedrich-Wilhelms-Universität Bonn, Universität Duisburg-Essen, Heinrich-Heine-Universität Düsseldorf, Martin-Luther-Universität Halle-Wittenberg, Medizinische Hochschule Hannover, Ruprecht-Karls-Universität Heidelberg, Universität zu Köln, Universität Leipzig, Universität zu Lübeck, Otto-von-Guericke-Universität Magdeburg, Johannes-Gutenberg-Universität Mainz, Medizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg, Philipps-Universität Marburg, Technischen Universität München, Carl von Ossietzky Universität Oldenburg, Universität Regensburg, Universitätsmedizin Rostock, Eberhard Karls Universität Tübingen		

Of the total of 16 replies, 5 medical schools (13.2%) (Universität des Saarlandes, Albert-Ludwigs-Universität Freiburg, Georg-August-Universität Göttingen, Christian-Albrechts-Universität zu Kiel, Universität Witten/Herdecke) responded not having COI policies or that COI were not part of the curriculum. The Universität des Saarlandes stated that there was no separate policy for the medical school, while the Albert-Ludwigs-Universität Freiburg declared not having a COI policy within the medical curriculum, as well as no explicit lectures on COI. In addition, the Christian-Albrechts-Universität zu Kiel reported no existing COI policy within their medical school, neither was the topic taught in the medical curriculum. The reply from the Georg-August-Universität Göttingen stated that basic knowledge about pharmacoeconomics was taught, however, not mentioning corruption and transparency within the medical system. As stated by the Universität Witten/Herdecke, COI management lies with the contracted teaching hospitals. The Friedrich-Alexander-Universität Erlangen-Nürnberg replied that several policies apply within their university; however, no COI policy relevant to this study, issued by the medical school itself is externally available. The Universität Greifswald and the Medizinische Fakultät der Universität Hamburg initially asked for more time to reply, yet did not send material by the end of the data collection period. The Universität Augsburg was still in the process of setting up a medical curriculum, welcoming medical students starting in 2019 and was hence not able to report on COI policies or teaching activities. No further response as to whether a general COI policy existed was received. The Westfälische-Wilhelms-Universität Münster and the Goethe-Universität Frankfurt reported no capacities to take part in our study, while the Justus-Liebig-Universität Gießen actively decided against participating. The Universität Ulm addressed neither COI policies nor curriculum contents in their reply. The remaining medical schools did not respond to any request during the data acquisition period.

Analysis of COI policies

The two included policies were assessed according to a predefined scoring system as set out in our codebook (see Supplementary File 2). Results of each analysis are listed in Figure 2.

With 12 out of 26 points, the Technische Universität Dresden achieved the highest score. Charité Universitätsmedizin Berlin scored 4 points in total. All other medical schools did not supply a valid COI policy and had no retrievable information on COI policies on their websites according to inclusion criteria (Figure 1).
We did not acquire any information about obligatory teaching activities on COI through web-based search or the deans' survey. However, through personal contacts and seeking advice from experts, we received information on courses that cover COI at 3 medical schools (7.9%): Charité Universitätsmedizin Berlin, Universität Mainz and Universität Leipzig. These teaching activities are either lectures in which COI is discussed (Universität Leipzig, Universität Mainz,

Charité Universitätsmedizin Berlin) or elective courses that students can choose within their curriculum (Charité Universitätsmedizin Berlin, Universität Mainz).

DISCUSSION

Statement of principal findings

In this cross sectional study and survey of German medical schools we found that only two German medical schools (5.3%) have policies relating to COI in place. Moreover, none of these policies sufficiently covered the broad spectrum of evaluated categories with relevance to COI, nor did they focus explicitly on the context of medical education. No medical school reported curricular teaching on COI. The maximum score achieved was 12 of 26. 36 (94.7%) schools were rated with a score of 0. Those also included non-responders to the survey without discoverable policies in the web-search (22 schools, 61%). These results indicate little effort by German medical schools to address the issue of COI in medical education.

Strengths and limitations of the study

In total, 16 out of 38 medical schools responded to our letter and emails and therefore COI teaching activities and policies by non-responding medical schools may have been missed. To address this issue we conducted a systematic web-search, which in general supported the results of the survey. The policy identified for Charité Universitätsmedizin Berlin was evaluated without response from the dean's office to validate the document retrieved online. The web-search was performed with few predefined search terms using integrated search engines on the websites of medical schools, thus limiting potentially retrievable documents. Consequently, the results of this study might underestimate the number of COI policies and teaching activities that are publicly available. However, scarce results among the 16 medicals schools participating in the survey as well as from the web-search indicate that too few German medical schools adopted policies on conflicts of interests and educate their students about conflics of interests.

Medical schools don't exist in a vacuum and further COI policies may exist at a university-wide level or at university medical centres. We argue that the consequences of COI in medicine potentially harm patient health and are therefore even more critical compared to COI that might occur in other fields. Thus, medical schools require more restrictive COI policies than other departments within a university. Teaching physicians are predominantly also employed by a university medical centre which might issue COI policies not specifically applying to their affiliated medical school. However, these policies are aimed at COI of physicians working in patient care and lack specific regulations that apply to the teaching environment of medical students. It predominantly lies within the capacity of teaching faculty at medical schools to introduce core knowledge on COI in the classroom. In this study, teaching on COI contributed to the overall score as one of 13 categories. This might underrepresent the importance of teaching activities within the efforts of medical schools to address COI during medical studies.

Strengths and limitations in relation to other studies, discussing important differences in results

Comparable studies were conducted in the United States, Canada, Australia and France, allowing for an international comparison of our results.[25–27,30] In general, North American medical schools tackle the issue of COI in medical education more proactively. In Canada 16 of 17 medical schools had some form of COI policy in place in 2013 [26] and in 2014, 136/160

US medical schools reported an existing policy on COI.[25] The Australian study found that 7 medical schools out of 20 had a COI policy.[30] The French study exposed similar results as our own data. They found no formal COI policy at any of the 37 French medical schools and only scattered COI teaching activities. Their response rate of 8.1% may be indicative of the low interest in the topic by medical schools at this time. The publication of these results led to increased media attention [31] and ultimately the French deans' conference adopted a nation-wide COI policy.[32]

The best performing policy in our study was an anti-corruption directive issued by the Technische Universität Dresden that included four restrictive and four moderate elements related to different scoring categories. Yet we were unable to retrieve this policy from the medical school's website during the performed web-search. Prior studies excluded non-public policies from analysis, since an inaccessible, not widely circulated policy is unlikely to have a relevant impact and may go unrecognized by academic staff.[26,30] In an earlier study two German medical schools were reported to have a policy on COI.[20] Our research could only verify one of those COI policy equivalents at TU Dresden. RWTH Aachen reported a policy in 2014 but did not reply to our study, nor was a policy identified on the school's website. Despite six medical schools committed to the development of a COI policy in 2014 [20], our results indicate that no policy has been published since. Furthermore, we did not receive any information about teaching on COI through the deans' survey. This is in contrast to the survey by Lieb et al.[20] In their study, deans from seven medical schools reported COI teaching activities (Universität Bonn, Universität Erlangen-Nürnberg, Universität des Saarlandes (Homburg), Universität Gießen, Universität Göttingen, Universität Frankfurt, Universität Köln). From these medical schools, only the dean's office of Universität Göttingen commented on COI teaching and declared that their curriculum included basic education on pharmacoeconomics but did not explicitly cover COI related aspects like transparency or corruption.

Implications for medical schools and policymakers

Education and policies on COI have been suggested to sensitise medical students in favour of the independence of medical education from undue industry influence.[4,22–24] Medical students themselves increasingly demand stronger COI regulations, disclosure of teaching faculty's COI and courses on COI. The German Medical Students' Association (bvmd e.V.) adopted a position paper on the independence of education in 2013.[33] In May 2019 the European Medical Students Association (EMSA) passed a policy titled "Conflicts of Interest in Medical Education Settings"[34] and the International Medical Students' Association (IFMSA) followed in August 2019 with a policy called "Integrity and transparency in medical education".[35] These actions are indicative of broader student interest in policy change.

We found COI teaching activity at German medical schools, if existent, to be an initiative by singular faculty members rather than a structured component of the curriculum. Those mostly encompassed elective courses or singular lectures that are not available to all students and hence received no score. The scarce efforts to include COI in teaching are all the more surprising, since the German National Competence-Based Learning Objectives for Undergraduate Medical Education (NKLM) include COI (without specifically naming them) in chapter 11.1.1.2.[36] Moreover, the IMPP (Institute for medical and pharmaceutical examination questions) that develops national exams for medical students in Germany introduced an item directly referring to COI in its latest edition published in November 2019. Recently, a randomized controlled trial showed that a structured and integrated curriculum on

COI and risk communication leads to a large and sustainable increase in risk communication performance among German medical students.[37] Taking the mounting evidence, broad student engagement and changing requirements into consideration, German medical schools are under pressure to adopt structured COI curricula and policies that are mandatory to all students and form part of a core curriculum.

Unanswered questions and future research

In the US, the regular AMSA scorecard assessed COI policies at U.S. medical schools until 2016 and contributed to a constant improvement in policies since its initiation in 2007.[25] Regular evaluation of the development of policies and curricula addressing COI might also be useful in Germany to incentivise and monitor progress towards better COI education at medical schools.

Policy development is a dynamic process and some schools signalled willingness to introduce teaching activities and considered COI policies after we contacted them. This, however, was also the case in previous studies.[20] Yet, our work indicates that little action was taken since then. Future research should further assess the impact of stringent policies during medical training on prescribing behaviour, and ultimately evaluate other patient relevant outcomes.

Conclusion

In contrast to other parts of the world, such as North America, German medical schools barely regulate students' contact with pharmaceutical companies or teach about impacts of conflicts of interest. Several organizations[38,39] and increasingly students themselves are demanding a cultural change in the medical profession starting with independent, unbiased medical education.[33–35] COI policies at medical schools have been shown to positively impact prescribing and practise.[22–24] Medical schools in Germany have a key responsibility to protect students from undue influence and enable them to critically appraise information to achieve the best possible patient care. Although national learning objectives include teaching on COI, German medical schools do too little and have a long way to go.

LEGENDS

Figure 1: Flowchart of included COI policies

Figure 2: Overview of strength of the two COI policies included. Empty circle = permissive/no policy (score = 0), half circle: moderate policy (score = 1), full circle = restrictive policy (score = 2). Criteria were pre specified in the codebook (see Supplementary File 2). Categories were assessed separately and without weighing.

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AUTHOR CONTRIBUTIONS

P.G., Z.F., L.U.H, L.S., M.S., S.T., T.W. and D.K. designed the study. P.G., Z.F., S.G., L.U.H., L.S., M.S, S.T., T.W. conducted the survey. M.S. and L.S performed the web-based search. P.G., L.U.H., S.T., T.W. evaluated obtained results. P.G. and L.U.H. wrote the manuscript. All authors reviewed the manuscript.

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The authors did not receive any funding for this study.

COMPETING INTEREST STATEMENT

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no financial support from any organisation for the submitted work; SG previously consulted for Universities Allied for Essential Medicines (UAEM) Europe e.V.; all other authors declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years and no other relationships or activities that could appear to have influenced the submitted work.

DETAILS OF ETHICAL APPROVAL

After formal exchange with a member of the German Ethics Council about the nature of this study, which only involves policies at an institutional level rather than patient data or other personal information, it was deemed unnecessary to ask for formal approval from an ethics committee.

PATIENT AND PUBLIC INVOLVEMENT STATEMENT

Neither patients nor public were involved in conceptualizing or conducting this study.

DATA SHARING STATEMENT

Data from web-searches will be made available upon request.

