

## CONFERENCE REPORT

# Report on the Cologne Consensus Conference 20–21 September 2013

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The European Cardiology Section Foundation (ECSF) inaugurated the Cologne Consensus Conferences (CCC) in 2012. ECSF is the parent organisation of the European Board for Accreditation in Cardiology (EBAC), one of the specialty accreditation boards of the European Union of Medical Specialists (UEMS) that accredits international continuing medical education/continuing professional development (CME/CPD) in the field of cardiovascular medicine.

CPD accreditation is currently facing a climate of change. The European associations of medical manufacturers have started a major move regarding sponsoring and transparency, which is closely related to questions of independence and quality of medical information. In parallel, editors of major medical journals have demonstrated increasing awareness of independence of content and prevention of scientific fraud. Thus, ECSF decided to create the CCC as an open forum for discussion of the advancement of accreditation rules, based on the experience of the past 10 years and taking into account contemporary concepts of CPD.

This year's CCC focused on the quality of medical information, educational quality, and the quality of the accreditation process and again offered an opportunity for discussion among regulators and accreditors, educationalists, and providers. This text provides a summary of the 2 days' CCC 2013, which was held under the patronage of the World Medical Association (WMA), Guidelines International Network (G-I-N), Accreditation Council for CME (ACCME, USA), and the Chamber of Physicians Northrhine (DE).

## Day 1

### Introduction

Professor Heinz Weber, chairman of the ECSF Council, and Marc Jan Eumann, representing the state government of North Rhine-Westphalia, welcomed participants to the third meeting of the CCC. The main topic was accreditation of CPD.

### Quality of medical information

*Professor Reinhard Griebenow*, conference chairman and president of EBAC, made the first formal presentation. He said that currently accreditation is granted in relation to the time spent engaging with the educational material and has no relationship with the quality of the material. He described the continuum of communication in medicine from randomised controlled trial (RCT) to guideline and commented on a domino effect where errors early in the continuum subsequently become accepted as truths. He mentioned evidence that industry-sponsored research is more likely to report better outcomes and favourable harm results than non-industry-sponsored research. He made a plea for a hierarchy in reporting trial results that must include mortality and morbidity and also that

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### History

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negative studies should always be published. The language of reports should discriminate among causal relationships and associations. Conclusions must accurately reflect the data and must not include biased statements not justified by study findings.

In questions after the presentation, doubt was expressed that, in the present European system, guidelines are not always accredited. A comment was made that it may be difficult to have negative studies accepted for publication.

*Professor Gerd Gigerenzer* from the Max Planck Institute for Human Development, Berlin, raised the question ‘What does a 30% chance that it will rain mean?’. Meteorologists, like doctors, communicate probability badly. Doctors do not understand statistical evidence, and patients similarly do not understand probabilities.

He cited a study where 98% of German women overestimated the benefits of mammography screening and 99% of UK men overestimated the benefits of prostate-specific antigen (PSA) estimation. The most realistic European nation was Russia, where the people are exposed to less information from doctors.

He then described the ‘seven sins that contribute to patients’ health illiteracy’.

1. Biased research funding, not directed to areas that are relevant to patient care (e.g. to development of checklists for procedures or to helping doctors become more statistically literate). It is more useful to investigate ways of improving health literacy in patients than to develop new cancer drugs.
2. Biased reporting in journals with lack of transparency and specifically mismatched framing using relative risks to report benefits and absolute risks to report harms. Journal editors and reviewers need education in transparent and honest presentation of data.
3. Biased reporting in health pamphlets (e.g. lead-time bias due to screening with no change in real mortality and overdiagnosis, where low risk cancers detected by screening are included with progressive cancers). This problem can be solved by generating ‘fact boxes’ in which data are presented in a transparent way. Sometimes it may help to show risks using icons rather than numbers.
4. Biased reporting in the media—journalists are statistically illiterate and should receive statistics training. There should also be media watchdogs to refute misleading claims.
5. Commercial conflicts of interest (COI)—problems with fee-for-service systems and CME sponsored by the pharmaceutical industry.
6. Defensive medicine—in a US study, 93% of doctors admitted practising defensive medicine because of litigation risk. In Switzerland, the hysterectomy rate in the general population is 16%, but it is only 10% in female doctors and doctors’ wives. Pressure should be brought to bear

on governments to amend legislation that favours the development of defensive medicine.

