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CONFERENCE REPORT

Cologne Consensus Conference, Management of Conflict of Interest, 12 and 13 September 2014, Cologne, Germany

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Abstract

On 12–13 September 2014 the third annual Cologne Consensus Conference (CCC) was held in Cologne, Germany. The two-day educational event was organised by the European Cardiology Section Foundation (ECSF) and the European Board for Accreditation in Cardiology (EBAC), a specialty CME-CPD accreditation board of the European Union of Medical Specialists (UEMS). The conference was planned in cooperation with an impressive group of international organisations and faculty members representing leading European and North American institutions. Each year, the CCC is organised around a specific topic area. For the conference's third iteration, the management of conflicts of interest (COI) was the focus. The CCC 2014 was an exceptional opportunity for international experts and leadership to gather and learn from one another through both the formal presentations and lively group discussions. This report provides a summary of the presentations and discussions from the educational event.

Keywords: conflicts of interest, COI, bias, disclosure, CME, CPD, Europe, relationships, educational event

Introduction

Professor Heinz Weber, Chairman of the ECSF Council, welcomed the approximately 60 participants by recognising that the management of conflicts of interest is a topic that is far-reaching, difficult to ascertain, subjective, and controversial. But a topic that is timely and critically important to preserving the public trust and ensuring the integrity of information and actions in the medical profession. Professor Weber went on to describe the conference goals as improving the understanding of common concepts and approaches, diminishing grey zones, and increasing harmonisation across the various groups and COI policies. He closed by wishing the assembly of experts two days full of stimulating and fruitful discussions; a hallmark of the Cologne Consensus Conference.

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History
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Conference programme and session summaries

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- Introduction
- What do we know about the effects of unmanaged COI?
- Declaring COI: it matters how we ask

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- Legal background for disclosure procedures

Physicians and their relationships

- What is COI and is it different between stakeholders?
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- Royal College of Physicians and Surgeons of Canada
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- COI: towards global consensus – the International Academy for CPD Accreditation

Current practice of disclosure of COI: scope, limitations, perspectives

- *European Medicines Agency* (EMA)
- *British Medical Journal* (BMJ)
- *European Heart Journal* (EHJ)
- *Association of Scientific Medical Societies* (Germany)

Summary and conclusion

Background

Chairs: Prof. Heinz Weber, MD, PhD; Chairman, ECSF Foundation Council
Prof. Alan Fraser; Wales Heart Research Institute

Introduction

Speaker: Prof. Reinhard Griebenow, MD, PhD; Conference Chair; Chairman, EBAC Advisory Committee
Prof. Reinhard Griebenow set the stage for the 2-day educational meeting with a general definition: "A conflict of interest is a set of circumstances that creates a risk that a professional judgement or actions regarding the primary interest will be unduly influenced by a secondary interest" (Thompson, 1993, p. 573).[1]

Although this definition of COI would be regularly cited throughout the day, Prof. Griebenow recognised that it does not provide practical guidance for actual COI management. As a result, he went on to propose nine theses that would serve as a conceptual framework for the rest of the conference.

- There is no better definition.
  The definition is all-encompassing and incorporates all types of COI: economic, financial, scientific, political, cultural, geographical, ethnic, racial, religious, gender related, and so on.
- COI is inevitable.
  With such a definition, everyone is ultimately conflicted in one way or another, often with a direct proportionality between professional success and magnitude of COI.
- COI matters.
  Data show that COI actually do, or are at least perceived to, impact behaviour. This may be facilitated by the fact that the translation of evidence into language has as yet not been standardised.
- Many, if not most, COI cannot be resolved.
  Moving from the conceptual to the practical, Prof. Griebenow introduced four possibilities for managing COI within the scope of CME-CPD accredited activities: removal, exclusion, recusal, and transparent declaration.
- Removal is often no option and exclusion is no option in CME-CPD.
  Removing the source of conflict is often neither practical nor a reasonable request to make on those contributing to the CME-CPD activity. Excluding those with COI is generally not an accepted option if you adhere to the belief that conflicts are inevitable and that everyone is conflicted in one way or another.
- Recusal should become standard; transparent and detailed declaration of COI is feasible, administrable, and key for participants.
  As presented by Prof. Griebenow, recusal suggests removing oneself from participation either literally or figuratively to avoid a COI. This may mean declining the invitation to present in cases of strong potential for bias or refraining from making judgements in related content. At a minimum, recusal implies a critical assessment of the COI and the potential impact on the content presented, while explicitly clarifying the relationships when presenting and marking any judgements or recommendations as potentially biased. Further, detailed declarations should be made available before, during, and after an event.
- The primary addressee of declarations of COI is the participant.
  Learners need time to reflect on the declared conflicts and form a basis for balanced judgement of the presented content. As such, transmission of COI information should be done before, during, and after the activity.
- Management of COI is key for credibility in CME-CPD.
  In the medical profession, where patient care is at stake, learners and the public need to trust the content that is being presented.
- Management of COI should be done with the highest scrutiny.
  In order to become truly effective, this must be part of a more comprehensive strategy addressing other areas of concern in CME-CPD, such as publication bias, translation of evidence into language, and so on.

Prof. Griebenow closed his introductory session by underlining that these concepts and more would be explored throughout the conference (Thompson, 1993).[1]

What do we know about the effects of unmanaged COI?

Speaker: Prof. Bernard Lo, MD; President, The Greenwall Foundation

Dr. Lo began his session by exploring the effect of industry sponsorship on clinical trial results. Dr. Lo described a recent meta-analysis examining 48 papers comparing drug or device research sponsored by industry versus those with other, non-industry sponsors. The study found that industry-sponsored clinical trials are more likely to report favourable results and conclusions, while being less likely to have concordance between those results and conclusions. Dr. Lo went on to explain some possible reasons for the association, including that industry only sponsors trials which have a high likelihood of efficacy and regulatory approval. Other reasons include publication bias against negative results, under-reporting of serious adverse effects for those studies with widely prescribed medications, and bias in the trial analysis and design.

