EDITORIAL

OPEN ACCESS Check for updates

Taylor & Francis

What Does CME Accreditation Stand for?

Reinhard Griebenow, Peter Mills and Joerg Stein

European Cardiology Section Foundation, European Cardiology Section Foundation (ECSF), Cologne, Germany; European Cardiology Section Foundation (ECSF), Cologne, Germany

Independence has been top of the agenda of accrediting bodies worldwide for many years and has just recently been aligned in a consensus document [1] adopted by major accrediting bodies. Furthermore, independence from any undue third-party influence has also been a top criterion to be assessed in the accreditation process. As a result, currently accrediting bodies demand that faculty should be carefully selected, in particular with regard to competing interests, and representatives of commercial interests can at no point take a role in continuing medical education(CME).

Nevertheless, the Marburger Bund (MB) position paper on the independence of CME [2] reminds us that aiming at the independence of CME needs to take a holistic view of all the factors which have an impact on items relevant to CME and its outcome. Though this position paper relates to a German background, it addresses some issues of general importance for medical education in general, and CME accreditation in particular:

(1) Physicians have globally claimed that professional autonomy is an indispensable prerequisite to establish a trustworthy physician-patient relationship [3], and that no third-party influence should ever interfere with this [4]. In the current increasingly complex health-care settings, it has become a challenge to maintain autonomy in medical decision-making, and this also relates to opinion forming by medical education. Since contemporary medicine is committed to the principles of evidence-based medicine, competence in evaluating trial design and statistical methods is also crucial to being able competently to exert professional autonomy. But this is still conceived by many physicians as "deculturalization" of medicine, which they think should be based on personally imparted clinical experience (from expert to trainee), and thus, at least in Germany, competence in methodology has still not become a mandatory and structured part of undergraduate syllabus.

EUROPEAN CME Forum

- Thus, for the time being, the minimum solution to this problem should be that accrediting bodies should make it obligatory that time is devoted to the topic of related methodological issues in each accredited CME activity.
- (2) The quantity and accessibility of evidence have become important: doubling time of "medical knowledge" has been estimated to be in the range of 73 days in 2020 [5], and consequently, the volume of publications summarising evidence (e.g. guidelines) has multiplied in only about two decades [6]. This clearly demonstrates that the sheer quantity of information can no longer be assimilated by the individual physician, whether presenter or learner in a CME context. This is further complicated by the fact that there exists no single source where all information on clinical trials can be found: in times of clinical mega trials, it usually takes years to analyse and publish all the data, and this, for various reasons, in most cases involves publication in multiple journals. Thus, as a contemporary example, the results of only the main outcomes of the FOURIER trial of evolocumab, a monoclonal antibody which results in cholesterol lowering, have so far been published in 12 full papers between 2017 and 2020, involving 7 different peer-reviewed journals (bibliography provided by the manufacturer).

But, since the quantity of time for CME, in general, has not proportionately been lengthened, this has also created a mounting content-time mismatch with the potential to introduce significant selection bias through segmentation of evidence due to time constraints. It

^{© 2020} The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (http://creativecommons.org/licenses/by-nc/4.0/), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

probably needs a complex intervention to solve this multi-layer problem, but the proposals made by MB deserve further consideration, since they attempt to preserve as much professional autonomy as possible for the individual physician:

- MB takes a strong stance for professional selfregulation in proposing that assimilation of large quantities of evidence in limited schedules should be achieved by systematic integration of aggregate data (like meta-analyses, systematic reviews) provided by independent, profession-led organisations (like the Cochrane Collaboration) with transparent procedures for assessment of evidence. Accrediting bodies should consider making this a general recommendation/rule in their accreditation frameworks.
- But MB also recognises the limitations of what the profession can achieve: in the light of the ongoing efforts of industry to limit transparency and restrict access to outcomes data in particular [7,8], regulators will definitely need to take action to ensure not only integrity of CME but also, even more importantly, patient safety [9,10]. It is not acceptable that content in CME is selected and presented without the influence of industry, if the content itself has already been biased by industry. Thus, organisations representing the interests of medical professionals, which might include, among others, the International Academy for CPD Accreditation, the global representation of accrediting bodies, and, in Europe, the Standing Committee of European Doctors (CPME), should probably join forces and start a joint initiative, in order to encourage regulators to create databases not only to serve licencing purposes but also CME [11].