7. Doctors’ lack of understanding of health statistics—American doctors do not understand the difference between 5-year survival statistics in cancer screening patients and mortality rates. There are similar findings in Germany—almost no German physicians understand lead time bias and overdiagnosis in screening programmes. Medical schools and CME should undertake to improve doctors’ statistical literacy.

He concluded by summarising the ways in which the profession can try to deal with the seven sins.

*Dr Regine Potthast*, Institute for Quality and Efficiency in Health Care, Cologne, discussed the contribution that can be made by clinical investigators. She said that, from accredited CME, a physician wants a synthesis of all relevant studies of appropriate quality that will help to guard against wrong decisions and false expectations. Drug trials must not only define risk benefit ratios for a new drug but also show that it is better than existing treatments. Therefore, trials must include a standard treatment as a comparator, and outcomes must be measured in terms of relevance to patient well-being. It is also important that studies are designed with appropriate control arms. There must be only one variable between control and trial arms and the trial drug must be compared to standard practice rather than to placebo.

Studies with positive results are published more quickly than studies with negative results, which may lead to a false judgment on the quality of a new drug. Indeed, negative studies may never be published. A further problem is the reduction in the amount of the study data when the study is published in a journal in comparison to the data actually obtained in the study. She concluded by emphasising that studies should not only seek to satisfy regulatory authorities but also define the new drug in relation to everyday practice; second, clinical evidence should be transparent and complete and all trial data should be publicly available.

Questions highlighted the difficulty in publishing all trial data and pleas were made that governments and journal editors should be persuaded to act in this area. However, journals are concerned with maintaining or improving their impact factors, and positive trials are more likely to be cited than negative trials. In addition, editors may be reluctant to publish negative studies that will not change clinical practice.

*Dr Norbert Steinkamp*, bioethicist, Institute for the Quality of Healthcare, Radboud University, Nijmegen, discussed ethical aspects of recommendations for clinical practice. He quoted Schofferman as showing that although physicians think of themselves as being impervious to marketing, the evidence indicates that they are indeed vulnerable to it. He then quoted Pellegrino, who said that a profession was distinguished from other occupations by the elimination of self-interest. Physicians should be

trusted to use their skills not for their own benefit. Doctors should be trusted to help patients, to preserve confidentiality, and to provide true information to patients.

He contrasted morality, which encapsulates man's convictions about right and wrong in human behaviour, with ethics, which involves critical reflection on morals, principles, and values. He described seven criteria that must be followed in clinical research: (1) value, (2) scientific validity, (3) fair subject selection, (4) favourable risk-benefit ratio, (5) independent review, (6) informed consent, and (7) respect for enrolled subjects. He then described six criteria for ethical clinical practice: (1) principles of beneficence and non-maleficence, (2) respect for the patient's autonomy and integrity, (3) respect for the doctor's autonomy and integrity, (4) shared decision-making and patient empowerment, (5) compassionate professional care, and (6) justice issues.

Recommendation goals for clinical practice include reduction in complexity of information generated by research, education of practising physicians, translation of information into the clinical context, and transfer of research data into a narrative of patient care. He finished by making a plea for medicine to be considered as a moral community for the benefit of patients and thereby allowing trust to be generated.

Discussion highlighted the dilemma between symptomatic relief and aggressive treatment that was unlikely to be successful in terminal illness. Inadequately powered studies were also mentioned as being unfair to patients and therefore unethical. Accreditation has a responsibility to consider these and similar issues when reviewing applications.

*Dr Juan Garcia Burgos*, European Medicines Agency, London, spoke on the role of regulators in providing information on healthcare. The EMA provides the member states and European institutions with scientific advice on the evaluation of the quality, safety, and efficacy of medicines. More specifically, the agency is responsible for (1) the evaluation of marketing and authorisation of applications submitted by pharmaceutical companies, (2) coordination of pharmacovigilance at the European level, (3) provision of scientific advice on the development of medicines, (4) evaluation of applications of orphan designation in EU for rare diseases, (5) evaluation of paediatric investigation plans, and (6), since 2005, provision to patients and health professionals of good quality, evidence-based, independent information on the safe use of medicines. The EMA is not responsible for controlling advertising or pricing and does not advise on clinical use. It is primarily concerned with patient safety.