TRANSPARENCY DECALRATION

The lead author and manuscript guarantor PG affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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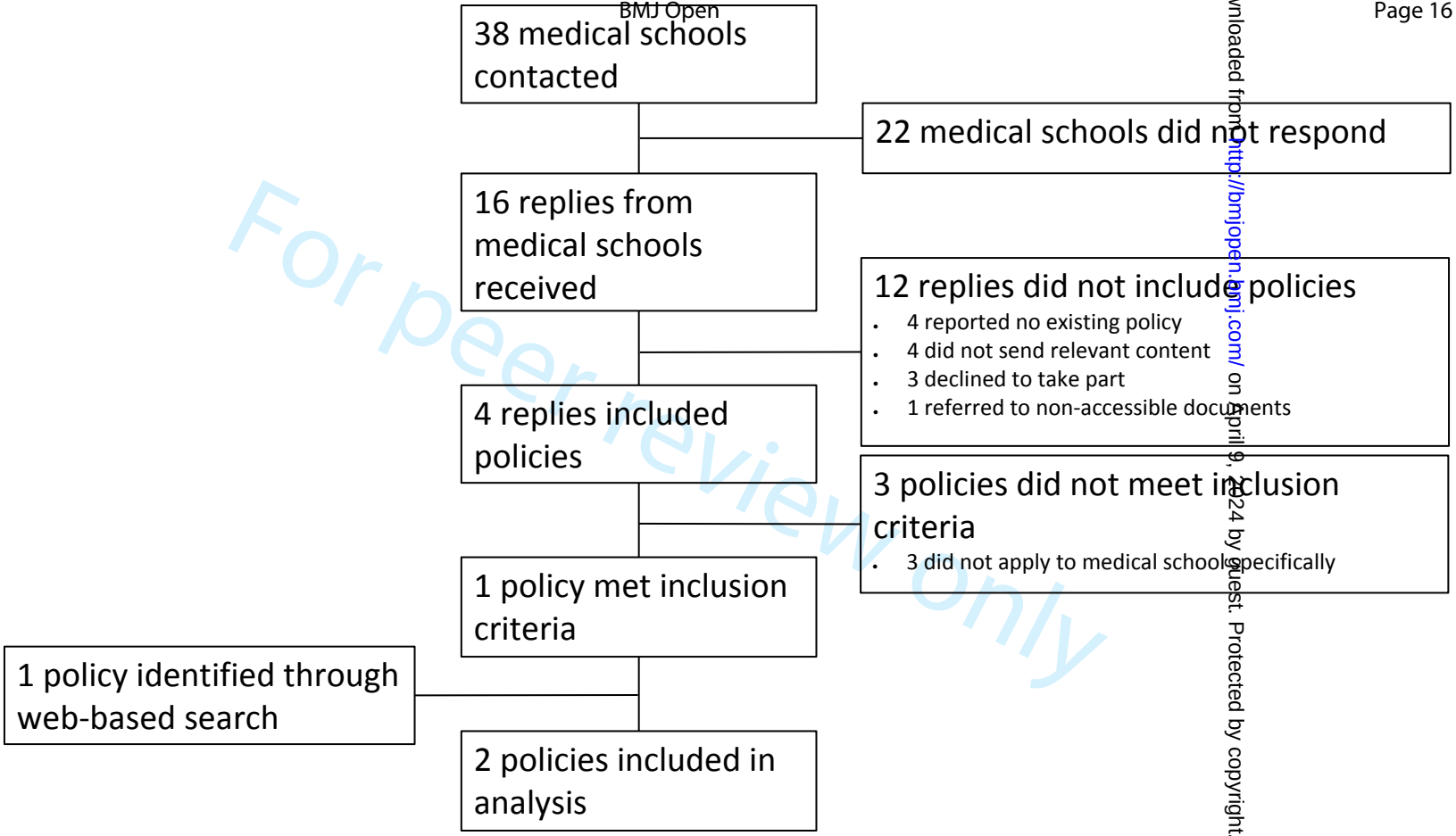


medical school	total score	gifts	meals	consulting	promotional speaking	CME lectures	promotional events	scholarships	ghost writing	sales representatives	disclosure	curriculum	extension	enforcement
Carl Gustav Carus der Technischen Universität Dresden	12	◑	◑	◑	○	○	◑	●	○	○	●	○	●	●
Charité – Universitätsmedizin Berlin	4	●	○	◑	○	○	○	○	○	○	○	○	◑	○

List of websites searched

Medical school	Websites searched
RWTH Aachen	https://medizin.rwth-aachen.de/
Universität Augsburg	https://www.med.uni-augsburg.de/ https://www.uni-augsburg.de/de/
Charité – Universitätsmedizin Berlin	https://www.charite.de/ https://www.fu-berlin.de/ https://www.hu-berlin.de/de
Ruhr-Universität Bochum	http://www.medizin.ruhr-uni-bochum.de/ https://www.ruhr-uni-bochum.de/de
Rheinischen Friedrich-Wilhelms-Universität Bonn	http://ukb.uni-bonn.de/42256BC8002AF3E7/direct/home https://www.uni-bonn.de/
Medizinische Fakultät Carl Gustav Carus der Technischen Universität Dresden	https://tu-dresden.de/med https://tu-dresden.de/
Universität Duisburg-Essen	https://www.uni-due.de/med/ https://www.uni-due.de/
Heinrich-Heine-Universität Düsseldorf	http://www.medizin.hhu.de/ https://www.uni-duesseldorf.de/home/startseite.html
Friedrich-Alexander-Universität Erlangen-Nürnberg	https://www.med.fau.de/ https://www.fau.de/
Goethe-Universität Frankfurt	http://www.uni-frankfurt.de/54233767/fachbereich http://www.uni-frankfurt.de/de?locale=de
Albert-Ludwigs-Universität Freiburg	http://www.med.uni-freiburg.de/de http://www.uni-freiburg.de/
Justus-Liebig-Universität Gießen	https://www.uni-giessen.de/fbz/fb11 https://www.uni-giessen.de/index.html
Georg-August-Universität Göttingen	https://www.med.uni-goettingen.de/index_de.php http://www.uni-goettingen.de/
Universitätsmedizin Greifswald	https://www.medizin.uni-greifswald.de/de/home/ https://www.uni-greifswald.de/
Martin-Luther-Universität Halle-Wittenberg	https://www.medfak.uni-halle.de/ https://www.uni-halle.de/
Universität Hamburg	https://www.uke.de/organisationsstruktur/medizinische-fakult%C3%A4t/index.html https://www.uke.de/index.html https://www.uni-hamburg.de/
Medizinische Hochschule Hannover	https://www.mh-hannover.de/
Ruprecht-Karls-Universität Heidelberg	http://www.medizinische-fakultaet-hd.uni-heidelberg.de/ https://www.uni-heidelberg.de/de

Universität des Saarlandes (Homburg)	http://www.uniklinikum-saarland.de/de/ https://www.uni-saarland.de/nc/startseite.html
Friedrich-Schiller-Universität Jena	https://www.uniklinikum-jena.de/ https://www.uni-jena.de/
Christian-Albrechts-Universität zu Kiel	http://www.medizin.uni-kiel.de/de http://www.uni-kiel.de/de/
Universität zu Köln	http://medfak.uni-koeln.de/ http://uni-koeln.de/
Universität Leipzig	https://www.uniklinikum-leipzig.de/ https://www.uni-leipzig.de/
Universität zu Lübeck	https://www.uni-luebeck.de/index.php?id=897 https://www.uni-luebeck.de/universitaet/universitaet.html
Otto-von-Guericke-Universität Magdeburg	http://www.uni-magdeburg.de/ http://www.med.uni-magdeburg.de/
Johannes-Gutenberg-Universität Mainz	http://www.um-mainz.de https://www.uni-mainz.de/
Medizinische Fakultät Mannheim der Ruprecht-Karls-Universität Heidelberg	https://www.umm.uni-heidelberg.de/home/
Philipps-Universität Marburg	https://www.uni-marburg.de/de/fb20 https://www.uni-marburg.de/de
Ludwig-Maximilians-Universität München	https://www.med.uni-muenchen.de/index.html https://www.uni-muenchen.de/index.html
Technischen Universität München	http://www.med.tum.de/de/die-fakult%C3%A4t-f%C3%BCr-medizin/ https://www.tum.de/
Westfälischen Wilhelms-Universität Münster	https://www.medizin.uni-muenster.de/fakultaet/start/ https://www.uni-muenster.de/de/
Carl von Ossietzky Universität Oldenburg	https://uol.de/medizin/ https://uol.de/
Universität Regensburg	https://www.uni-regensburg.de/medizin/fakultaet/ https://www.uni-regensburg.de/
Universitätsmedizin Rostock	https://www.med.uni-rostock.de/ https://www.uni-rostock.de/
Eberhard Karls Universität Tübingen	https://www.medizin.uni-tuebingen.de/de/ https://uni-tuebingen.de/
Universität Ulm	https://fakultaet.medizin.uni-ulm.de/ https://www.uni-ulm.de/
Universität Witten/Herdecke	https://www.uni-wh.de/gesundheit/department-fuer-humanmedizin/#profil https://www.uni-wh.de/
Julius-Maximilians-Universität Würzburg	https://www.med.uni-wuerzburg.de/startseite/ https://www.uni-wuerzburg.de/startseite/

Conflict of Interest Policies at German medical schools – A long way to go

Codebook

Version January 2018*

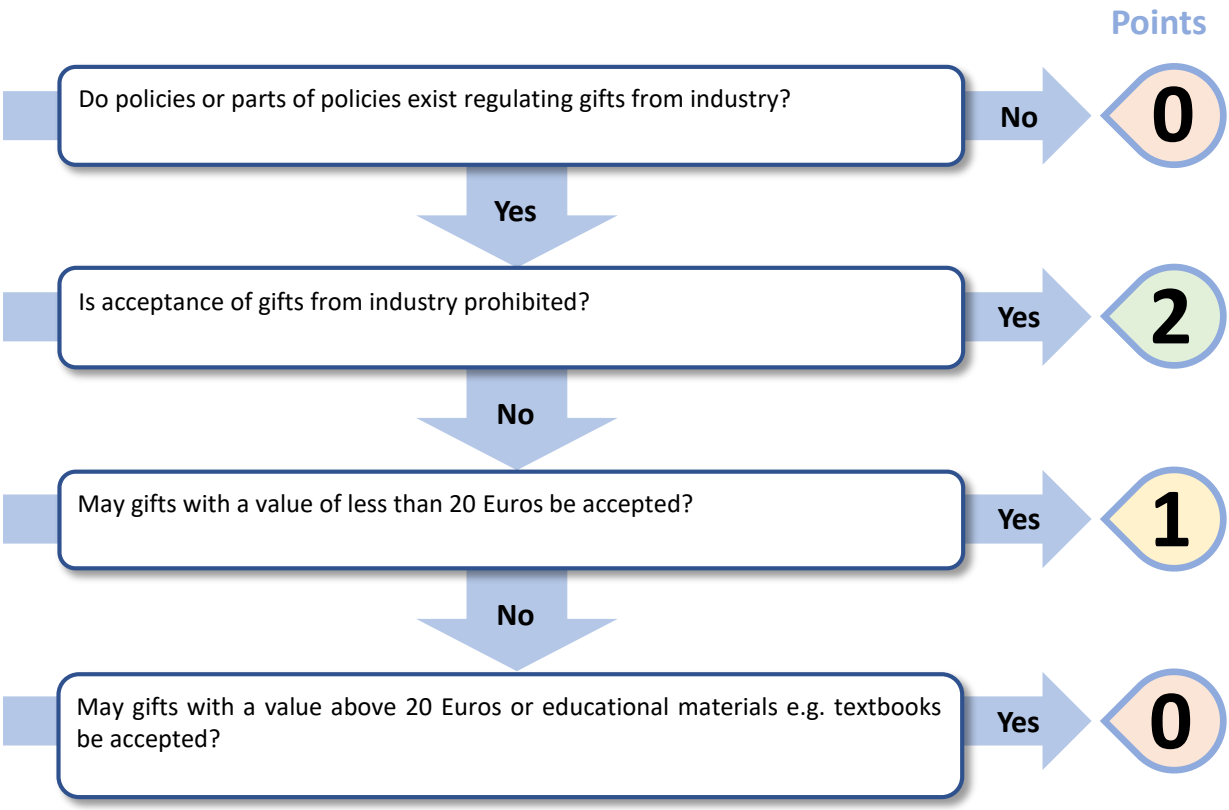
Working Group Conflicts of Interest
Universities Allied for Essential Medicines Europe