Maintaining intellectual autonomy through building competence and ensuring full access to all data (i.e. transparency) is the only way to contain latent doubts and distrust, already present in the medical community [12–15], and for which the current corona crisis has provided only the most recent striking reason [9,10,16–19].

(3) Language is a crucial tool not only in physicianpatient interactions but also in physician-physician communication, and determines our concepts, practice, and motivation in delivering healthcare Thus, as can be demonstrated during the current COVID-19 pandemic, the difference in language between remdesivir is a "breakthrough" [20–22] or that it is "helpful but not a wonder drug" [23] will have an important effect on the readers' reactions.

Efforts are ongoing to translate "symbols" (like p-values) into meaningful clinical decisions. These range from new ways in statistical reporting [24,25] to finding appropriate wording to differentiate between "noticeable" and "valuable change" in outcomes in clinical trials [26]. However, it is still the case that; disparate appraisals (e.g. "strong" recommendations based on expert consensus, i.e. in the absence of publicly available evidence, or use of subgroup analyses as proof of efficacy); misinterpretation [27–29], and spinning [30], alone or in combination with incomplete reporting [31,32] are not uncommon. Although more research is clearly needed on language in physician–physician interactions, current findings show devastating differences in the effects of language on decision-making, e.g. in the wording of guideline recommendations [33,34].

On this background MB proposes:

- Strict separation of description of strength of evidence from presenters'/authors' opinions: For the time being this is likely to be the only way to avoid confusing evidence with opinion, and the bar should be set very low, including the avoidance of labelling a statistical difference as "highly significant".
- Use of subjunctive mood of verbs for all findings from non-randomised investigations: As has impressively been demonstrated with hydroxychloroquine in the COVID-19 pandemic [35,36], currently the bar seems to be set so low that any evidence is considered as a call for action [37,38], despite not being able to justify off-label prescriptions of potentially harmful drugs. This reduces considerations of the strength of evidence to an academic exercise with little (if any) impact on clinical decisionmaking. Notwithstanding that also randomised trials need to be scrutinised, the MB proposal to use the subjunctive mood of verbs for all findings from non-randomised investigations at least tries to give the two classes of evidence a linguistic representation, signifying (at least in German language) differences in confidence to support clinical decisions. However, this approach is not evidence-based, and thus needs further evaluation. Importantly it shows that also more research is needed to clarify potential differences in language perception across different languages and/or cultures [39]. It also

emphasises that it is likely to be impossible to differentiate all levels of evidence with appropriate discriminative power solely by language, and thus, it may be a helpful supportive measure to demonstrate to participants' differences in strength of evidence through some sort of diagrammatic hierarchical presentation of content, as proposed by MB.

• Respect professional autonomy and don't try to push decisions in cases of weak evidence: Most accrediting bodies demand, that CME presentations should be "balanced". As pointed out this has a perspective related to quantity and availability as well as to quality of evidence, but it also relates to decision autonomy of the individual physician. Or to put it in other words, where evidence does not speak for itself, third party recommendations cannot justifiably claim to impact on the individual physician-patient relation. CME, in such cases, has not only to discourage largely arbitrary decisions (as with the use of hydroxychloroquine for COVID-19) but must also not suggest certainty where there is none. Thus, the only way to preserve decision autonomy is to provide physicians with the available problem-related information (evidence), but leave the ultimate decision entirely to the treating physician without interference from third parties.

To find solutions to language issues will not be an easy matter, but is crucial, since time is against us: our ability to memorise grades of trustworthiness of information fades with time ("sleeper effect", 40) and later debunking of erroneous beliefs, once formed, may be complex [41].

Do we need more engagement of professional unions in discussing principles of CME? Professional unions champion professional autonomy and intellectual integrity in everyday medical decisions to support their members in their fight against economisation, if not commercialisation of health-care systems. In view of the broadly designed strategy pursued by industry, ranging from influencing trial design to lobbying with policymakers [42–44], in order to safeguard their interests, accrediting bodies will probably need support from all stakeholders with an interest in independent CME.