Dr. Lo continued by examining the impact of industry sponsorship on readers of journal articles. He described a randomised study of how physicians interpret research funding disclosures. The study, published in the *New England Journal of Medicine* (September 2012), found that physicians rated the credibility of industry-funded abstracts lower than trials with government funding or no funding described, even when following the same methodology. This suggests that individual physicians may give inappropriate weight to declared conflicts compared to actual bias, diminishing the credibility and trustworthiness of the study.

Furthermore, Dr. Lo outlined some key concepts for COI policies. First, identify relationships that raise significant concerns of conflict and potential bias; relationships cannot be assessed or managed unless first disclosed. He went on to suggest that the disclosure process itself has inherent challenges. He noted the diverse requirements about what to disclose, imprecise categories, and the risk that the administrative burden of collecting disclosure could shift the focus from taking the necessary steps to avoid actual bias. In other words, the burden of COI policies should not outweigh the benefit. He suggested that such policies be empirically tested and data driven. Dr. Lo closed by supporting self-regulation, with professional societies taking the lead in creating and implementing policies to address bias and COI.

Declaring COI: it matters how we ask

Speaker: Prof. Christopher Baethge, MD, PhD; Editor-in-Chief, Section Science and CME, Deutsches Ärzteblatt and Deutsches Ärzteblatt International

Offering a view of COI not often heard in CME-CPD conferences, Dr. Baethge described some of the psychological factors behind COI and the potential for bias. He began by introducing the concept of reciprocity. Humans return favours, feeling ashamed if they do not, and punishing others who do not appropriately reciprocate. This is, in fact, an important archaic human behaviour fundamental to group formation, social bonding, and division of labour. In short, when receiving a benefit or favour from another, it is human nature to feel compelled to reciprocate with some sort of return. This urge exists beyond conscious control, working subliminally to drive unconscious behaviours. Although not the only mechanism at work, reciprocity is a powerful force often contributing to the under-reporting of COI, as the person may be unaware that there is anything to declare.

Dr. Baethge went on to describe a study examining the effects of simply changing the manner in which COI disclosure was collected in three German journals. Initially, disclosure instructions were general. Authors were requested to include "financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what was written in the submitted work" (definition of COI from the International Committee of Medical Journal Editors [ICMJE]). The question was broad and allowed authors to provide disclosure information in a free-text format. Moving beyond this general, unstructured approach, the disclosure collection method then developed to employ a detailed form with directed, closed-ended questions requiring a yes–no answer and additional information when answered affirmatively.

Analysis of the study results showed a direct association between the directed, close-ended questions and an increase in the percentage of positive COI statements, compared to the previously open-ended, free-text format (see Figure 1). Although a limited study, one can conclude that authors will make more accurate and detailed COI declarations when the tool used is straightforward with directed, closed-ended questions and categories.

Legal background for disclosure procedures

Speaker: Peter Hustinx; European Data Protection Supervisor

Speaking as the European Data Protection Supervisor (EDPS), Hustinx contributed valuable recommendations regarding European privacy and data protection regulations. The EDPS advises and oversees EU institutions and bodies involved in collecting, recording, retrieving, and making available to others an individual's personal data. Hustinx began by explaining that EU data protection laws are based on the conviction that the right to a private life and protection of personal data are fundamental rights to be diligently safeguarded. However, he also recognised the critical importance of managing COI and promoting transparency in order to ensure the authority, objectivity, and integrity of the medical profession. The EDPS's role is

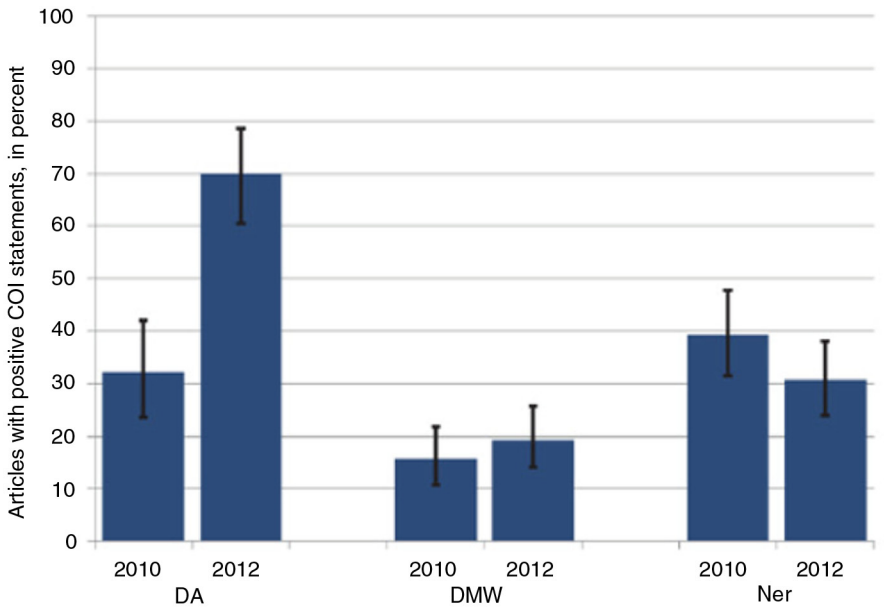

Figure 1. Percentage of articles with positive COI statements in 2010 versus 2012 in three German journals (reproduced from the presentation by C. Baethge).

to assist organisations in finding the right balance between the two fundamental, but seemingly conflicting, objectives of transparency and privacy. In support of this mission, in 2014, the EDPS released practical guidelines focusing on the key concepts of:

- Lawfulness of processing
  Is the request for personal information based on legitimate and defensible purposes and appropriate legal grounds? Is the professional or legal obligation to provide this information in balance with the need for privacy?
- Necessity and proportionality
  Is the purpose for collecting and further processing the information clearly stated? Are we asking for too much information that may not be relevant to the indicated purpose? How long will the information be retained? To whom will it be made accessible and for how long?
- Rights of data subjects
  A key element is to ensure that those whose information is being collected are duly informed of the process and have the right to access the information, rectify it as necessary, and ultimately have it deleted in case of a valid objection.