*Official Codebook in German

UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

Table of contents

1. Gifts from industry

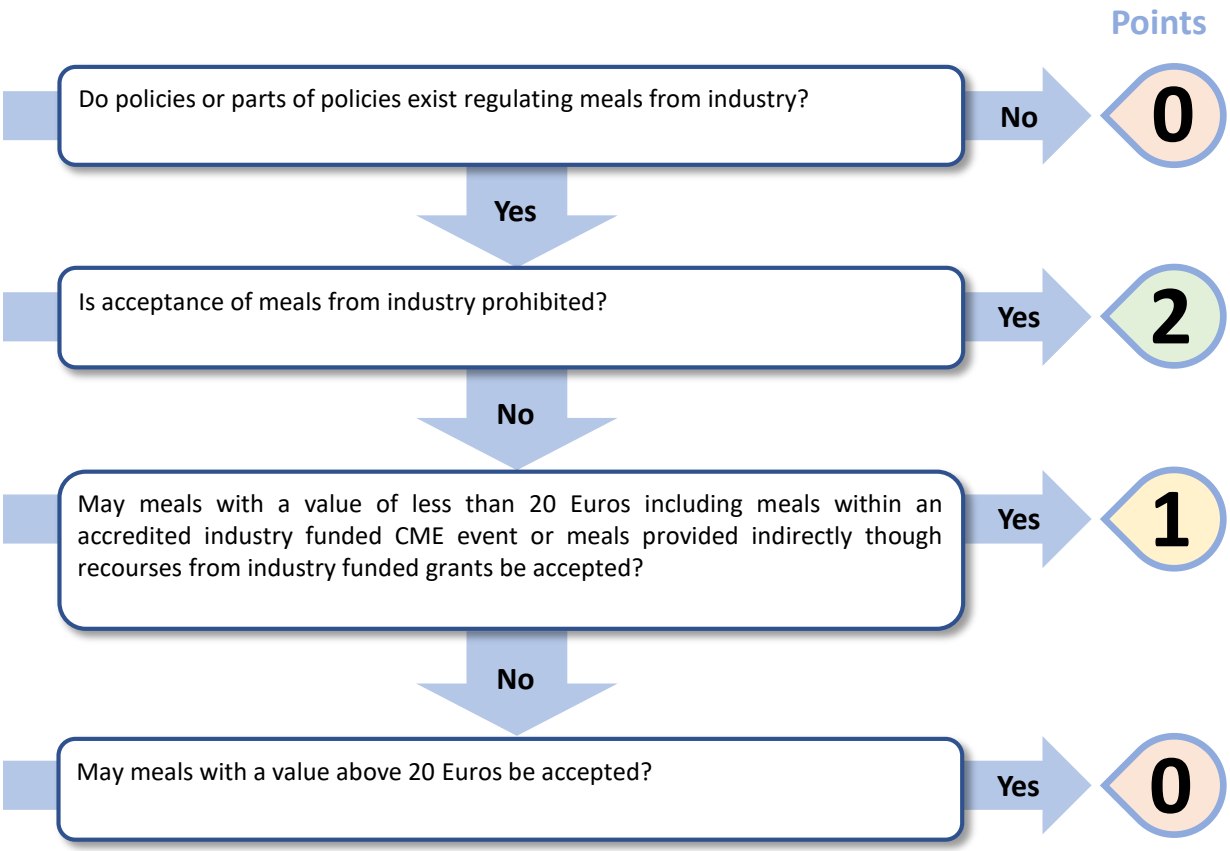


Definition:
Every object or service that is provided free of charge is considered to be a gift with the exception of meals (see criterion 2).

Notes:
Qualification for 2 points:

- Examples for prohibited gifts from industry:
  - Educational gifts to students or medical schools, e.g. textbooks, articles or online subscriptions. Policies that allow educational gifts score 0 points regardless of the recipient (individual person or institution) and also if the identity of the donor is not disclosed on or in the gift.
- Examples for permitted gifts from industry:
  - Gifts primarily addressing patients e.g. posters explaining a procedure or showing an anatomic model.
  - Small gifts like conference bags or bottles of water.

2. Meals from industry

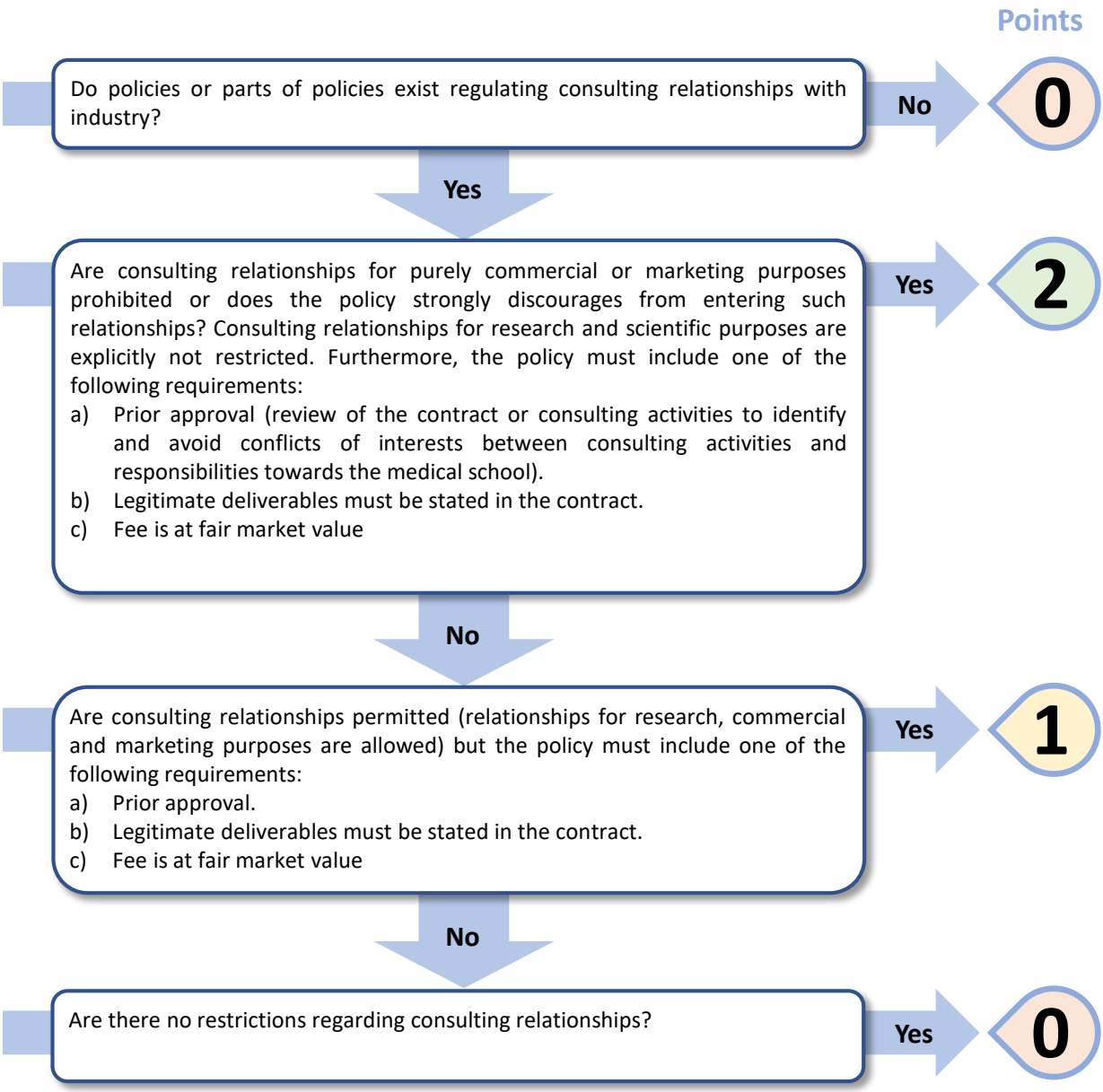


Definition:
This criterium considers meals during CME and non-CME events as well as meals provided on and off campus.

Notes:
Qualification for 2 points:

- Examples for **prohibited** meals form industry:
  - Every industry sponsored meal on campus.
  - Industry sponsored meals during promotional events off campus (e.g. dinner with promotional presentation).
  - Meals in the course of industry-sponsored CME events if not paid by a non-industry party such as medial societies, organizing departments or through participation fees.
- Examples for **permitted** meals form industry:
  - Industry sponsored meals during large academic events such as annual meetings of medical societies if the meals are provided to every participant.
  - Industry sponsored meals which are part of an approved research contract.
  - Meals that are anonymously provided by more than one industrial sponsor.