Acknowledgments

We owe references 39 and 40 to Dr. Jennifer Mayer, Social Cognition Center, University of Cologne, Cologne, Germany.

Disclosure Statement

Authors' declarations of interests can be found under "Supplementary Material".

References

- Consensus statement for independence and funding of CME/CPD. [cited 2020 Jun 1]. Available from: https:// academy4cpdaccreditation.files.wordpress.com/2018/11/ consensus-statement-for-independence-and-funding-ofcme_cpd_final_sept-en1.pdf
- [2] Gehle HA, Herrmann H. Criteria to assess independence of continuing medical education (CME)- Independence through competence and transparency. J Eur CME. 2020;9:1. DOI:10.1080/21614083.2020.1811557.
- [3] World medical association declaration of seoul on professional autonomy and independence. [cited 2020 Jun 1]. Available from: https://www.wma.net/policies-post /wma-declaration-of-seoul-on-professional-autonomyand-clinical-independence/
- [4] World medical association declaration of geneva. [cited 2020 Jun 1]. Available from: https://www.wma.net/poli cies-post/wma-declaration-of-geneva/
- [5] Densen P. Challenges and opportunities facing medical education. Trans Am Clin Climatol Assoc. 2011;122:48-58.
- [6] Kann B, Johnson SB, Aerts HJWL, et al. Changes in length and complexity of clinical practice guidelines. Oncology. 1996–2016. DOI:10.1001/jamanetworkopen.2020.0841.
- [7] Court of justice upholds EMA's approach to transparency. [cited 2020 Jun 1]. Available from: https://www. ema.europa.eu/en/documents/press-release/courtjustice-upholds-emas-approach-transparency_en.pdf
- [8] Köhler M, Haag S, Biester K, et al. Information on new drugs at market entry: retrospective analysis of health technology assessment reports versus regulatory reports, journal publications, and registry reports. BMJ. 2015;350:h796.
- [9] Available from: https://www.iqwig.de/en/press/pressreleases/all-clinical-trial-data-on-covid-19-medicinesand-vaccines-should-be-published-on-the-day-ofmarketing-authorisation.13015.html
- [10] Available from: https://www.fda.gov/news-events/fdavoices/insight-fdas-revised-policy-antibody-testsprioritizing-access-and-accuracy
- [11] Zarin DA. The culture of trial results reporting at academic centers. JAMA Internal Medicine. 180(2):319– 320. DOI: 10.1001/jamainternmed.2019.4200
- [12] Drazen JM. Believe the data. N Engl J Med. 2012;367 (12):1152–1153.
- [13] Kesselheim AS, Robertson CT, Myers JA, et al. A randomized study of how physicians interpret research funding disclosures. N Eng J Med. 2012;367:1119–1127.
- [14] Dal Ré R, Kesselheim AS, Bourgeois FT. Increasing access to FDA inspection reports on irregularities and misconduct in clinical trials. JAMA. 2020;323:1903– 1904. doi: 10.1001/jama.2020.1631.