Hustinx emphasised that the EDPS guidelines provide a baseline of standards and acceptable practices that should equally guide COI policies and procedures in CME-CPD. He closed by explaining that the EDPS also works closely with colleagues in EU member states to translate the guidelines into local laws and improve European harmonisation.

Physicians and their relationships

Chairs: Murray Kopelow, MD, MS (Comm), FRCPC; President and CEO, Accreditation Council for Continuing Medical Education

Otmar Kloiber, MD; Secretary General, World Medical Association

What is COI and is it different between stakeholders?

Speaker: Sean Hayes, PsyD; AXDEV Group International

Hayes began by providing several definitions of COI and bias, the common thread being their risk to the objectivity and integrity of professional judgement and actions. Hayes then went on to challenge the same definitions for their limitations and subjectivity, questioning whether we may be actually biased towards bias. He developed this by examining the various types of bias that can influence CME-CPD (see Figure 2) and its impact on learners.

He went on to cite the US Institutes of Medicine (IOM) who in their 2009 report *Conflict of Interest in Medical Research, Education, and Practice* (2009) stated that "The focus on conflicts of interest related to financial ties with industry distracts attention from other threats to objectivity and public trust, such as career ambitions, a desire for recognition, intellectual bias, personal ties, and physician payment methods." Hayes therefore proposed several practical measures for mitigating risks of bias and COI in CME by describing a recent performance improvement initiative. In this example, key measures for COI management included:

- Independent, multi-stakeholder planning team.
- Early agreement on the roles and responsibilities of the collaborators.
- Potential COI and risk mitigation strategies for each of the various stakeholders that were proactively identified in the initial planning phases.
- Used evidence to drive educational content.
- Locally validated content by the target audience.

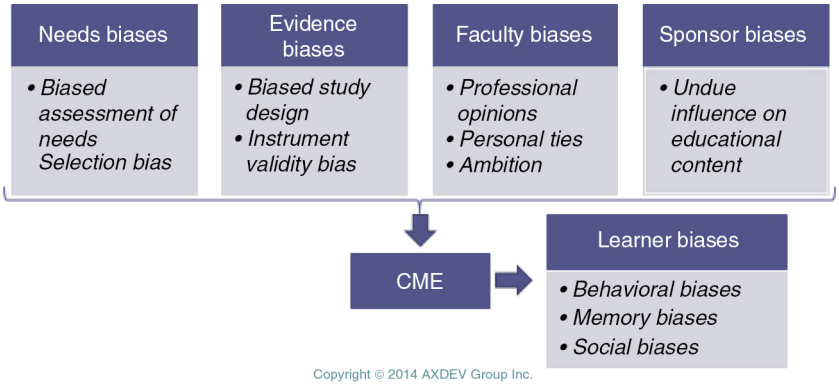

Figure 2. Types and examples of bias influencing CME-CPD (reproduced from the presentation by AXDEV Group).

- Comprehensive evaluation plan developed in the design phase that included an IRB approved evaluation and measurement of programme impact on patient care.

In conclusion, Hayes summarised that COI is different between stakeholders and conceded that it is virtually impossible to eliminate all risks of bias. However, risks can be mitigated by using a mix of strategies going beyond solely focusing on COI disclosure.

Non-financial COI

Speaker: Amir Qaseem, MD, PhD, MHA, FACP; Director, Clinical Policy, American College of Physicians; Chairman, Guidelines International Network

Dr. Qaseem began by presenting the ICMJE definition of non-financial COI: "Personal relationships, academic competition, intellectual passion; relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, the submitted work." The concern, according to Dr. Qaseem, is that the focus is currently on financial COI, while other non-financial influences are generally less emphasised, but equally important. However, this is changing and many international organisations are now beginning to address the issue of non-financial COI; or rather "non-direct financial interests," a term proposed by Dr. Qaseem illustrating the belief that most non-financial relationships ultimately contribute to financial gain (e.g. employment and resulting salary). Dr. Qaseem went on to further assert that all those involved (clinicians, patients, policy makers, staff, etc.) should disclose all relationships, both financial and non-financial. In summary, everyone should disclose everything. In order to minimise the risk of bias and manage the vast disclosure information that would result, Dr. Qaseem made several recommendations:

- Use of a standardised form.
- Set a clearly defined time period.
- Make no distinction between actual and perceived COI.
- All disclosure is made public for the primary interests to assess if COI or not.
- Information is regularly updated.
- Chairs should have no financial conflicts and no directly relevant non-financial conflicts.

COI of providers

Speaker: Eugene Pozniak; European CME Forum; Siyemi Learning

Flashing his disclosure slide for about a second, Eugene Pozniak began by demonstrating the limitations of this primary disclosure and transparency practice in Europe. He then graphically illustrated the various types of activities that are produced, ranging from pure promotion to formally accredited education by CME providers (see Figure 3).

Pozniak went on to distinguish different types of CME providers in Europe: academic (medical societies/associations, local employer, or hospital) and commercial. He described how providers are implicated in the planning and delivery of educational programmes, from securing funding to evaluation and management of the COI process. Given this key role, he questioned why in Europe providers are not required to disclose their own COIs. In fact, quality providers with a proven track record of independence and adherence to the many rules are a vital resource in managing COI and delivering content free from bias. Despite this, the contributions of the provider community remain under-recognised within some important European CME-CPD organisations. Pozniak concluded with a positive vision for the future role of the provider: formal recognition of the provider as an integral part of the CME programme. With that should come the expectation that CME-CPD providers be held to the same strict transparency and disclosure requirements as any other contributor.