3. Consulting relationships



Note: please continue on page 6

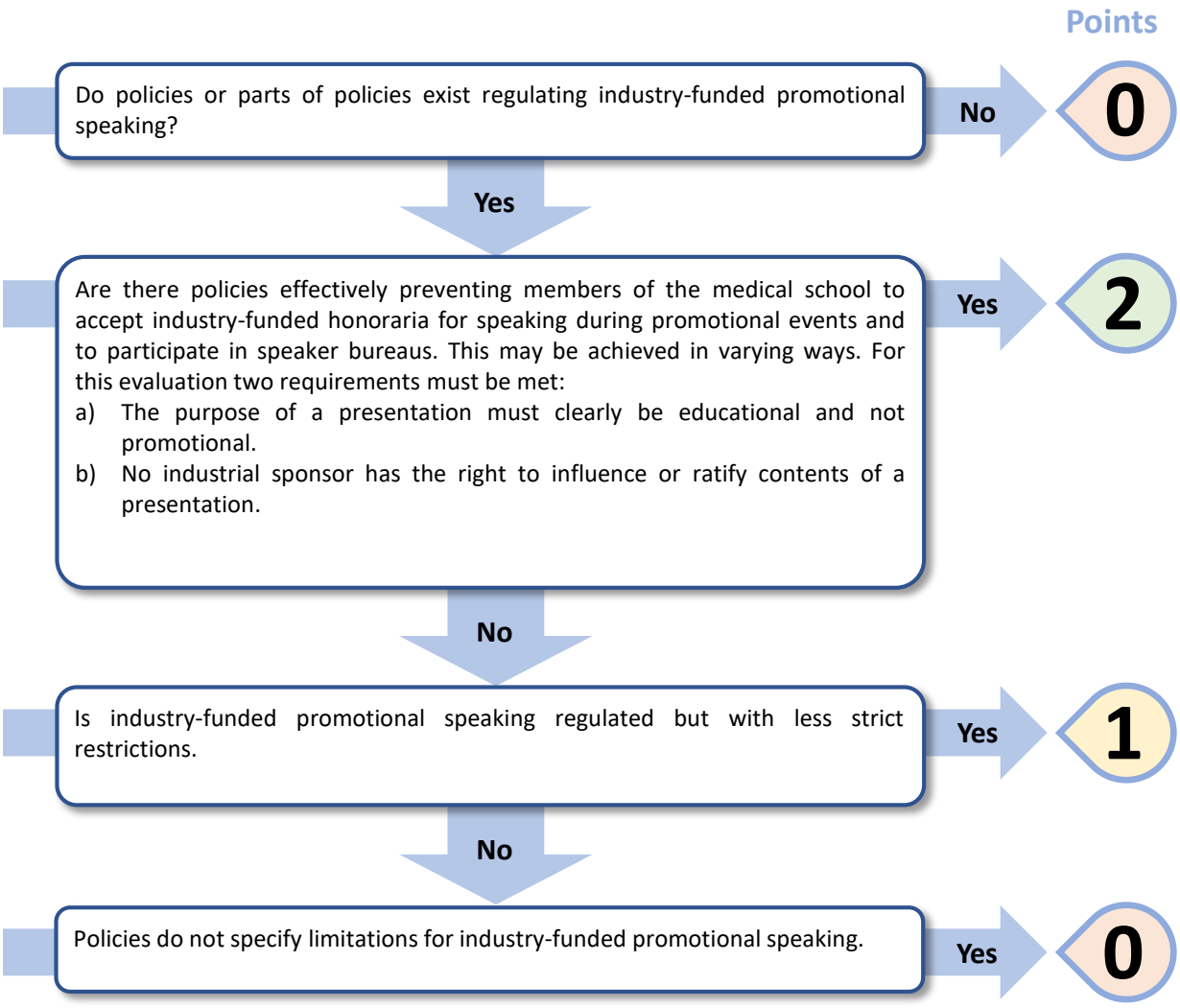
3. Consulting relationships

Notes:
Within this study consulting relationships are evaluated separately from industry-funded promotional speaking. Some Institutions regard theses speaking relationships as part of consulting. In this case the part of a policy that addresses speaking relationships is not relevant for this criterion but will be evaluated within criterion 4.

Qualification for 2 points:

- **Permitted** consulting relationships:
  - A policy does not have to state explicitly that consulting relationships are prohibited but should include terms like “for scientific purposes”.
  - Some scientific consulting relationship might include marketing components (e.g. if a scientist is involved in the development of a new surgical instrument and helps the manufacturer to create contents to advertise for the tool’s properties). These consulting relationships are acceptable within a model policy as the core of the consultation is scientific in nature.
- **Prohibited** consulting relationships:
  - Consulting with the sole aim to help marketing a commercial product without scientific background (e.g. consulting with regard to different channels of advertisement and their effective use).

4. Industry-funded promotional speaking



Notes:

This section does not refer to accredited CME events. In German and English language different terms are linked to industry-funded promotional speaking such as “speaker bureaus”, “promotional talks”, peer-to-peer education or “lunch and learn” in English and “Lunch-Symposium” or “Satelliten-Symposium” in German. Some policies include limitations for compensation and reimbursement. Yet, criteria a) and b) must be met to score 2 points.

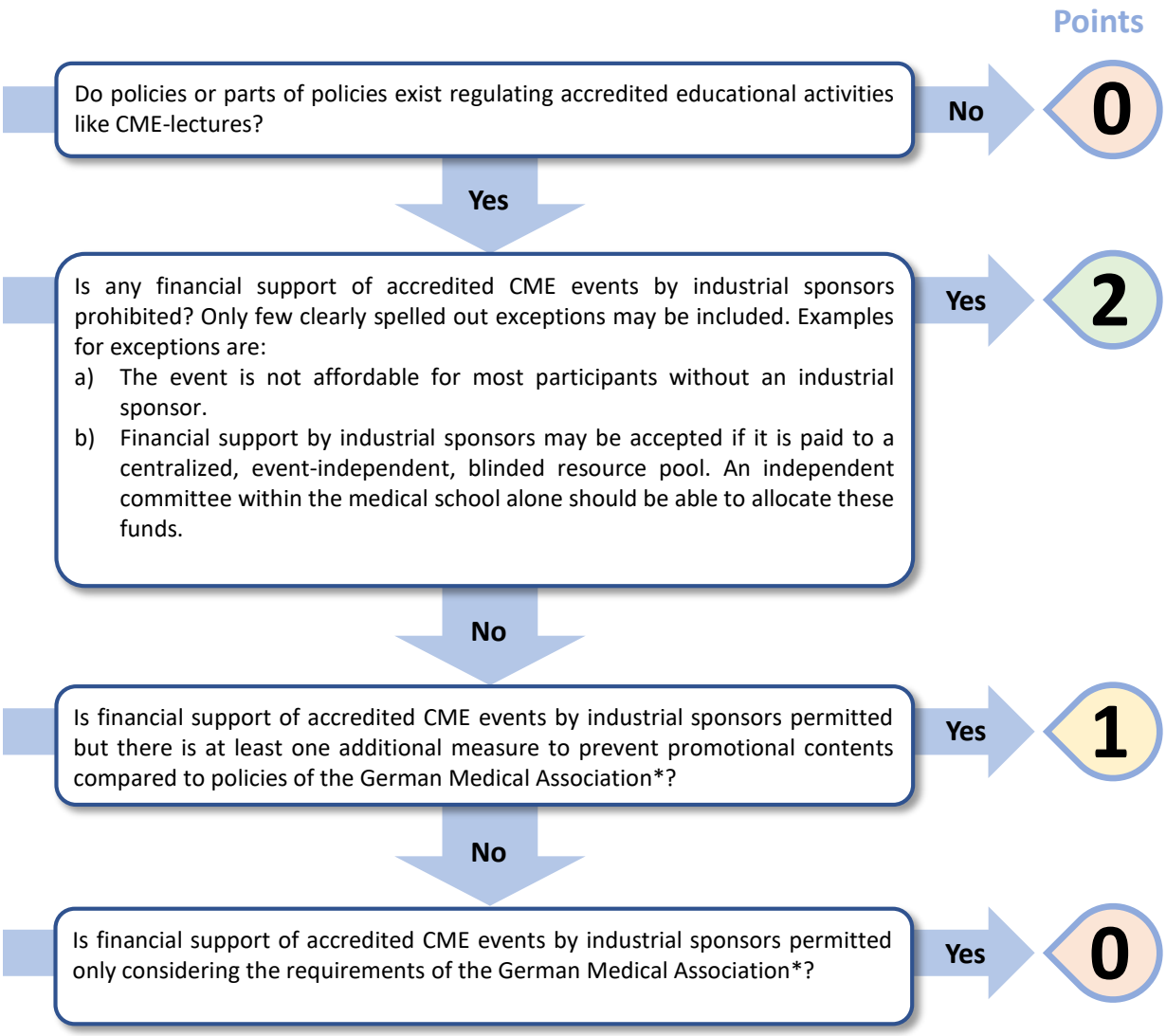
Qualification for 2 Points:

- Industry-funded speaking has to be purely educational without promotional aspects. To address this requirement policies may include terms like “scientific”, “objective” or “independent”. Within this study policies with such terms will be regarded as sufficient to prevent promotional speaking and therefore qualify for 2 points.

Qualification for 1 point:

- Policies that discourage from industry-funded promotional speaking qualify for 1 point. For 2 points policies must prohibit industry-funded promotional speaking.

5. Accredited educational activities like CME-lectures



Note: please continue on page 9

5. Accredited educational activities like CME-lectures

Notes:

Qualification for 2 points:

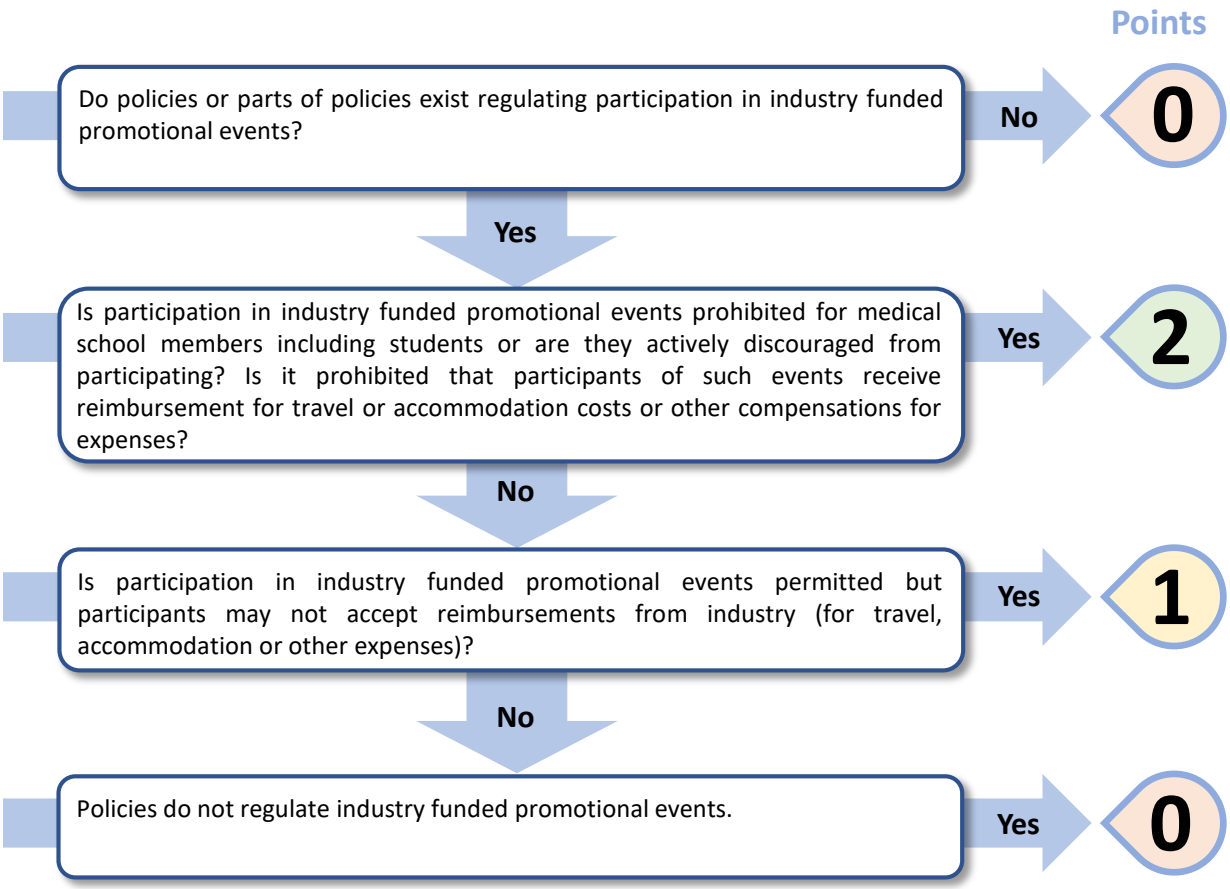
- **Prohibited** financial support for CME events by industrial sponsors:
  - The sponsor determines content or topic of the event or chooses a specific department as recipient of the financial support.
- **Permitted** financial support for CME events by industrial sponsors:
  - Industrial sponsors pay financial support to a blinded, independent resource pool that allocates funds without influence by the sponsors.
  - Support for educational or method training, that is unavailable for the institution without the collaboration with an industrial sponsor.

Qualification for 1 point:

- **Permitted** financial support for CME events by industrial sponsors:
  - Financial support by industrial sponsors according to the recommendations of the German Medical Association (Bundesärztekammer) and one additional measure to strengthen the educational character of an CME event. Examples of such measures are:
    - More then one sponsor has to fund the event.
    - Financial support has to be managed by a central CME office within the medical school and not by the department or the persons organizing the event.
    - Participants themselves have to cover some of the costs (e.g. meals, registration, …).