There are two systems for marketing approval in Europe. A centralised procedure is performed by the EMA, but there is also a decentralised procedure that provides national licenses. Both systems allow harmonised scientific opinions and information to doctors and patients. However, the centralised system just involves one application and evaluation, and there is only one authorisation for all the EU countries and one version of product

information. This system is preferable to the decentralised, national system.

The following medicines must be evaluated at the EMA: (1) treatments for rare diseases; (2) drugs for human immunodeficiency virus (HIV), cancer, diabetes, and neurodegenerative diseases; (3) drugs for autoimmune and viral diseases; (4) all biotech products; (5) gene therapy; and (6) monoclonal antibodies and most other innovative products.

The EMA provides information mainly via its website. The information changes during the different stages of drug development and includes safety data for all medicines authorised in the EU. He then described the life cycle of a drug in his system:

**Pre-authorisation:** applicable to orphan drugs and paediatrics. In addition, clinical trials are documented in the EU Clinical Trials Register website linked to the EMA website, with information on trial design, sponsorship, therapeutic area, and status of the trial.

**Authorisation:** when a drug is authorised, the European public assessment report (EPAR) summary is published online with all details of the new drug in all EU languages along with product information that is designed for the medical profession and for patients.

**Post-authorisation:** additional information on new therapeutic indications or new contraindications is added to the website.

Communication about safety referrals is performed by the Pharmacovigilance Risk Assessment Committee (PRAC), which meets monthly. Its recommendations are syndicated to the press, patients, and to healthcare professionals. The EMA also publishes the monthly *Human Medicines Highlights* newsletter, which includes details of new drugs and safety issues that have been dealt with during the previous month.

A further database of the EMA provides information on adverse drug reactions for medicines authorised in the EU—but so far only for medicines approved via the centralised procedure. The reports are constantly updated.

He concluded by saying that the EMA provides up-to-date, evidence-based information on the rational and safe use of medicines. Presenters of CME/CPD should be aware of all pertinent EMA data on relevant drugs that should be transmitted to healthcare professionals.

During questions, it was admitted that a major difficulty in transmitting information throughout Europe is related to language. It was suggested that use of icons and fact boxes might be helpful. Criticism against the EMA was expressed because it had not alerted Europe to some recent instances where drug companies had withheld important information about new drugs. Dr Burgos pointed out that the EMA had no power to force pharmaceutical companies to release data, and this required involvement by national governments.

*Dr Georg Röggl*, assistant editor of the *British Medical Journal (BMJ)*, discussed what editors can do to improve the quality of medical information. He quoted Douglas Altman who wrote in 1994 about the scandal of poor

medical research and stated that we need less research, better research, and research done for the right reasons. He suggested that researchers make so many errors because research is often carried out for career advancement by doctors who are ill-equipped to perform the research and nobody stops them. This occurs when research ethics committees do not consider the scientific aspects of proposed studies. Different issues are addressed by journalists. He quoted Ben Goldacre who writes for the British *Guardian* newspaper and who campaigns against pharmaceutical companies who do not publish all the results of clinical trials. However, journalists and politicians also mislead the public.

He then described the mission statement of the *BMJ* (a publication that is downloaded by 1.67 million users each month). Its impact factor is 17.215 and readers' comments on articles are published online within 48 hours. The *BMJ* operates an open peer review system and reviewers sign their reports. The journal gives priority to original studies that can improve medical practice and has a rejection rate of around 93%. It does not just publish positive studies but will publish negative ones, if important. However, it does not accept laboratory based or animal research or studies on volunteers rather than on patients. These are considered too preliminary for *BMJ* readers. It does not publish prevalence or cost of illness studies, open loop audits without intervention and re-audit, or placebo-controlled drug or device trials. The research message must be important, clear, and original. The study design must be appropriate for the question being asked. There must be adequate control groups. Randomised control trials must have adequate statistical power, validated research instruments, minimal deviations from the trial protocol, and proper analysis of harms.

The validity of studies requires consideration of inclusion and exclusion criteria, whether study participants are representative of most patients with the disease, and whether the intervention is compared against best current treatment rather than against placebo. The study's research question should still be relevant and not out-of-date. The *BMJ* looks for appropriate checklists for RCTs, meta-analyses, and observational studies. Studies also need a study protocol and ethics committee approval.