Transparency initiatives of industry

Speaker: Holger Diener, JD; Managing Director, Legal Counsel, Voluntary Self-Regulation of the Pharmaceutical Industry

Diener opened by briefly introducing the German Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. (Association of Voluntary Self-Regulation for the Pharmaceutical Industry). The FSA was founded in 2004 by 39 pharmaceutical member companies. Today, FSA members cover over 70% of the total turnover of prescription-only products in Germany. In its efforts to improve public trust, the FSA addresses COI through transparency with its codes

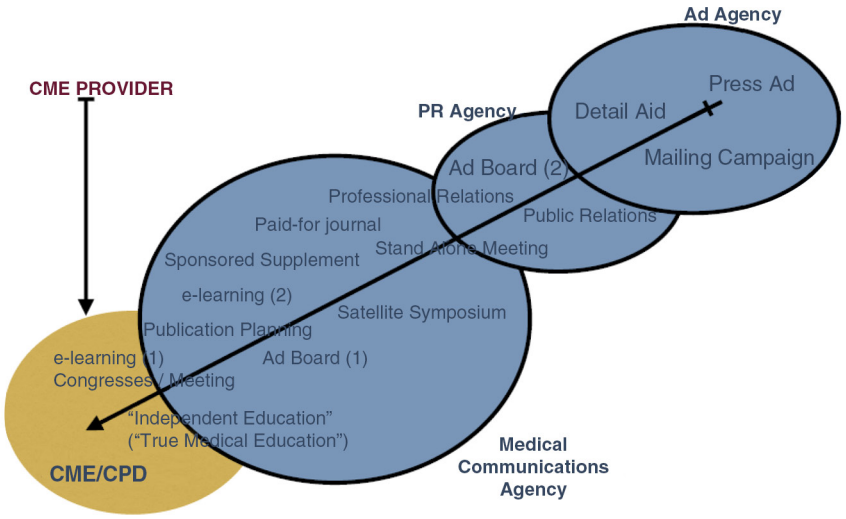

Figure 3. Types of activities produced by organisations in Europe (reproduced from the presentation by E. Pozniak).

of conduct for interactions with healthcare professionals requiring the following.

- Publications made by third parties about medicinal products must clearly disclose sponsorship by a member company.
- Contractual partners must disclose their relationships with member companies if the subject matter being presented is the same as that of their contractual relationship.
- Event organisers must disclose member company sponsorship (both condition and scope) when the event is announced and when it takes place.
- Member companies must publish monetary and in-kind donations with a value of more than 10,000 Euro per recipient, per year.
- Member companies must make publically available a list of all the patient organisations they support financially throughout Europe.

In addition, starting in 2016, all transfers of value whether direct or indirect to individual healthcare professionals or organisations must be disclosed and made publically available. Adherence to the FSA Codes is not voluntary and sanctions for non-compliance include fees up to 400,000 Euro (payable to charity) and disclosure of company name on the FSA website.

Diener shared some positive repercussions of the transparency initiatives, including that many event organisers are now publishing sponsorship of all companies, not just of FSA member companies. He also recognised that there are still challenges finding balance between transparency initiatives and data privacy laws. Although, as pressure for improved transparency increases, organisations will be less able to refer to data protection arguments. He concluded by summarising that reactions in Germany have been overall positive and that while much work has been done, there still remains much to do in order to achieve the necessary transparency that creates confidence and dispels distrust.

Current standards in disclosure and management of COI

Chairs: Prof. Lampros Michalis, MD, PhD; Member, EBAC Advisory Committee
Peter Mills, MD, BM, BcH (Oxon), BsC, MA, FRCP; Member, ECSF Board

Why do COI raise concern?

Speaker: Humayun J. Chaudhry, DO, MS, MACP; President and CEO, Federation of State Medical Boards

Dr. Chaudhry began by introducing the Federation of State Medical Boards (FSMB) of the United States, an organisation founded in 1912 and now representing the country's 70 state medical and osteopathic boards. The FSMB's mission is to lead by promoting excellence in medical practice, licensure, and regulation. Dr. Chaudhry described several key changes in health care delivery in the United States that are significantly impacting the medical profession. First, the diversification of the health care delivery team. In this care model, physicians play a central, but changing, role amongst the inter-professional team members (see Figure 4). As a result, when addressing COI, conflicts of all team members should be addressed as a risk for bias that can impact medical objectivity and judgement. As the team-based care model quickly advances, organisations such as the FSMB are adapting and beginning to study a team-based approach to regulation, increasingly interacting with a broader range of regulatory bodies such as state boards of nursing and pharmacy.

Dr. Chaudhry went on to explain additional complexities of managing COI where conflicts may arise from the physician payment system itself. This is especially true in the United States where physician ownership of health care facilities and subsequent self-referral practices remain problematic. Aggravating this risk, the work environment has substantively changed where doctors find themselves with reduced autonomy, increased administrative burdens, and declining incomes. As a result, physicians are torn between their dual roles as medical professionals whose

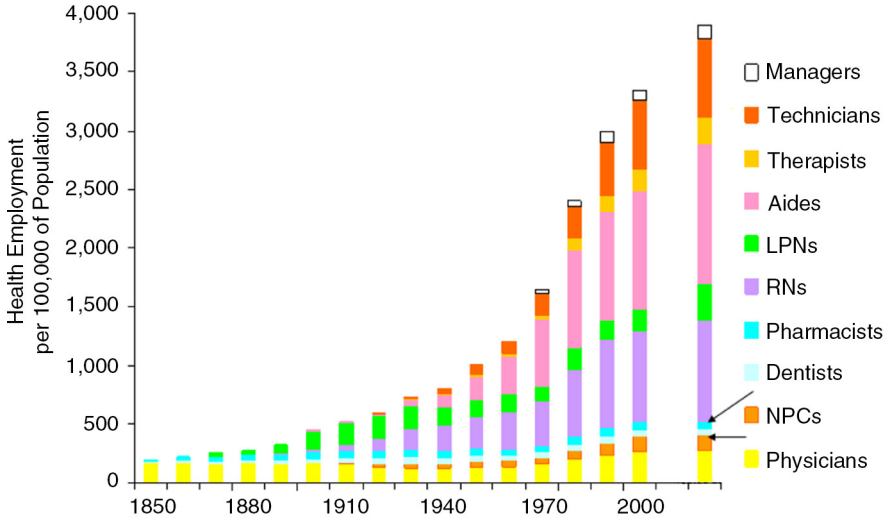

Figure 4. Physicians, non-physician clinicians, and other health workers, 1850–2010 (reproduced from the presentation by H. Chaudhry).

primary objective is to render service to humanity, and as individuals wishing to earn a living within a health care system where financial incentives for medical and surgical procedures are common. In response to this conflict, the US government has adopted legislation such as the Stark Laws and the Physician Payment Sunshine Act. Dr. Chaudhry not only acknowledged the role of government regulation of physician practice in the area of medical licensure and discipline but also noted the value of prospectively encouraging physician behaviours through the use of guidelines, collaboration, and support to identify areas for improvement and implement positive change.