*[https://www.aerztekammer-berlin.de/10arzt/25_Aerztl_Fb/30_Downloads/10_EmpfehlBAEKFobi.pdf, accessed January 29, 2020]

6. Participation in industry funded promotional events



Notes:

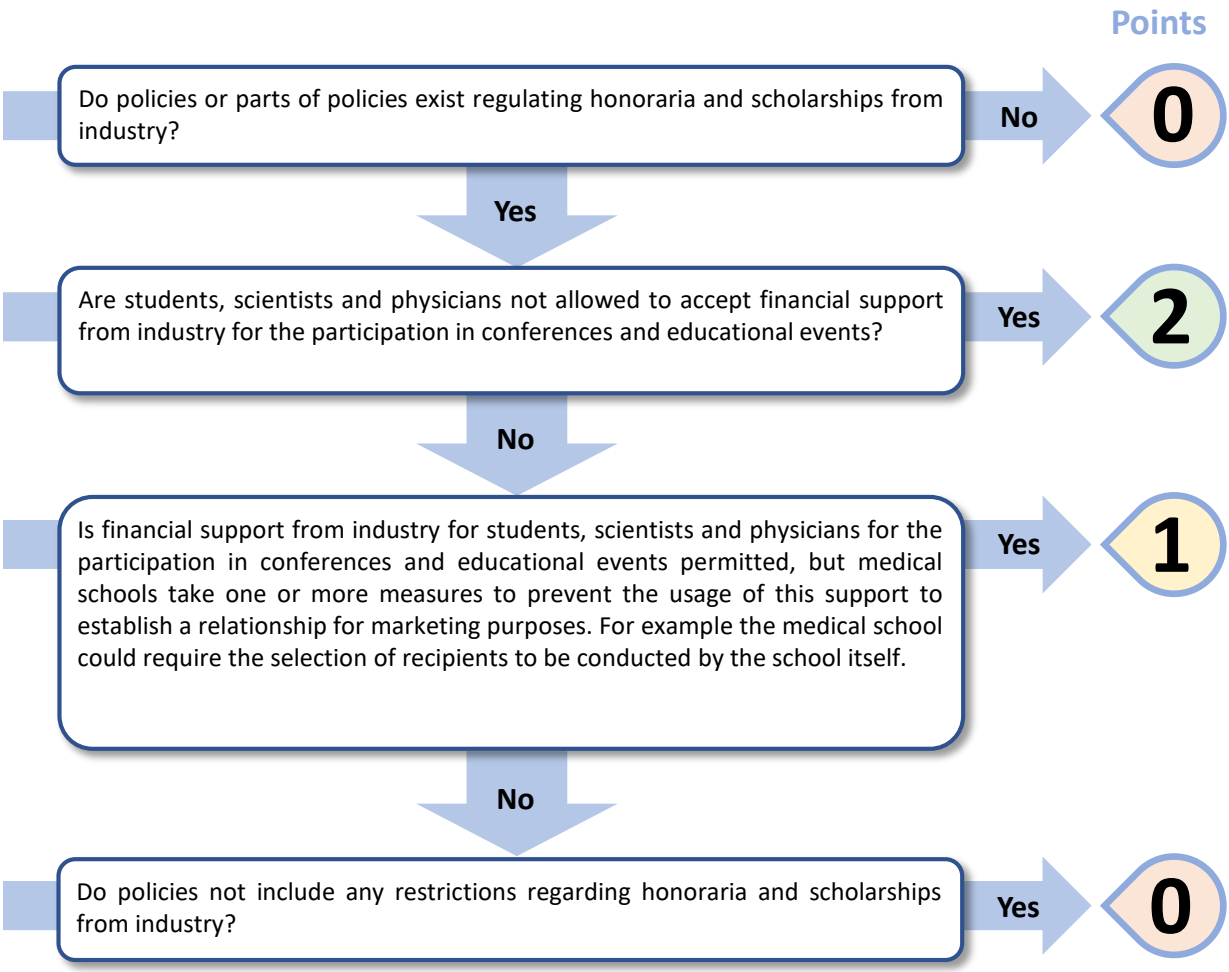
Qualification for 2 points:

- The policy has to prevent or actively discourage medical school members including students from participating in non-accredited CME events that are hosted by industry (this excludes annual meetings of scientific and medical societies, if they offer accredited educational events next to an industry-sponsored program)
- This criterion does not cover events where medical school members are invited as speakers. (See 4. Industry-funded promotional speaking)

Qualification for 1 point :

- Policies permitting the participation in industry funded events which are advertised as “promoting evidence-based medical practice” or “based on scientific research” do not prohibit participation in promotional events and therefore score “1” point.
- If the police encourages individuals to critically evaluate the scientific character of an industry-funded event, the policy does not actively discourage from participating in industry funded promotional events and therefore scores “1” point.

7. Honoraria and scholarships from industry

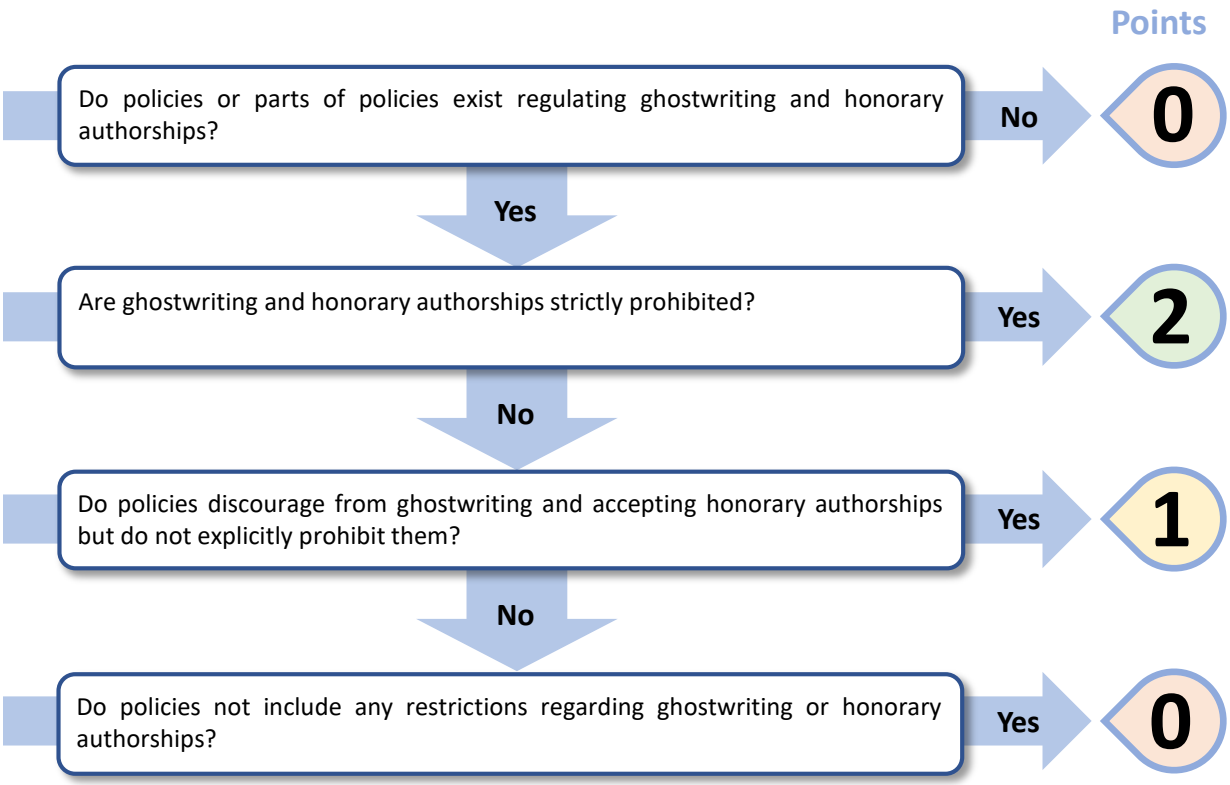


Definition:
This criterion refers to financial support from industry for travel costs and attendance fees for scientific conferences and educational events.

Notes:
Qualification for 2 points:
- Examples for **prohibited** support by industry:
  - Stipends from industry for the participation of students, scientists and physicians in scientific conferences and educational events. If such support is permitted but the sponsor has no influence on the selection of awardees, the policy qualifies for "1" point.
- Examples for **permitted** support by industry:
  - Competitive, performance-based support exclusively for scientific and medical education. The sponsor has no influence on the selection of recipients and the sponsor remains anonymous.
  - Support for educational events concerning medical devices that were acquired by the institution.

Qualification for 1 point:
- Policies permit financial support by industry, but the sponsor has no influence on the selection of recipients.

8. Ghostwriting und honorary authorships



Notes:

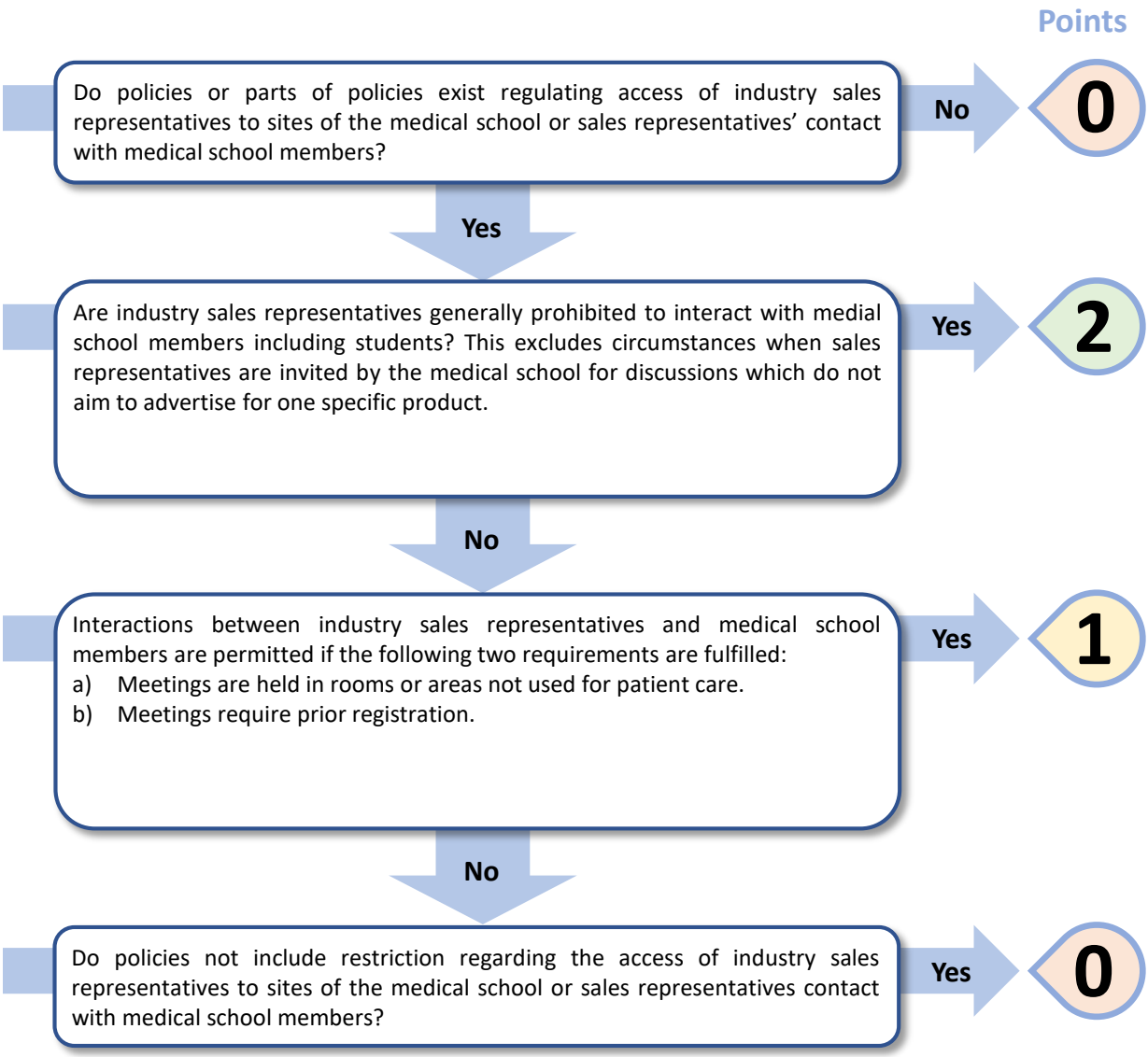
Qualification for 2 points:

- Policies clearly state that ghostwriting and honorary authorships are not permitted or that medical school members have to adhere to the standards of the International Committee of Medical Journal Editors (http://www.icmje.org/).