*Dr Amir Qaseem*, chairman of the Guidelines International Network, Berlin, and director of clinical policy of the American College of Physicians, spoke on the role of medical scientific societies in relation to the quality of medical information. He noted how fast medical literature is expanding. RCTs in MEDLINE have increased from 5,000 annually in 1978–1985 to 25,000 annually in 1994–2001. There are 15 million citations on MEDLINE with 10,000–20,000 added every week. Physicians, patients, legislators, and insurance companies need to participate in available medical education, which is now a multibillion dollar industry. Commercial support for CME now operates at US\$1.2 billion annually with profit margins for medical societies at 46.3%. Everything is a business.

Medical specialty societies have an important role in defining and advancing healthcare standards. Members and patients rely on societies to be authoritative and independent, and public confidence in the objectivity of these societies is critical. Education is delivered at conferences, in courses, with the use of practice guidelines, through the definition of ethical norms, and by publication in journals. However, there are concerns about the quality of content, lack of uniform standards, COI, poor formulation of key questions, lack of a standard reporting system, and failure to address all outcomes.

The societies must play a part in minimising COI, encouraging full disclosure of financial and non-financial conflicts by everyone involved in educational programmes, and in describing how COI are recorded and resolved. The societies must be independent of influence by the pharmaceutical industry while admitting that some of their funding comes from the industry. COI requirements must be known by members. All financial support must be disclosed, and the role of sponsoring organisations must be clear and transparent. All education should be evidence-based with quantification of benefits, harms, and costs. The widely accepted standards for guideline preparation should be followed.

*Dr Murray Kopelow*, chief executive officer of the Accreditation Council for CME (ACCME), Chicago, spoke on the role of accreditors in relation to the quality of medical information. In contrast to the criteria for acceptance of papers for journals, accredited CME does not need to be new, but it must be true and important to the learner. There are three main elements in the ACCME system, and the first is practice-based content relevant to professional practice gaps. This is not restricted to clinical practice gaps but includes educational, research, and administrative practice. The second element is independent accredited CME, which has been required in the United States since 1985. Commercial interests can pay for CME but cannot control it. The provider of CME separates promotion from education and actively promotes improved healthcare. The third element comprises other valued attributes. The CME must be designed to change competence, performance, and outcomes; the educational formats must be appropriate for the activity (e.g. didactic or interactive depending on the goal of the activity).

In a highly regulated region such as the United States, accreditors must not allow a regulatory vacuum but must determine the correct amount of regulation to encourage providers to be active. Experience shows that the right amount of regulation does lead to increased educational activity. Providers may not receive guidance from a commercial interest on the content of an activity or on who should deliver the content. This is not just an ethical rule, it is enforceable by law. When industry infringes upon this law, people go to jail. ACCME's main function is to prevent bias, not to ensure truth in education. The providers are responsible for validating the clinical content of their activities, and all recommendations must be based

on evidence accepted by the profession. Similarly, research that is quoted must conform to accepted experimental standards and not be based on limited anecdotal information. Providers who advocate unscientific methods of diagnosis or treatment are not eligible for accreditation (e.g. advocates of alternative medicine). In addition to these primary measures for the prevention of bias, secondary measures require documentation of personal COI resolution and full disclosure.

During questions, Dr Kopelow was asked about requests for proposals (RFP). He said commercial interests were entitled to identify practice gaps but could not design activities to deal with them. He was asked to describe the range of continuing education providers in the United States. He replied that they were represented by the participants of the conference: commercial medical communication agencies, medical societies, medical schools, hospitals, government agencies, and state medical societies but not commercial interests that provide drugs or devices. There was also a suggestion that hybrid accreditation systems might develop that include both activity and provider accreditation.

*Holger Diener*, from the Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA), Berlin, spoke about the role of industry in relation to the quality of medical information. His organisation is composed of 62 pharmaceutical companies with 25 dependent companies. He discussed the codes of conduct that define the relationship between the industry and healthcare professionals. Penalties for violations of the codes may be as much as €400,000.

Information about medicines is complex and continually expanding. Therefore, there must be close cooperation between drug companies and the medical community to provide patients with the best available treatment. This exchange of information must follow strict rules to avoid the impression of bias. It must be accurate, balanced, objective, and complete. It must encourage sensible use of medicines. Nevertheless, there is a perception in some places that the drug industry deliberately misleads doctors and that doctors should therefore avoid all exposure to information from the industry. He then quoted Ben Goldacre, who has written that almost everybody has COI, but that does not mean that it influences behaviour. The most common approach to COI is that it should be declared rather than outlawed, otherwise all communication between the industry and doctors will stop. Complete transparency is the key. All sponsorship must be fully disclosed.