View of Accreditors

Chairs: Prof. Lampros Michalis, MD, PhD; Member, EBAC Advisory Committee
Peter Mills, MD, BM, BcH (Oxon), BsC, MA, FRCP; Member, ECSF Board

American Accreditation Council for Continuing Medical Education

Speaker: Murray Kopelow, MD, MS (Comm), FRCPC; President and CEO, Accreditation Council for Continuing Medical Education
Dr. Kopelow opened the session by stating that within the ACCME's accreditation system, COI are managed in real time thanks to the network of providers and their direct engagement with learners. He explained that the Standards for Commercial Support (SCS) are the basis for this and went on to outline a 10-point solution for managing COI throughout the planning process (see Figure 5).

In this system, there are clear foundational expectations for independence that ensure that the educational needs, objectives, content, those controlling content, selection of educational methods, and evaluation of the activity remain free from the control or influence of a commercial interest (a commercial interest is defined by the ACCME as "… any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients"). The ACCME's SCS include the following minimum requirements for the disclosure of personal COI.

- All those in control of content (including staff, planners, faculty, authors, reviewers, etc.) must disclose.
- Relevant financial relationships with a commercial interest as defined above.
  - Relevant – only relationships related to the content presented.
  - Financial – the ACCME does not require disclosure of non-financial relationships.
  - In any amount.
- Within the past 12 months.
- Applies to the person, spouse, or partner.
- Anyone not complying with the disclosure requirement is to be excluded from participation in the activity.

The provider must implement a mechanism to resolve all identified conflicts prior to the educational activity being delivered to learners. Disclosure of all personal COI must also be made to learners before the activity and must include the name of the individual, name of the commercial interest(s), and the nature of the relationship with each company. If no relevant financial relationships exist, this must also be disclosed to learners. Finally, the ACCME SCS also require that the source of all commercial support to the activity itself be disclosed to learners prior to commencement. Dr. Kopelow concluded by underlining that the SCS are designed to safeguard accredited CME from commercial influence, while also allowing room for the profession to express itself without the fear of persecution due to real or perceived conflicts.

Royal College of Physicians and Surgeons of Canada

Speaker: Craig Campbell, MD; Director CPD, Royal College of Physicians and Surgeons of Canada
Representing another North American accrediting body, Dr. Campbell opened by introducing the Royal College's

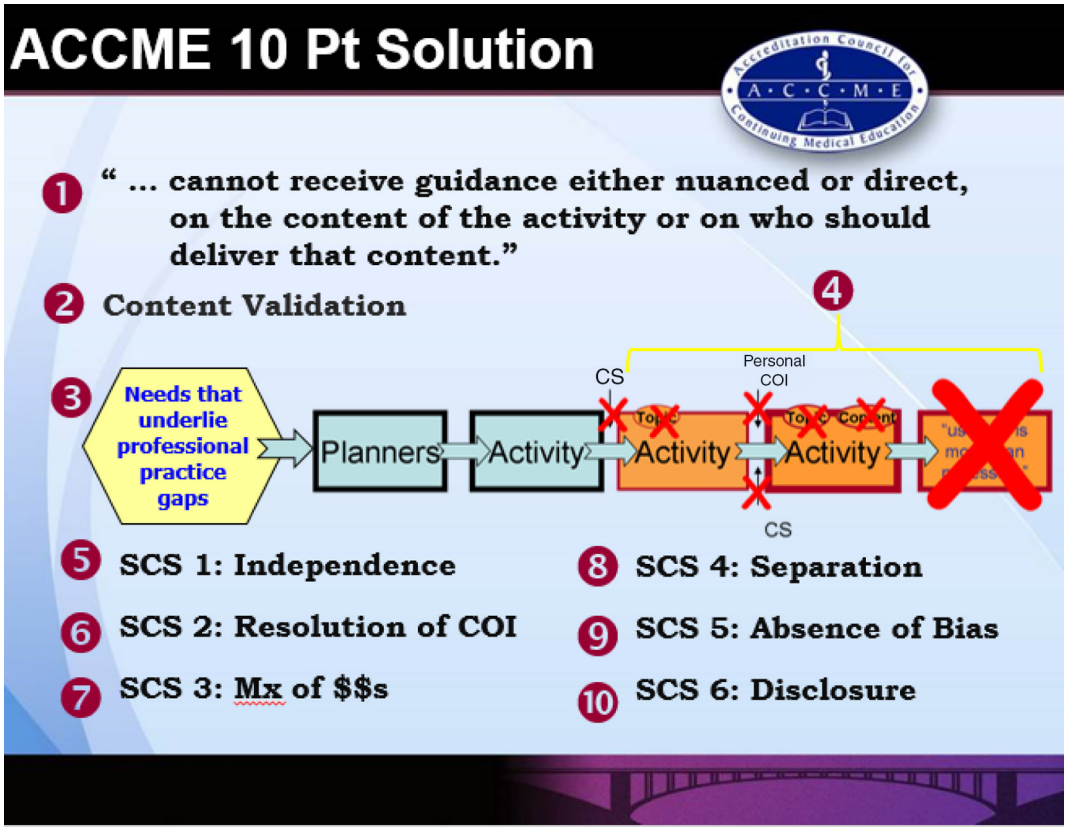

Figure 5. ACCME 10-point solution to COI management (reproduced from the presentation by M. Kopelow).

continuing professional development accreditation system. In 2001, the mandatory Maintenance of Certification Program was implemented, with a formal CPD accreditation system introduced in 2004. Within this structure, providers are responsible for upholding and implementing the educational and ethical standards across a wide range of CPD activities. Dr. Campbell went on to outline guiding principles for the development of COI requirements within the Royal College system, beginning with the key ethical mandate of ensuring that CPD addresses the educational needs of the medical profession, and not the promotional needs of industry. COI policies must therefore safeguard the independence of accredited continuing professional education by reducing the potential for influence by commercial interests and reducing sources of systematic bias. He went on to describe the Royal College's requirements for gathering, disclosing, and managing conflicts.