Qualification for 1 point:

- Policies permit the publication of scientific articles written by industry if this is clearly declared within the article.

9. Industry sales representatives

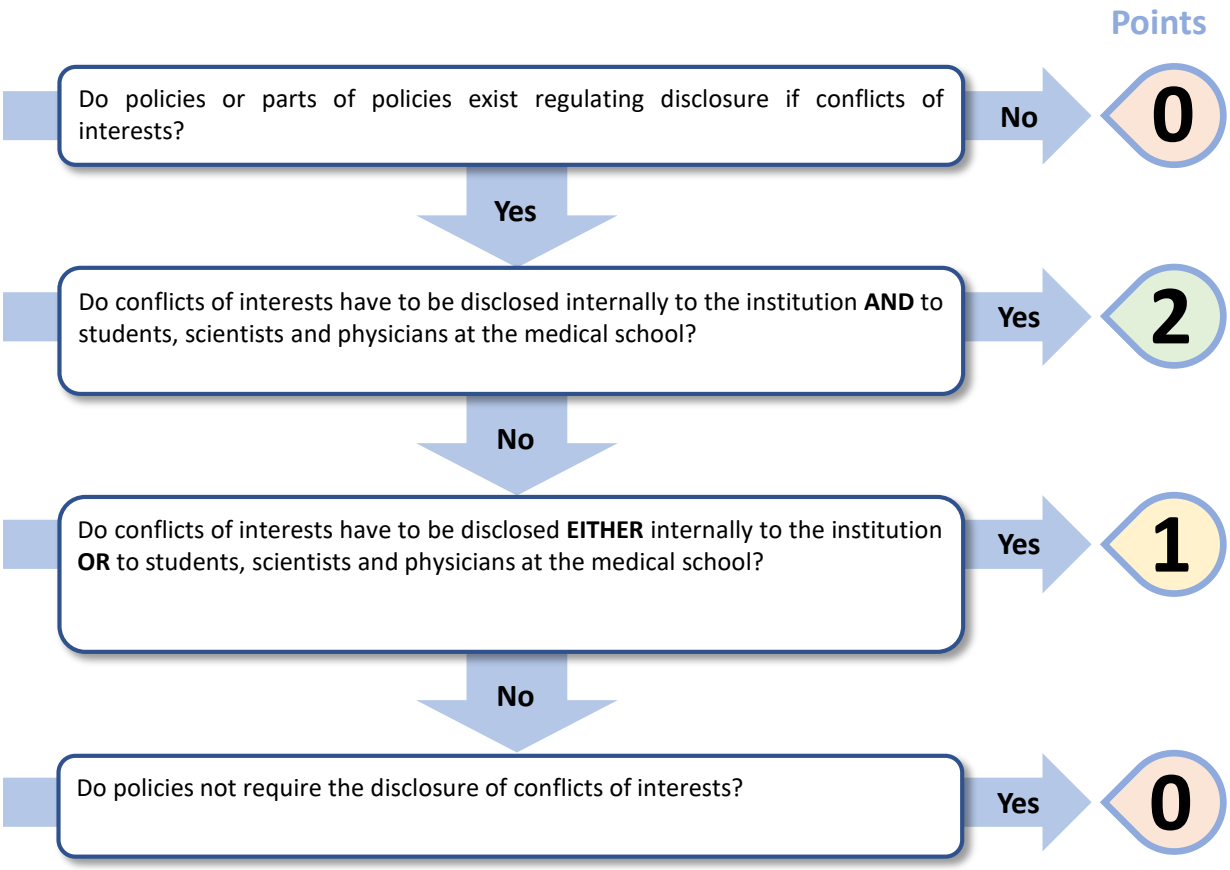


Notes:
Regularly, industry sales representatives are required to wear visible identification. Such policies do not score "2" points because for this analysis identification is not considered being equal to prior registration.

Qualification for 2 points:

- **Permitted** access of industry sales representatives:
  - Policies may permit access of industry sales representatives to committees of purchase or pharmaceutical departments to present information on new products that the institution considers for purchase.
  - Policies may permit access to the medical school and the university medial center to deliver samples as long as these are handed over to a centralized office and no marketing interaction takes place.

10. Disclosure of conflicts of interests



Notes:

"Internal" disclosure:

- Refers to disclosure of conflicts of interests of a medical school member to the institution.

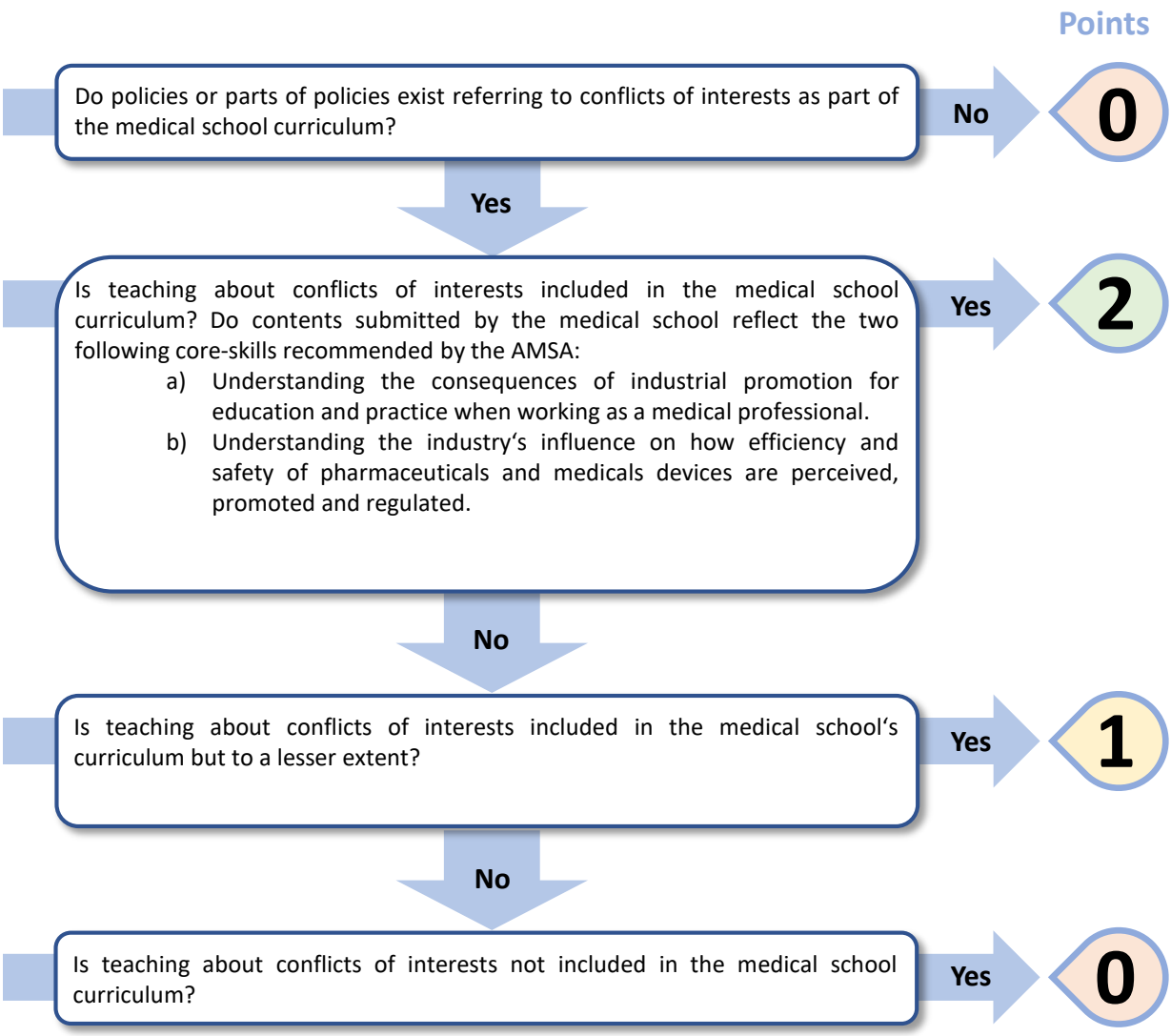
"External" disclosure:

- Disclosure to students, scientists and physicians: Refers to disclosure on slides during presentation or oral disclosure.

General:

- Disclosure of conflicts of interests within a publication is not regarded as relevant "external" disclosure within the medical school in this category.
- Disclosure on a publicly available website is not sufficient to fulfil the requirements for "external" disclosure.

11. Medical school curriculum on conflicts of interests



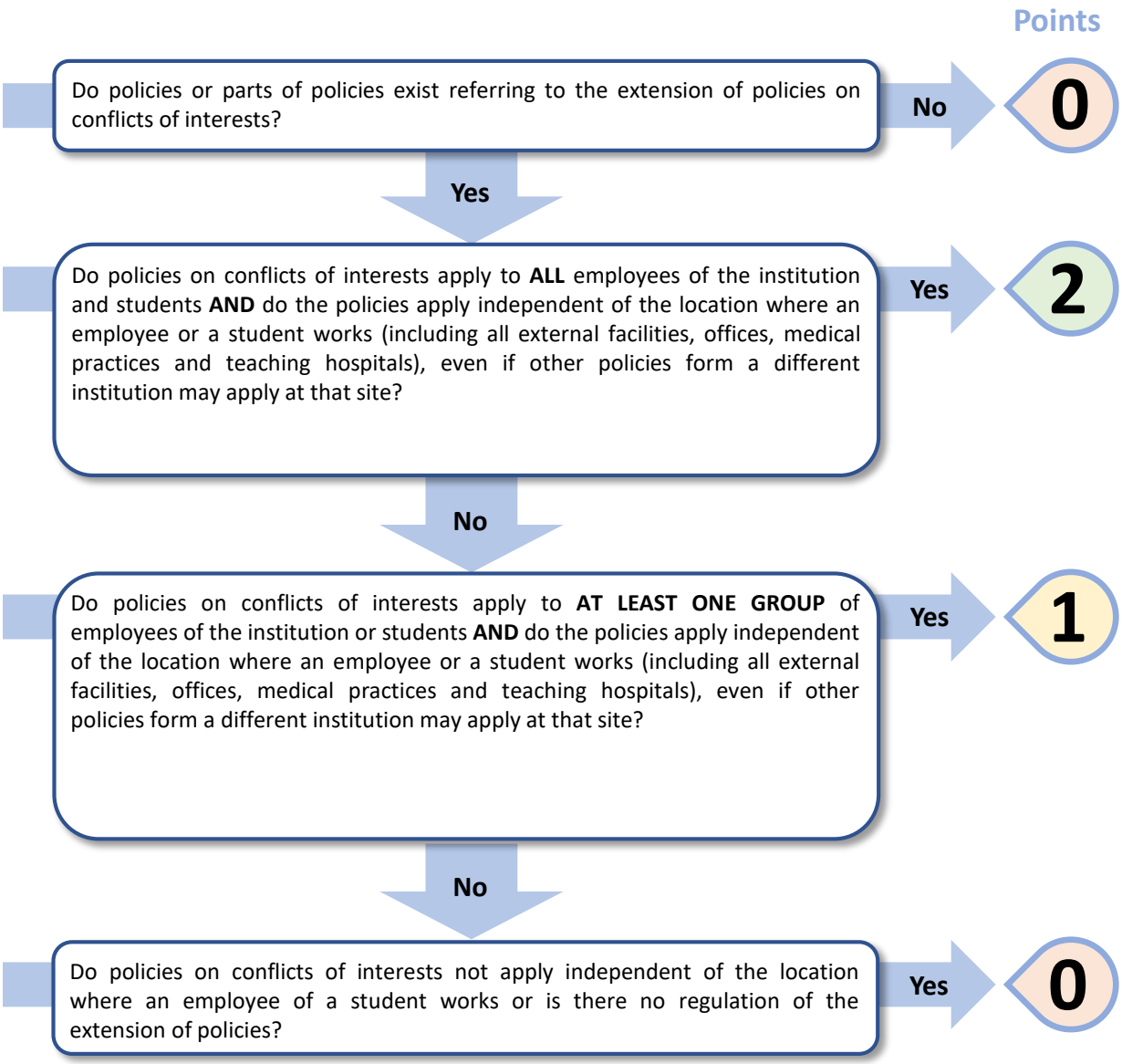
Notes:
Policies explicitly have to apply to medical students.
AMSA: American Medical Student Association