He then referred to the Sunshine Act in the United States, which was followed earlier this year in Europe by the European Federation of Pharmaceutical Industries and Associations (EFPIA) disclosure code of transfers of value from pharmaceutical companies to healthcare professionals. The EFPIA categories of disclosure include funding for research and development, donations and grants to healthcare organisations, contributions to costs of events, and consultancy fees.

## Day 2

### Educational quality in CME/CPD

*Professor Janet Grant*, director of the Centre for Medical Education in Context and professor emerita of the Open University, spoke on doctors' changing knowledge, their community of practice, and CPD. CPD involves patient safety and ethics, cost-effectiveness, professional regulation and development, personal and professional satisfaction, and international standards. Contextual factors in CPD may be economic, personal, social, professional, political, academic, local, and national. It should be based on personal needs, service requirements, and professional needs.

Medical education comprises knowledge, skill, practice, and professional context of which the latter becomes increasingly important. It is a play of three acts, first medical school, then post-graduate training, and finally, CPD. Abstract learning is replaced by theory in practice, which itself becomes the source of learning needs and the focus of development.

Individuality characterises a profession. Experience is different for all professionals and information in memory is organised in different ways. Doctors use increasing knowledge in diagnosis until they become consultants, after which they need to use less knowledge because experience partially replaces the need for book learning. There is little uniformity in the ways doctors think about clinical problems, particularly as they become more senior. The variability relates to memory structures that are individual, tailored through practice, and that become better organised with experience.

Doctors develop individual approaches to practice, with individual learning needs. There is no best method of learning, and linking CPD to known needs may not prepare for the future nor promote an individual's development. Doctors are aware of how best they learn and know what they need to learn. Occasionally, a new area will require teaching, but in general, CPD will arise from the practice and judgment of doctors. There should not be a pre-specified curriculum.

CPD is a simple four-step process: (1) WHAT will be learned, (2) HOW will it be learned, (3) LEARN, (4) USE the learning and show effects. After identifying what to learn, the method of learning varies from reflection to peer review and quality assurance processes, and the effect ensures that the learning derives from a relevant need. How to learn requires a personal development plan with the effect that a rational and transparent record is created. The learning step is carried out in any way that is deemed appropriate by the learner such that the process is personally effective. The use of the learning and showing its effects requires dissemination to others and incorporation into practice with the effect that the learning is carried back to the workplace.

In some respects, collecting CPD credits has little benefit. There is no real underlying rationale, no relationship to need, no evidence of effect on practice, and doctors

participate for no good reason. The main criticism is that the collection of credits ignores context and community, which are essential for good CPD, and so we have to try to do better.

*Professor Martin Fischer*, chair for medical education, Ludwig Maximilian University, Munich, spoke about how CME course directors and presenters meet the needs of the participants. First, he considered the effectiveness of CME formats. Interactive methods are very effective, especially those related to daily practice, outreach activities, and skills with active repetition; less effective are audit, unmoderated quality groups, and opinion leaders; least effective are traditional lectures and print media. He presented a US pyramid figure indicating retention rates, with the *lecture* at the narrow peak associated with 5% retention, followed toward the base of the pyramid by *reading*, *audiovisual*, *demonstration*, discussion groups, *practice by doing*, and *teaching others* at the large pyramid base associated with 80% retention. He described a curriculum development cycle with seven steps: general needs assessment, needs of targeted learners, learning goals, teaching methods and strategies, implementation, evaluation and feedback, and maintenance with sustainability. The curriculum can thus be subdivided into what is declared (what is assumed the students are learning), what is taught (the presentation), what is learned (actual learning), and what is examined (what students are asked after learning).

Competence is difficult to define and to measure. Evidence is needed but what should be the measuring currency is improved participant outcomes! He contrasted instruction versus construction; first is information presentation, where learning materials stimulate sensory memory; next is information organisation, using short-term memory; that is followed by information integration in long-term memory augmented by prior knowledge.