- COI management is a shared responsibility between the CPD organisation, scientific programme committee members, and individual faculty members.
- All faculty and scientific planning committee members must disclose.
- Gathering COI declarations is facilitated using structured COI forms with definitions and targeted questions.
- Faculty are required to disclose financial support, research grants, membership on advisory panels, and so on.
- All relationships must be disclosed, regardless of relevance to the topic or sponsors.
- Within the past 24 months.

Relationships must also be communicated to participants of the CPD activity through the programme materials and as part of the second slide of the presentation. Dr. Campbell went on to provide potential options for actually managing COI that included simply declaring the conflicts and evaluating for impact, adjusting the focus or topic, performing a full content review, or withdrawing the invitation to speak. Dr. Campbell also made some practical suggestions for improving disclosure to learners.

- Faculty should explicitly link relationships with specific content being discussed.
- Faculty should describe how COI were addressed.
- Speakers should pause and allow participants to ask questions.
- Declarations should be included in printed materials or on a central web service posting all COI.

Dr. Campbell closed by recognising that there is not one prescriptive solution to managing COI. Like other organisations, the Royal College is continually grappling with COI issues and how to ensure the integrity of its CPD accreditation system.

European Accreditation Council for Continuing Medical Education

Speaker: Zlatko Fras, MD; UEMS Liaison Officer

Providing the perspective of a European accreditation system, Dr. Fras began by introducing the UEMS, founded in 1958 to represent the interests of specialist doctors at an international level. The UEMS established the EACCME in January 2000, with the aim of encouraging high standards in the development, delivery, and harmonisation of continuing medical education. In 2011, the UEMS-EACCME® implemented criteria for the accreditation of e-learning materials, followed in 2013 with the implementation of a substantially revised set of criteria for the accreditation of Live Educational Events (LEE) (UEMS 2012/30). In this event accreditation system, criteria 24–27 and 29–31 address management of COI and require the following.

- Written declarations of potential or actual COI of the scientific and/or organising committee, whether due to a financial or other relationship, must be provided to the EACCME upon submission of the application.
- Faculty must also provide written declarations of potential or actual COI, although not required upon submission of the application.
- Providers must demonstrate how actual conflicts have been resolved.
- Declarations must be made readily available with the programme of the LEE or on the website of the organiser.
- The programme must present a scientifically balanced perspective of the subjects included.
- All sponsorship and advertising components must be clearly separated from the scientific and educational elements.
- All industry funding must be declared and documented for transparency purposes.
- Events provided by the pharmaceutical and medical equipment industry will not be considered for accreditation.
- The scientific and/or organising committee must confirm that it has determined the content to be free from any sponsor influence.

Dr. Fras stressed that if medical institutions do not act voluntarily to strengthen their COI policies and procedures, as the UEMS-EACCME has done with its new criteria, the pressure for external regulation is likely to increase. In closing, Dr. Fras recommended that speaker COI forms should be available on the event website and in the abstract book, speakers should list their affiliations on their presentation's second slide, and the evaluation should include a question on perceived bias.

COI: towards global consensus – the International Academy for CPD Accreditation

Speaker: Jennifer Gordon, MEd; Associate Director CPD, Royal College of Physicians and Surgeons of Canada

Jennifer Gordon described a new international organisation established to promote and enhance the development, implementation, and evolution of CME-CPD accreditation systems throughout the world. As a result of international groups of experts bridging national boundaries and building common ground amongst international accreditation systems, the International Academy for CPD Accreditation was created in 2013. The organisation was born of a need and desire to bring these experts in CME-CPD together to share best practices and learn from one another. Currently, the academy comprises 25 members in 12 countries, with an ever-increasing global interest and reach.

Although a young organisation, the academy has established clear goals and projects (see Figure 6). Specifically related to COI management, Gordon explained that the academy is examining multiple CME-CPD taxonomy and SCS from accreditation systems around the world. The goal is to analyse and assess the similarities and differences among the COI policies and identify opportunities for developing common or substantively equivalent standards. Gordon concluded her presentation by leading a discussion around questions that all organisations, regardless of their provenance, are contending with: what would an international standard for COI look like, is global consensus possible, or how could this be integrated into substantive equivalency agreements?

Current practice of disclosure of COI: scope, limitations, perspectives

Chairs: Craig Campbell, MD; Royal College of Physicians and Surgeons of Canada

Prof. Reinhard Griebenow; MD, PhD, EBAC Advisory Committee and Conference Chair

European Medicines Agency

Speaker: Frances Nuttall; Senior Policy Advisor, European Medicines Agency

Nuttall opened the afternoon sessions on Day 2 by describing how the EMA manages COI within its organisation. With a mission of fostering scientific excellence in the evaluation and supervision of medicines for the benefit of the public and animal health, the EMA has implemented strict policies and procedures to closely manage COI. She also emphasised the importance of these policies remaining balanced between the need for independence and transparency and the need to secure the most qualified and independent scientific expertise.

Since the agency's establishment in 1995, all those employed by and involved in EMA activities are required to provide thorough declarations of COI. These declarations must include all financial relationships of both the individual and their close family members. Declarations are maintained and publically accessible on the EMA website. When reviewing the disclosure declarations, the EMA considers whether the individual is in a decision-making or advisory role, along with the nature of the declared interest and its impact on the expert's independence (see Figure 7). Nuttall further explained that the EMA has also implemented a review process to ensure the accuracy and completeness of the disclosure information itself. This quality control involves a sampling process of comparing