- [15] Zhai M, Lye CT, Kesselheim AS. Need for transparency and reliable evidence in emergency use authorizations for coronavirus disease 2019 (COVID-19) therapies. JAMA Intern Med. 2020;180(9):1145.
- [16] Available from: https://www.washingtonpost.com/ health/2020/05/04/fda-steps-up-scrutiny-coronavirusantibody-tests-ensure-accuracy/
- [17] Mahase E. Covid-19: antibody test that claims to be 99% accurate is certified by EU. BMJ. 2020;369:m1742.
- [18] Mahase E. Covid-19: "Unacceptable" that antibody test claims cannot be scrutinized, say experts. BMJ. 2020;369: m2000.
- [19] Mahase E. Covid-19: two antibody tests are highly specific but vary in sensitivity, evaluations find. BMJ. 2020;369:m2066.
- [20] Zagury-Orly I, Schwartzstein RM. Covid-19-A reminder to reason. N Engl J Med. 2020; 383:e12. DOI:10.1056/NEJMp2009405.
- [21] https://www.ksta.de/koeln/-durchbruch-fuerrisikogruppe-wird-aus-remdesivir-eine-alternative-zum -impfstoff-36742410
- [22] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the treatment of Covid-19- preliminary report. N Engl J Med. DOI:10.1056/NEJMoa2007764.
- [23] Mahase E. Covid-19: remdesivir is helpful but not a wonder drug, say researchers. BMJ. 2020;369:m1798.
- [24] Evans SJW, Mills P, Dawson J. The end of the p-value? Br Heart J. 1988;60:177-180.
- [25] Harrington D, D'Agostino RB, Gatsonis C, et al. New guidelines for statistical reporting. J N Engl J Med. 2019;381(3):285–286.
- [26] Weinfurt KP. Clarifying the meaning of clinically meaningful benefit in clinical research. JAMA. 2019;322 (24):2381–2382. DOI:10.1001/jama.2019.18496.
- [27] Braithwaite RS. EBM's six dangerous words. JAMA. 2020;323(17):1676-1677.
- [28] Smith PRM, Ware L, Adams C, et al. Claims of "no difference" or "no effect" in Cochrane and other systematic reviews. BMJ Evid Based Med. DOI:10.1136/bmjebm-2019-111257
- [29] Corneli A, Calvert SB, Powers III, et al. Consensus on language for advance informed consent in health care-associated pneumonia clinical trials using a Delphi process. JAMA Network Open. 2020;3(5):e205435.
- [30] Khan MS, Lateef N, Siddiqi TJ, et al. Level and prevalence of spin in cardiovascular clinical trial reports with statistically nonsignificant primary outcomes. JAMA Network Open. 2019;2(5):e192622.
- [31] Rubinstein SM, Sigworth EA, Etemad S, et al. indication of measures of uncertainty for statistical significance in

abstracts of published oncology trials. JAMA Network Open. 2019;2(12):e1917530.

- [32] Lundh A, Lexchin J, Mintzes B et al. Industry sponsorship and research outcomes (Review). [cited 2020 Jun 1]. Available from: https://www.cochranelibrary. com/cdsr/doi/10.1002/14651858.MR000033.pub3/ epdf/full
- [33] Nast A, Sporbeck B, Jacobs A, et al. Perception of the binding nature of guideline recommendations. Ger Arztebl Int. 2013;110:663–668.
- [34] Weberschock T, Dreher A, Follmann M, et al. Bindingness of recommendations in guidelines: survey on perception among guideline developers. ZEFQ. 2016;113:1–8.
- [35] Vaduganathan M, van Meijgaard J, Mehra MR, et al. Prescription fill patterns for commonly used drugs during the Covid-19 pandemic in the USA. JAMA. 2020; 323(24): 2524–2526.
- [36] Magagnioli J, Narendran S, Pereira F et al. Outcomes of hydroxychloroquine usage in USA veterans hospitalized with Covid-19 medRxiv preprint doi: 10.1101/ 2020.04.16.20065920
- [37] Kim MS, Prasad V. The clinical trials portfolio for on-label and off-label studies of eculizumab. JAMA Intern Med. 2019. DOI:10.1001/ jamainternmed.2019.4694
- [38] Fanaroff AC, Califf RM, Windecker S, et al. Levels of evidence supporting american college of cardiology/ American Heart Association and European society of cardiology guidelines, 2008-2018. JAMA. 2019;321 (11):1069–1080.
- [39] Guinart G, Kane JM, Corell CU. Is transcultural psychiatry possible? JAMA. 2019;322(22):2167–2168.
- [40] Weiss W. A "sleeper" effect in opinion change. J Abnormal Soc Psychol. 1953;48(2):173–180.
- [41] Cook J, Lewandowsky S. The debunking handbook.
 St. Lucia, Australia: university of Queensland; 2011.
 November 5. ISBN 978-0-646-56812-6. Available from: http://sks.to/debunk
- [42] Rasmussen K, Bero L, Redberg R, et al. Collaboration between academics and industry in clinical trials: cross sectional study of publications and survey of lead academic authors. BMJ. 2018;363:k3654.
- [43] Wouters OJ. Lobbying expenditures and campaign contributions by the pharmaceutical and health product industry in the USA, 1999-2018. JAMA Intern Med. 2020;180(5):688-697.
- [44] Moynihan R, Bero L, Hill S, et al. Pathways to independence: towards producing and using trustworthy evidence. BMJ. 2019;367:16576.