Qualification for 2 points:
Policies have to require a curriculum to include teaching the two above mentioned skills. This may also be reflected indirectly by teaching materials submitted by the medical school. Detailed recommendations of the AMSA for a model curriculum can be accessed here: https://www.amsa.org/wp-content/uploads/2015/03/ModelPharmFreeCurriculum.pdf, accessed January 29, 2020

During the survey, medical schools are asked whether or not their curriculum addresses conflicts of interests. The answer to this question will be considered for this category since most medical schools do not have policies clearly stating on conflicts of interest as obligatory component of the curriculum.

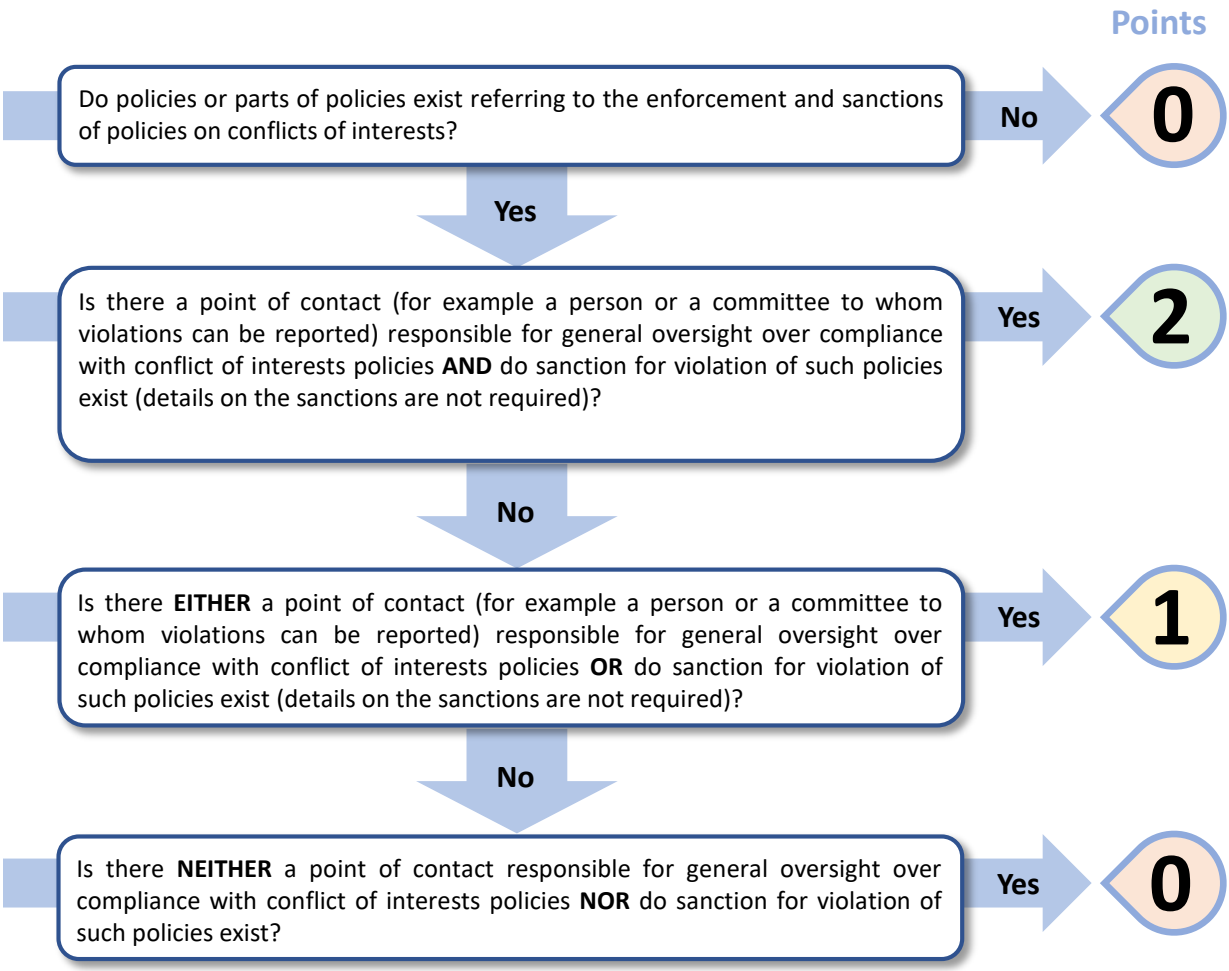
Qualification for 1 point:
Policies requiring regular training about conflicts of interests for scientists, physicians or other non-student medical school members do not qualify for "1" point.

12. Extension of policies



Notes:
A model policy will explicitly state that policies on conflicts of interests apply independent of the location. As an example, at medical schools with policies prohibiting the acceptance of meals sponsored by industry, students would not be allowed to do so also when they work outside of their university medical center e.g. during rotations in their practical year or during internships at hospitals where less strict policies might apply.

13. Enforcement and sanctions of policies



Notes:

AG Interessenkonflikte - UAEM e.V. - Am Köllnischen Park 1 - 10179 Berlin
E-Mail: *interessenkonflikte@gmail.com*; **Homepage:** *uaem.org*

«Titel» «Vorame» «Nachname»
«Fakultät»
«Universität»
«Straße»
«Postleitzahl» «Stadt»

27. Mai 2018

Studie zur Regulierung von Interessenkonflikten

Sehr «Anrede1» «Geschlecht» Professor «Nachname»,

im Namen der Arbeitsgruppe Interessenkonflikte der Studierendeninitiative Universities Allied for Essential Medicines (UAEM) und der Bundesvertretung der Medizinstudierenden in Deutschland (bvmd) möchten wir Sie und Ihre Fakultät herzlich dazu einladen, an unserer **„Studie zur Regulierung von Interessenkonflikten an medizinischen Fakultäten in Deutschland“** teilzunehmen.

Kooperationen mit der Industrie spielen in vielen Bereichen der Medizin eine wichtige Rolle. Auch angehende Mediziner/Medizinerinnen kommen früh im Studium mit Akteuren der Industrie, insbesondere der pharmazeutischen Industrie, in Kontakt. Die Ausbildung innerhalb des Medizinstudiums legt dabei wichtige Grundbausteine für den Umgang mit öffentlich-industriellen Kooperationen und die adäquate Vermeidung von Interessenkonflikten. Deshalb repräsentieren medizinische Fakultäten zentrale Schlüsselstellen beim Schutz Medizinstudierender vor der unangemessenen Beeinflussung durch industriell geleitete Interessengruppen.

Unser Ziel ist es mit dieser Studie zu erfassen, welche Maßnahmen zur Vermeidung von Interessenkonflikten an den 38 deutschen medizinischen Fakultäten implementiert sind. Dazu betrachten wir genauer, welche Richtlinien in 13 auf früheren Studien[1,2,3,4] basierenden Kategorien zum Umgang mit Interessenkonflikten existieren, so z.B. in den Kategorien „Geschenke von Industrieunternehmen“, „Beratungsverhältnisse zu Industrieunternehmen“ oder „Offenlegung von Interessenkonflikten“. Außerdem bewerten wir nach definierten Kriterien, wie weitreichend die Richtlinien formuliert und umgesetzt wurden. Eine ausführliche Einsicht in Kategorien und Bewertungskriterien haben wir für Sie unter folgender Webadresse bereitgestellt: *http://t1p.de/bewertungskriterien-interessenkonflikte*

Damit wir auch die Richtlinien Ihrer Fakultät innerhalb der Studie berücksichtigen können, bitten wir Sie darum, uns jegliche Form von Richtlinie (oder Teile einer Richtlinie) mit Bezug auf den Umgang mit Interessenkonflikten zukommen zu lassen. Wir bitten Sie ebenfalls Informationen zum Geltungsbereich und über Maßnahmen zur Durchsetzung der Richtlinien, sowie Informationen über Lehrinhalte im Kurrikulum, die sich mit dem Umgang mit Interessenkonflikten beschäftigen, beizufügen.

Im Rahmen der Auswertung werden die Richtlinien der einzelnen Fakultäten in Deutschland sowohl untereinander, als auch international mit Richtlinien medizinischer Fakultäten in Ländern verglichen, in denen bereits ähnliche Studien[1,2,3,4] durchgeführt wurden. Analog zu vorangegangenen Studien streben wir eine Publikation der Ergebnisse unserer Studie an.

Die Studie wird unterstützt und begleitet von **Prof. Dr. David Klemperer** (Arzneimittelkommission der deutschen Ärzteschaft, Autor „Interessenkonflikte in der Medizin“) und **Dr. Christiane Fischer** (Deutscher Ethikrat, Geschäftsführerin von MEZIS e.V.).

Mit unserer Studie wollen wir einen Beitrag zum konstruktiven Austausch über den Umgang mit Interessenkonflikten in der Medizin leisten. Wir freuen uns über Ihre Antwort und stehen Ihnen für Rückfragen jederzeit zur Verfügung.

Mit freundlichen Grüßen,

Universities Allied for Essential Medicines (UAEM) Europe e.V. und die Bundesvertretung der Medizinstudierenden in Deutschland (bvmd) e.V.