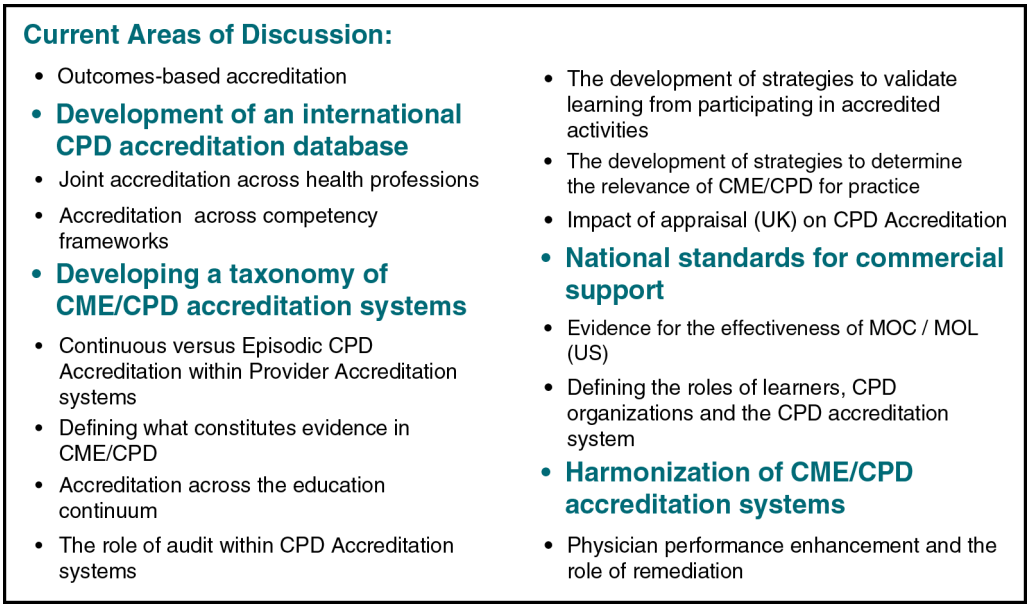

Figure 6. International Academy for CPD Accreditation goals and projects (reproduced from the presentation by J. Gordon).

declarations with CVs and obtaining clarifications from the individual, as necessary. In cases of an incorrect or fraudulent declaration, the EMA would consider excluding the expert, staff would be subject to disciplinary procedures including potential termination, the information could be made public, and the European Anti-Fraud Office notified. Nuttall closed by recognising that the agency is experiencing improved readiness of individuals to provide this important information. She credited this to an increasing consensus on the principles of COI management and also to the maturation of the EMA's policies, which are reviewed every 3 years and are publically available on the agency's website.

British Medical Journal

Speaker: Mabel Chew, MBBS (Hons) FRACGP; Associate Editor, British Medical Journal

Showing evidence and examples of why managing competing interests is so important was how Dr. Chew began her presentation. She continued by explaining COI management policies implemented by the *BMJ* for both research papers and education articles. In the case of research papers, all authors are required to complete the *BMJ* disclosure form (the ICMJE form) and provide information on their associations with entities that provided support for the submitted work, entities that could be viewed as having an interest in the general area of the work, and also non-financial associations that may be considered relevant to the submission. Authors are then required to include a summary statement for inclusion in the published article. Full disclosure forms must be made available by the authors upon request.

The process for education articles (clinical reviews, practice articles, and state of the art reviews) is one that has undergone changes. Until late 2013, the *BMJ* required that authors read a three-page policy and declare their interests as applicable. The *BMJ* would only reject articles from those with too egregious a link. However, unlike research, education articles do not report direct data but convey an author's interpretation of selected data, translated

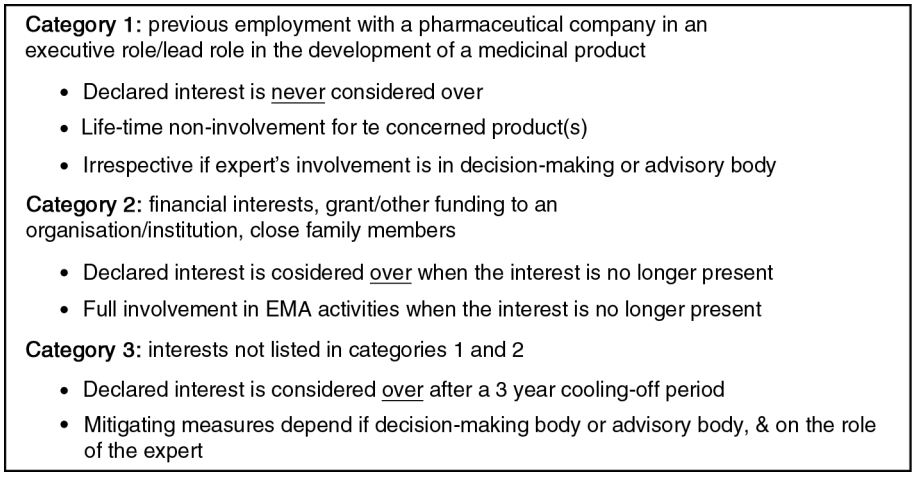

Figure 7. European Medicines Agency categories for nature of declared COI (reproduced from the presentation by F. Nuttall).

to clinical advice, with a direct bearing on patient care. Biases are thus less visible to the general medical reader; resulting in complex COI cases that are difficult to manage. The *BMJ* therefore revised its COI policy to better address these challenges and now requires authors of education and editorial articles to submit:

- A structured and directive form with definitions and examples of what to disclose.
- Detailed declaration of financial and non-financial competing interests.
- Interests in the 36 months before the declaration and those known to occur in the coming 12 months.
- Description of the relationship, how it relates to the article topic, and any contractual agreements to disseminate product information.
- Who prompted submission and whether professional writers contributed (for unsolicited articles).

This information is collected from authors before deciding whether to commission them, to encourage unsolicited proposals, or to proceed with unsolicited submissions. Currently, a summary COI statement is included in the final article, but the *BMJ* has started publishing the complete form alongside guideline summaries also, and plans to do so for other education articles and editorials. Dr. Chew went on to explain that declarations are assessed by the handling editor and, to ensure fair and consistent application of COI policies amongst the editorial team, may be discussed at a regular editors' meeting. The *BMJ* does not publish summaries of guidelines with industry funding, articles by authors on speakers' bureaus, or articles by authors who are employees, board directors, or stockholders of companies with products relevant to the article. Thus, the *BMJ* has chosen to focus on implementing a more robust COI disclosure and management process. However, Dr. Chew explained that the *BMJ* is also seriously considering whether to mandate that authors of education articles and editorials be altogether free of industry-linked financial competing interests, and would welcome opinion on this. The view of many conference delegates was that this would be going too far and would exclude useful expertise.