He supported formative assessment before and at the beginning of a CME event carried out by questionnaires, self-assessment, and external assessment. One study suggested that knowledge retention was better served by retesting learners rather than by repeating the learning activity, although the effect was only evident shortly after the activity. Progress along the continuum of competence is aided by combining teaching methods—lectures, virtual patients, standardised patients, patient simulators, and ending up with real patients.

There is no learning without feedback. Summative information is not helpful, and feedback is best when formative and knowledge of correct results is given along with specific actions for gap reduction. He described the “sandwich” approach with the separate phases of gaining attention, processing information, storing information, and applying information. This approach contributes to higher learning levels, a positive learning climate with retention of information, and to improved self-study behavior.

Outcome measurement occurs at four levels: Reaction—did the learners like the training? Learning—what was learned? Behaviour—what was applied at the workplace? Results—what was the impact? The evaluation framework comprises process, outcome, and transfer—hopefully resulting in added value, cost reduction, and improved cost-benefit ratios.

He finished by emphasising key points: (1) assess needs before and during the event, (2) test participants, (3) let participants elaborate and collaborate, (4) give formative feedback, (5) try the sandwich approach and combine methods, and (6) teachers should take risks to activate their learners.

*Dr Martin Balzan*, president of the Pneumology Section and Board of UEMS and secretary of the European Board for Accreditation in Pneumology, spoke about the theory and practice of e-CME. In the business world, e-learning marketing claims it has lower costs, faster delivery, more effective learning, lower environmental impact, and that it is more convenient. There is evidence that blending live events with e-learning is more effective than e-learning alone. In medicine, user convenience of e-learning is clear. Doctors can choose their preferred time and place for learning. Protected time is not required, and it is female friendly because women have family responsibilities that make demands on the organisation of their time.

A US meta-analysis of online learning showed that students engaged in online learning performed somewhat better than with face-to-face instruction. Further improvement occurred when the two modalities were blended together. A UK study of medical trainees concluded that an e-learning course in evidence-based medicine was as effective in improving knowledge as a standard lecture course and was potentially cost-effective. A recent *Learning Insights* report, noted that there is less need to assess learning; what matters is how well staff do the job. Passing a test does not mean that behaviour will be changed in the workplace. Dr. Balzan referred to the European Respiratory Society's e-learning programme, which includes case reports, CME tests, procedure videos, and CME online modules. He also mentioned e-learning clinical scenarios that are designed to improve decision-making but are still in their infancy in medicine.

*Dr. Balzan* went on to describe his own experience in Malta where he has developed a Moodle online e-learning management system that is sharable content object reference model (SCORM) compliant. It includes weekly presentations by consultants during clinical meetings and is followed by quizzes prepared from material covered in the lectures. Articulate™ was the software used. He has also observed the usage pattern of trainees and assessed feedback on usefulness. He found that the trainees left everything until the last minute, especially the males. Much of the learning activity took place at the weekends and after working hours, again more noticeably with the male trainees. Males spent more time on the modules than did the females. It was generally felt that the system was a

useful tool that increased knowledge. Compliance was good when the system was incorporated into the curriculum. He was concerned that males spent more time on the modules than females and wanted to assess if the learners were actually in front of the screens during the supposed learning. He found that many trainees learned to skim through the slides, and that often they were not in front of the screens all the time. He concluded that the systems must be designed so as to ensure proper compliance.

During discussion, it was suggested that it is no longer acceptable to expect trainees to study during non-working hours. Another possibility mentioned was that e-CME might take place using social media.

*Martina Siedler*, head of e-publishing, Springer Medizin Journals, Heidelberg, spoke about the concept and rules of procedure for CME publishing. Springer Medizin has more than 65 scientific journals and magazines and publishes 55 journals with CME. In 2012, Springer launched e-Akademie, a new learning platform. The company focuses on CME quality in scientific knowledge, medical practice, and procedures. Each journal has a 'CME' editorial board that invites experts to submit CME papers. Articles and multiple choice questions (MCQs) are peer-reviewed by appropriate specialists. Evaluation and a help desk are available for authors. The majority of CME participants are aged 40–70 years. There are almost twice as many males as females, and most participating physicians are in private practice. Peak participation is between 5 pm and 7 pm, and Sunday is the most popular day. Springer's aim is to continuously improve its quality control at all levels.

During discussion, it was noted that impact factor was related primarily to research communication; at present, journals are deeply engaged in CME, which is not encompassed by impact factor consideration. It was suggested that, in the future, journals should be less concerned with the traditional concept of the impact factor.