Referenzen:

1. Carlat DJ, Fagrelius T, Ramachandran R, Ross JS, Bergh S. The updated AMSA scorecard of conflict-of-interest policies: a survey of U.S. medical schools. BMC Medical Education. 2016;16:202. doi:10.1186/s12909-016-0725-y
2. Shnier A, Lexchin J, Mintzes B, Jutel A, Holloway K. Too Few, Too Weak: Conflict of Interest Policies at Canadian Medical Schools. Wray KB, ed. PLoS ONE. 2013;8(7):e68633. doi:10.1371/journal.pone.0068633
3. Scheffer P, Guy-Coichard C, Outh-Gauer D, et al. Conflict of Interest Policies at French Medical Schools: Starting from the Bottom. Wray KB, ed. PLoS ONE. 2017;12(1):e0168258. doi:10.1371/journal.pone.0168258
4. Mason PR, Tattersall MHN. Conflicts of interest: A review of institutional policy in Australian medical schools. Med J Aust 2011;194:121–5

Erklärung zur Studienmotivation

Um Interessenkonflikte zu definieren, orientieren wir uns an der Definition der AWMF von 2010[1]:

»Interessenkonflikte sind definiert als Gegebenheiten, die ein Risiko dafür schaffen, dass professionelles Urteilsvermögen oder Handeln, welches sich auf ein primäres Interesse beziehen, durch ein sekundäres Interesse unangemessen beeinflusst werden.«

Für uns ist das primäre Interesse das Patientenwohl beziehungsweise das Interesse der Allgemeinheit, in dem auch eine hochwertige medizinische Ausbildung liegt. Von sekundären Interessen spricht man im Zusammenhang mit Eigeninteressen einzelner Ärzte, Fachgruppen, o.ä. Hier lässt sich zwischen materiellen und immateriellen sekundären Interessen unterscheiden: Materielle Interessenkonflikte können zum Beispiel durch die Annahme von Geschenken, Honoraren oder anderen Vergünstigungen von pharmazeutischen Unternehmen entstehen. Beispiele für immaterielle Interessenkonflikte sind unter anderem der Wunsch nach Anerkennung oder beruflicher Karriere.

Entscheidend ist, dass Interessenkonflikte durch das Nebeneinander von primären und sekundären Interessen zwangsläufig in den meisten medizinischen Einrichtungen entstehen. Das Vorhandensein eines Interessenkonfliktes ist grundsätzlich neutral zu bewerten.

An Schnittstellen zwischen Industrie und dem öffentlichen Bereich sind Interessenkonflikte nicht vermeidbar. Auch Universitäten sind Teil dieser Schnittstellen und die Kooperation von Fakultäten und Industrie ist im universitären Alltag nicht wegzudenken. Daher sehen wir zum Beispiel Industriesponsoring nicht per se negativ an. Dabei ist allerdings zu beachten, dass eine unabhängige, qualitativ hochwertige Aus-, Weiter- und Fortbildung einerseits und Marketinginteressen von Industriepartnern andererseits nicht miteinander vereinbar sind. Hier muss versucht werden, eine unangemessene Beeinflussung zum Beispiel durch entsprechende Regelungen zu verhindern. Unangemessene Beeinflussung, die in verzerrten Urteilen und Handlungen („Bias“) münden kann, liegt meist außerhalb der eigenen Wahrnehmung und geschieht somit unbewusst. Die Offenlegung von Interessenkonflikten ist daher ein notwendiger und entscheidender erster Schritt in der Reduktion und Vermeidung von Interessenkonflikten beziehungsweise zur Vermeidung ihrer schädlichen Konsequenzen.

Während im Forschungskontext auch in Deutschland zunehmend mehr Transparenz und Regelungen bezüglich Verbindungen zur Industrie gefordert und realisiert werden, fehlen vergleichbare Bemühungen im Rahmen der medizinischen Grundausbildung[2]: Bislang wurde die universitäre Ausbildung kaum im Hinblick auf Kontakte zur Industrie und eventuell auftretende Interessenkonflikte reflektiert. Insbesondere das Medizinstudium als stark persönlichkeits- und berufsprägende Phase bietet aber viel Potential für die Beeinflussung der Studierenden durch Dritte. Um Studierende optimal auf einen professionellen Umgang mit Interessenkonflikten in der öffentlich-industriellen Zusammenarbeit vorzubereiten, ist daher die Thematisierung im Studium sowie die adäquate Erfüllung der Vorbildfunktion durch Lehrende unerlässlich. Wichtig ist dabei vor allem, Interessenkonflikte nicht zu leugnen oder wegzuwünschen, sondern sie zu regeln.

Vor diesem Hintergrund führen wir eine „Studie zur Regulierung von Interessenkonflikten an medizinischen Fakultäten in Deutschland“ durch, die zeigen soll, welche Maßnahmen aktuell zur Kontrolle von Interessenkonflikten angewandt werden.

AG Interessenkonflikte
Universities Allied for Essential Medicines (UAEM) Europe e.V.
Bundesvertretung der Medizinstudierenden in Deutschland (bvmd) e.V.

Referenzen:

1. AWMF 2010 (Hrsg). Empfehlungen der AWMF zum Umgang mit Interessenkonflikten bei Fachgesellschaften. Erarbeitet von einer ad-hoc-Kommission der AWMF und verabschiedet vom Präsidium der AWMF am 23. April 2010; Bauer H, Gogol M, Graf-Baumann T, Haverich A, Klemperer D, Selbmann H-K, Spies C, von Wichert P, Wienke A. (Mitglieder der ad hoc Kommission). Verfügbar: http://www.awmf.org/fileadmin/user_upload/Leitlinien/Werkzeuge/empf-coi.pdf (Zugriff am 25.03.2018)
2. Lieb, K. & Koch, C. Interessenkonflikte im Medizinstudium. Fehlende Regulierung und hoher Informationsbedarf bei Studierenden an den meisten deutschen Universitäten. GMS Z. Med. Ausbild. 31, 1–12 (2014).

Letter sent to deans

English version

Dear <name of dean>

on behalf of the working group on Conflicts of Interest of the student initiative Universities Allied for Essential Medicines (UAEM) and the German Medical Students' Association (bvmd), we would like to invite you and your faculty to participate in our "Study on the Regulation of Conflicts of Interest at Medical Schools in Germany" .

Cooperation with industry plays an important role in many areas of medicine. Early in their studies, prospective doctors also come into contact with actors from industry, especially from the pharmaceutical industry. The education of students within the medical course lays out important foundations for handling public-industry cooperations and adequately preventing conflicts of interest. This is why medical schools have a key position in protecting medical students from undue influence by industry-led interest groups.

The aim of the study is to determine which measures to avoid conflicts of interest have been implemented at the 38 German medical schools. We will evaluate existing policies, considering 13 categories based on previous studies (Scheffer et al. 2017, Carlat et al. 2016, Shnier et al. 2013, Mason et al. 2011) for dealing with conflicts of interest, e.g. the categories "Gifts from Industry", "Consulting Relationships" or "Disclosure of Conflicts of Interest". We will also use defined criteria to assess the strength of the policies and their implementation. Please find all details on the categories and evaluation criteria following the link below:
http://t1p.de/bewertungskriterien-interessenkonflikte

In order to take the policies of your school into account for the study, we kindly ask you to send us any form of policy (or parts of a policy) with regard to dealing with conflicts of interest. Additionally, we ask you to also include information on the scope and measures to enforce these policies, as well as information on any teaching content in the curriculum of your medical school addressing conflicts of interest.

As part of the analysis, the policies of all medical schools in Germany are compared with each other, as well as internationally with policies of medical schools in countries in which similar studies have already been carried out. The results of our study will be submitted for scientific publication.

The study is supported by Prof. Dr. David Klemperer (Drug Commission of the German Medical Association, author „Interessenkonflikte in der Medizin“) and Dr. Christiane Fischer (German Ethics Council, Managing Director of MEZIS e.V.).

With our study we want to contribute to the constructive discourse on dealing with conflicts of interest in medicine. We look forward to your response and are available should you have any further questions.

Best regards,

Universities Allied for Essential Medicines (UAEM) Europe e.V. and German Medical Students’ Association (Bundesvertretung der Medizinstudierenden in Deutschland e.V., bvmd)

Statement of Motivation

In order to define conflicts of interest, we use the 2010 AWMF definition:

»Conflicts of interest are defined as conditions, which create a risk for professional judgment or action, relating to a primary interest being inappropriately influenced by a secondary interest.«

Our primary interest is the wellbeing of the patient or the general public, which also includes high-quality medical education. Secondary interests include the self-interests of individual doctors, specialist groups, etc.. A distinction can be made here between material and non-material secondary interests: material conflicts of interest can arise, for example, by accepting gifts, fees or other benefits from pharmaceutical companies. Examples of non-material conflicts of interest include the desire for recognition or a professional career.

It is important to consider that conflicts of interest will inevitably arise from the coexistence of primary and secondary interests at most medical facilities. The existence of a conflict of interest should generally be regarded as neutral. Conflicts of interest cannot be avoided at the intersection between the industrial and the public sector. Universities are part of these intersections and cooperation between faculties and industry are an integral part of everyday university life. Therefore, we do not perceive e.g. industry sponsoring as negative per se. It should be noted, however, that independent, high-quality education and training on the one hand, and marketing interests of industrial partners on the other are not compatible. Prevention of inappropriate influence, for example through appropriate regulations, must be attempted. Inappropriate influence, which can result in distorted judgment and action ("bias"), is usually not perceived as such and thus happens subconsciously. The disclosure of conflicts of interest is therefore a necessary and decisive first step in the reduction and prevention of conflicts of interest and in preventing their harmful consequences respectively.

While transparency and regulations regarding connections to industry are increasingly demanded and implemented in the research context in Germany, comparable efforts within the framework of basic medical training are missing (Lieb and Koch 2014): Until now, there has hardly been any reflection regarding contacts with industry and potentially arising conflicts of interest in university training. As the period in life in which medical studies are pursued is a highly personality-shaping and career-shaping phase, it offers a lot of potential for influencing students through third parties. In order to best prepare students in professionally dealing with conflicts of interest in public-industry cooperation, it is therefore essential to address students during their studies and for teachers to act as role models in this regard.

With this in mind, we are conducting a “Study on Conflicts of Interest Policies at Medical Schools in Germany”, which intends to show the measures currently controlling conflicts of interest.

Working Group on Conflicts of Interest
Universities Allied for Essential Medicines (UAEM) Europe e.V.
German Medical Students’ Association (Bundesvertretung der Medizinstudierenden in Deutschland e.V., bvmd)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	See**:
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title (page 2)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract (page 3)
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Explained (Page 4, lines 45 ff.)
Objectives	3	State specific objectives, including any prespecified hypotheses	Objectives stated. (Page 5 lines 5-8)
Methods			
Study design	4	Present key elements of study design early in the paper	Clearly outlined survey, web search (Page 5, 6)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Dates of web-search and survey given, (page 5) setting: German medical schools clarified (page 5), Responsibilities and mode of data collection clarified (page 5).
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	All German medical schools listed as members of Medizinischer Fakultätentag (see page 5, line 18, list of websites searched in supplementary material, page

			40)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	See codebook in supplementary material (page 42-58) and method section outlining criteria (page 5)
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	See codebook in supplementary material (Page 42-58)
Bias	9	Describe any efforts to address potential sources of bias	Data extraction and analysis was double-coded. (page 5) We pre-specified analysis criteria within our codebook (page 42-58)
Study size	10	Explain how the study size was arrived at	All medical schools listed as members of Medizinischer Fakultätentag (page 5)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	NA
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	See flow diagram (page 31)
		(b) Give reasons for non-participation at each stage	See flow diagram (page 31)

		(c) Consider use of a flow diagram	See flow diagram (see page 31)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	See results section (page 7f)
Outcome data	15*	Report numbers of outcome events or summary measures	Absolute numbers given (results, page 7)
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	See results (page 7)
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	See first paragraph (page 9)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	See: limitations (page 9f)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	See paragraph on comparison with other studies. (page 9f)
Generalisability	21	Discuss the generalisability (external validity) of the study results	See paragraph on comparison with other studies. Page 9f)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	No funding (see page 12)

*Give information separately for exposed and unexposed groups.

** Page numbers refer to the manuscript PDF proof of resubmission (July 22 2020)

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.