European Heart Journal

Speaker: Jan Steffel, MD; Associate Editor, European Heart Journal

Continuing the journal editor's perspective on COI management, Dr. Steffel reviewed core principles for the evolution of a research project, which generally finds root in the author's interests. As a result, there are intellectual (author's favourite hypothesis), financial (how to support the project), and professional (does it promote the author's career) interests to be considered. Like several other organisations presenting throughout the conference, the *EHJ* collects COI information using the ICMJE's disclosure form. Therein, Dr. Steffel drew attention to the importance of Section 3, which addresses relevant financial activities outside the submitted work that are broadly relevant and which could be perceived to also influence the submitted work. Acknowledgement of the disclosure information is included at the end of the article and indefinitely accessible for all readers online. The *EHJ* currently does not make the entire form available but is considering doing so. The journal does not have a formal process for verifying accuracy of authors' disclosure statements, but Dr. Steffel believes that with the proliferation of transparency initiatives such as the Sunshine Act and EFPIA Disclosure Code, the medical community will auto-regulate and self-impose increased disclosure accuracy. Dr. Steffel did note that the *EHJ* does not require reviewers to disclose. Although currently voluntary, this may become mandatory in the future. In closing, Dr. Steffel underlined the importance of increasing consensus amongst the various organisations' COI policies and cited rising use of the ICMJE's disclosure form as a positive example of harmonisation.

Association of Scientific Medical Societies (Germany)

Speaker: Prof. Ina Kopp, MD, PhD; Chair of the Guidelines International Network (G-I-N)

Rounding up the second day of formal presentations, Dr. Kopp began by providing some background to the guideline development process in Germany. Representing the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF) she explained that ownership and responsibility for guidelines lies within the profession, namely with the scientific medical societies. In Germany, support, coordination, and quality assurance are provided by the national umbrella organisation AWMF. The AWMF networks with national quality initiatives to promote implementation and evaluation of guidelines and serves as the primary contact to the Guidelines International Network G-I-N. AWMF maintains a quality managed public guideline registry, currently containing approximately 700 publications developed by the 168 member societies. Documented declaration and management of COI is an integral part of this guideline development and maintenance process and the AWMF collects disclosure information as follows.

- Structured and directive form with definitions and examples of what to disclose.
- Provision of detailed information on financial and non-financial interests for discussion and appraisal within the guideline development group.
- Required for individual, institution, and close family members.
- Request to make declarations public in summary format, with the option to provide either detailed information or yes/no answers per category of the form.
- Consensus not to provide detailed amounts publicly.

The COI declaration summary is included in the guideline report, with additional information available upon request. As part of its COI management policy, the AWMF prohibits direct commercial funding or influence

over guideline development. They also require that persons perceived as unduly biased by COI should be excluded from critical appraisal of the evidence and decisions on recommendations. Ultimately, the AWMF will reject for publication any guidelines with problematic funding or lack of proper COI documentation and transparency. Dr. Kopp also presented results of a 2013 AWMF study on trends in COI management by the guideline development groups. Results showed that the vast majority of guideline development groups in Germany opted for publication of detailed information about COI. However, there remains a lack of evidence for effectiveness of COI management with multiplicity of forms, definitions, terminologies, legal implications regarding data protection, and so on. She concluded by reiterating the common message heard throughout the conference that COI are unavoidable and as such, management strategies need to be tested and evaluated in order to deal with uncertainties better and enhance ethical decision-making.

Summary and conclusion

The CCC provided an exceptional opportunity for international experts and leadership to gather and learn from one another through both the formal presentations and lively group discussions. From the start, all agreed on the critical importance of managing COI in order to preserve the integrity of the medical profession and ensure the public trust therein. There was also consensus that it is the responsibility of the profession itself to self-regulate, without which there would surely be an increase in external regulation and government legislation. There was no question that doing so is a challenging task when considering the omnipresence of bias and the impossibility of mitigating all conflicts and risk. So, how much policy is enough but not too much? How to find the right balance between the burden and the benefit of COI management? How to ensure that policies are not so restrictive that relationships with industry are stigmatised to the point of creating unwarranted scepticism regarding content or discouraging beneficial collaborations?

Over the 2-day conference there was much discussion about trying to answer these questions. All agreed that the emphasis should ultimately be on avoiding bias in the content presented, and that COI management as part of a comprehensive strategy is a means to achieving this end. Practically speaking, however, there still remain important variations regarding the "who, what, when, and how" of the various processes. Some address only financial relationships, while others include non-financial interests ranging from religious beliefs to personal relationships. Some apply to a 12-month time period, others to several years. Some consider all conflicts equally regardless of the nature or financial level, while others use a risk stratification process to quantify the level of risk for bias (EBAC is currently working on such a system, to be presented in 2015). There was agreement that creating a common set of terminologies and categories would facilitate the process and improve standardisation. This, encouragingly, seems like an achievable goal already being addressed by the International Academy for CPD Accreditation. Although there is not one universal disclosure form, there are increasing similarities and principles employed across systems. Specifically in the medical journal community, the ICMJE disclosure form is being widely used, showing that practical and sustainable consensus is achievable in some areas, even if similar levels of standardisation have yet to be achieved in CME-CPD.

The CCC 2014 set out to improve understanding of common concepts and approaches, diminish grey zones, and increase harmonisation across the various groups and COI policies. All will surely agree that positive steps were made during the time in Cologne. Nevertheless, the charge now is for participants and leadership to go beyond the conference's information exchange and stimulating discussions and translate what was learned into actionable improvements adapted to their own unique systems and domains; all the while doing so in greater alignment with the broader community.

The next Cologne Consensus Conference will take place on 11 and 12 September 2015 in Cologne, Germany, and will focus on "Providers in CME-CPD." For more information on future and past conferences, including presentations and reports, please visit: http://e-cs-f.org/en/about-ecsf/activities-and-projects.html

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