### Quality of the accreditation process

*Dr Murray Kopelow*, chief executive officer of the Accreditation Council for CME, Chicago, spoke on sources of accreditation variability. In the United States, there are approximately 25,000,000 individual registrants annually in CME, which is composed of nearly 150,000 activities with almost a million hours of instruction. There are some 700 nationally accredited providers and nearly 1,500 providers accredited by state medical societies. ACCME rules are set down in 'Updated Accreditation Criteria' and 'Standards for Commercial Support'. The endpoint is the provision of optimal patient care.

The ACCME process starts with a provider self-study, which is then reviewed by the ACCME. Activity files are reviewed by a surveyor and these two sources of information are integrated. There may then be new information after the provider is interviewed. The Accreditation Review Committee makes a recommendation, which is then considered by the ACCME board. The board makes the

decision on accreditation status. Each year, there are 150 accreditation reviews and 90 progress reports from providers who have previously been non-compliant. The ACCME process must be reproducible and valid. Internal controls are necessary to maintain consistency. Layered strategies are used to maximise validity and reliability: (1) a foundation of ethics and values, (2) published rules and processes, and (3) rule-based outcomes. As an organisation matures, volunteers are complemented by professional staff necessary to maintain fair and consistent treatment of providers. There must be one set of requirements for all providers with explanations and interpretations published on the ACCME website. Staff are designated to be responsible for internal and external communication, and there must be common understanding among all staff members about the rules. Internal controls require standardisation of all aspects of the process, its interpretation, and the outcomes. As the system has become more established, the degree of non-compliance has decreased. The reliability of accreditation decisions is supported by comparison between ACCME decisions and those of state medical societies that have been found to be similar. It is important that the system does not overburden providers with bureaucracy so that providers are able to concentrate on education rather than accreditation.

*Professor Lampros Michalis*, professor of cardiology, Ioannina, Greece, spoke about professional autonomy in CME/CPD. Medical professionalism includes maintenance of competence, adherence to ethical codes of conduct, exercise of discretionary judgment, and dedication to self-regulation. This allows medicine to enter into a contract with society granting it a monopoly over the use of its knowledge base, the right to autonomy in practice, and the privilege of self-regulation.

Professional autonomy is the freedom to exercise our own judgment in the treatment of our patients. It is important because it is an essential component of high-quality medical care. Areas of self-regulation include quality of care provided to patients, cost consciousness, conduct of physicians, and newly developing problems. However, autonomy is being re-evaluated by society because of recent high profile medico-legal cases, a public perception that doctors protect their own, a suspicion that research may be biased by industry, and because of the technological revolution that has allowed access to previously restricted medical information. There is now discussion on whether a new social contract between doctors and society is needed.

One of the justifications for autonomy is doctors' engagement in CME/CPD in order to apply the latest knowledge for the promotion of health and to ensure ethical standards governing the thoughts and behaviour of doctors. CME/CPD should be provided by the profession through medical schools, hospitals, and medical societies. New knowledge and skills are based on new drugs, instruments, and diagnostic tools—all of which are produced by industry, whereas management strategies are developed by doctors. This interaction between doctors

and the industry enables great advances in patient care but also leads to COI that can affect the delivery of care to patients and that may damage the reputation of the profession.

COI may be present in the education of doctors, in relation to their institutions, and may be associated with research activities. The latter must be conducted for the advancement of medical science, and all relevant relationships should be disclosed. Trials should be accessible through public registries. Financial arrangements must be fully disclosed. The research should be owned by the investigator and not the sponsor, and the investigator should have the right to publish negative results and to release relevant information at any time.

In industry-sponsored research, the doctor must comply with the law and the Helsinki Declaration and must apply his clinical judgment in the performance of the research. Ideally, research should be supported financially by more than one company. Identifiable information about research patients should be confidential and not given to a sponsor. When results are published, sponsor details must be provided. Results may not be suppressed by commercial interests. Doctors' financial compensation should be unrelated to results. Investigating doctors must not allow themselves to be subjected to external pressure in the publication of their results.

In industry-sponsored CME, hospitality should not exceed what is locally customary and generally acceptable. Doctors should not receive direct payment for travel and subsistence at conferences. Accompanying persons at international meetings should not be helped financially by sponsoring companies. Presentations should not be influenced by sponsors, and all support must be publicly disclosed. Speakers must fully disclose their own financial affiliations. Sponsors may not influence programme design, choice of speakers, or publication of presentations. Financial support is given as a contribution to general—rather than specific—costs of the event.

In order to maintain autonomy in CME/CPD, the medical profession should have independent bodies that will create regulations adequate to reassure the public. These bodies will negotiate with government agencies involved in introducing new laws that may impact the medical profession. Dr. Michalis concluded by saying that, if these measures are taken, professional autonomy in CME/CPD will remain feasible.

*Dr. Ferdinand Hundt*, head of clinical research and regulatory affairs, Berlin University for Professional Studies, and Professor Heinz Weber, chairman of the ECSF Council, debated whether industry representatives should be allowed to present in accredited CME/CPD activities.

*Dr Hundt argued* in favour, from a German perspective. He quoted from German law that 'Arts and sciences, research, and teaching shall be free', but that the freedom of teaching shall not release any person from allegiance to the constitution. Doctors are influenced by their employment as general practitioners, by their hospitals, health

insurance companies, government agencies, political parties, trade unions, industry, medical professional associations, and by scientific societies. However, the CME code requires that educational content must be free from economic interests, and that the COI of organisers and the scientific head and speakers must be disclosed. Only a medical doctor can be nominated as the scientific head, and he or she must be present during the meeting.

Doctors engaged in CME are required to be independent of ideological and commercial interests. Dr. Hundt felt that all doctors had such interests but had to find ways to control them. Speakers must have multi-year medical experience that excludes presentation by non-medical experts. Presentations should be interactive, and informative summaries in the form of handouts should be provided. Sponsors may not influence the form and content of CME. Connections between speakers and industry must be disclosed. Product advertising on invitations and programmes of single-sponsor CME is not permitted. All CME must communicate a balanced overview. Accompanying commercial programmes may not take place along with the accredited CME. Dr. Hundt quoted an updated Cochrane review that concluded that interactive education was more effective than didactic presentation and that a mixture of both was most effective.

By implication, although not explicitly stated, Dr Hundt appeared to be supporting industry involvement in CME/CPD if German law and codes of conduct were not contravened.

*Professor Weber* argued against the proposal for industry involvement in the presentation of CME. He began by saying that doctors have an ethical duty to engage in CME/CPD. In Europe, the cost of CME is not adequately supported by governments and employers. When there is industry support of CME, communication may lack objectivity. Patients now expect more from contact with a doctor. They want information, personal investigation, drug prescriptions, and referral to appropriate specialists. The patient wants to understand his or her disease and wants a realistic prognosis. They may also want to know who is the 'best doctor' for their case. Doctors are under conflicting pressures. On the one hand, industry attempt to provide incentives for doctors to prescribe specific drugs; on the other hand, the healthcare system wants doctors to be economical in prescribing medications.

Industry bias is manifested by companies that finance studies with associated commercial interests. Study designs may be biased. Companies now promote diseases treatable by their drugs, rather than promoting their drugs for established diseases. Scientific presentations may be scrutinised by companies. There may be publication bias in which negative studies are not published. Academic bias is also related to conflicts of interest, publication bias, direct payment from companies, lack of balance and objectivity, and even scientific fraud (with selective statistical analysis).



*Professor Weber* quoted from the ESC that no employee of a medical company can serve as a member of a programme committee and from EACCME that the industry partner will not interfere with the educational programme. Dr Weber endorsed these statements and concluded that his answer to the proposal that industry may be directly represented in CME/CPD activities is 'NO'. His model for cooperating with industry requires an academic provider for educational events; this provider may be a university or other academic institution to which industry will make an unrestricted grant. The academic provider will appoint an academic director who will be responsible for the program. The academic provider may have to engage the

services of CME companies for operative support for which the academic provider will pay. There should be no money flow from industry to the CME companies or to the academic director and speakers.

At the final roundtable discussion, there was agreement that the meeting had been valuable, interesting, and informative. Professor Griebenow was thanked for organising it, and participants looked forward to next year's meeting, which will concentrate on management of COI (to be held Sept. 12th/13th, 2014). The presentations of the CCC 2013 will also be available on the ECSF homepage ([www.e-cs-f.org](http://www.e-cs-f.org)).