Pregledni članak / Review article

Odnosi između stručnih medicinskih udruga i zdravstvene industrije vezano uz znanstvenu komunikaciju i stalno medicinsko usavršavanje: Izjava o smjernicama Europskog kardiološkog društva

Relations between professional medical associations and the health-care industry, concerning scientific communication and continuing medical education: a Policy Statement from the European Society of Cardiology

ESC Board*
Europsko kardiološko društvo
European Society of Cardiology

SAŽETAK: Etička je obveza liječnika da budu upoznati s trenutnim dostignućima. Stručne medicinske udruge, poput Europskog kardiološkog društva (ESC), podupiru te vrste obveze. Troškovi stalnog medicinskog usavršavanja (SMU) u Europi su nedovoljno pokriveni od vlade i poslodavaca, ali ipak se stučne udruge kritiziraju zbog primanja alternativne financijske potpore od strane industrije. Medicinska edukacija i osposobljavanje u području istraživanja uključuje obuku procjene kvalitete i pouzdanosti bilo koje informacije. Postoje realne opasnosti neobjektivne pristranosti kod bilo kojeg oblika znanstvene komunikacije uključujući intelektualnu, stručnu i financijsku te je izrazito važno da se to uoči i razotkrije. Neophodna je bliska suradnja bazičnih i kliničkih istraživača iz akademskih institucija s jedne strane te s druge strane s inženjerima i znanstvenicima istraživačkih odjela za medicinske uređaje i farmaceutskih tvrtki. Ona je ključna za razvoj novih dijagnostičkih metoda i postupaka. Promidžba industrijskih inovacija može ubrzati njihovu primjenu u kliničkoj praksi. Sveučilišta, u ovom trenutku, često potiču svoje akademsko osoblje na zaštitu svog intelektualnog vlasništva ili na komercijalizaciju svojih istraživanja, što samo po sebi ne predstavlja komercijalnu aktivnost niti predstavlja veze koje su postale meta kritika. Pod kritikom je uočeni utjecaj komercijalnih tvrtki na donošenje kliničkih odluka ili na poruke koje prenose stručne zdravstvene organizacije. Ovaj dokument donosi stav ESC o aktualnoj raspravi te savjetuje kako smanjiti komercijalni utjecaj u znanstvenoj komunikaciji i na SMU te kako osigurati odgovarajuće etičke standarde i transparentnost u odnosima između medicinske struke i industrije.

KLJUČNE RIJEČI: znanstvene komunikacije, stalno medicinsko usavršavanje.

SUMMARY: Physicians have an ethical duty to keep up-to-date with current knowledge. Professional medical associations such as the European Society of Cardiology (ESC) support these obligations. In Europe, the costs of continuing medical education (CME) are insufficiently supported from governments and employers; however, medical associations have been criticized for accepting alternative financial support from industry. Medical education and training in research include learning how to assess the quality and reliability of any information. There is some risk of bias in any form of scientific communication including intellectual, professional, and financial and it is essential that in particular, the latter must be acknowledged by full disclosure. It is essential that there is strong collaboration between basic and clinical researchers from academic institutions on the one hand, with engineers and scientists from the research divisions of device and pharmaceutical companies on the other. This is vital so that new diagnostic methods and treatments are developed. Promotion of advances by industry may accelerate their implementation into clinical practice. Universities now frequently exhort their academic staff to protect their intellectual property or commercialize their research. Thus, it is not commercial activity or links per se that have become the target for criticism but the perceived influence of commercial enterprises on clinical decision-making or on messages conveyed by professional medical organizations. This document offers the perspective of the ESC on the current debate, and it recommends how to minimize bias in scientific communications and CME and how to ensure proper ethical standards and transparency in relations between the medical profession and industry.

KEYWORDS: Scientific communications, CME.

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Uvod

U posljednjih nekoliko desetljeća kardiologija je postala grana medicine koja se brzo razvija. Mnoga poboljšanja dolaze iz bazičnih i kliničkih istraživanja provedenih na sveučilištima i od strane tvrtki koje se bave farmaceutskim i medicinskim uređajima. Inovacije su djelomično ostvarene i učinkovitom suradnjom kliničkog osoblja, sveučilišta i industrije. Takvi oblici suradnje su važni i ako je znanstveni napredak moguće održati, potrebno ih je poticati i podržavati kroz odgovarajuća ulaganja.

Primjena medicinskih dostignuća je moguća samo ako se učinkovito prenose do znanstvenih i kliničkih zajednica, a svaki kardiolog mora biti upoznat s njima kako bi pacijentima osigurao najbolju skrb temeljenu na napretku u medicini. Glavni motiv predstavljanja novih lijekova, uređaja i dijagnostičkih alata od strane industrije je poslovne komercijalne prirode. Kada industrije podupire, direktno ili indirektno, medicinske edukacije ili znanstvene skupove, moguć je izostanak objektivnosti u znanstvenoj komunikaciji. Zabrinutost da tako stečeni interesi mogu narušiti objektivnost pri obrazovanju te time utjecati na donošenje kliničkih odluka, doveli su do pojačanog nadzora povezanosti industrije, medicinske profesije i stručnih udruga.[1-5]

Veze između industrije, zdravstvenih stručnjaka i zdravstvenih društava moraju se promatrati kritički, kako bi se osigurala etičnost i transparentnost takvih odnosa. Za stručno medicinsko društvo kao što je Europsko kardiološko društvo (ESC) to je osobito važno unutar područja znanstvene komunikacije i stalnog medicinskog usavršavanje (SMU). Svrha ovog članka je skrenuti pažnju na tu problematiku i opisati politiku ESC prema istoj.

Znanstvena komunikacija i stalno medicinsko usavršavanje

Rezultate medicinskih istraživanja prenosi i distribuira više različitih organizatora SMU pomoću različitih edukacijskih alata (**Tablica 1**). Edukacijske programe obično organiziraju skupine organizacija koje nastupaju kao partneri (**Slika 1**).

Table 1. *Settings and providers of continuing medical education.*

Settings	Providers
Hospital meetings	Educational supervisors
CME courses	Clinical colleagues
Distance learning programmes	Hospital meetings, grand rounds
	Universities and medical schools
Medical textbooks	Governmental ministries and official advisory or regulatory authorities
Medical journals	
Clinical guidelines	Professional medical associations
Internet resources	Charitable foundations
Webinars	Pharmaceutical and device companies
Word of mouth/social networks	For-profit CME companies
	Journalists and lay press
Industry-sponsored meetings	Patient associations and organizations
Medical congresses	

Introduction

In recent decades, cardiology has been a fast-moving medical speciality. Many advances have come from basic and clinical research conducted by universities and by pharmaceutical and medical device companies. Innovations have been realized in part through productive collaborations between clinicians, academia, and industry. Such links are essential and need to be encouraged and supported by appropriate investment if medical progress is to be sustained.

The implementation of medical advances is possible only if they are communicated effectively to the scientific and clinical communities, and each cardiologist must keep up-to-date to be able to offer patients the best possible care based on medical progress. When new drugs, devices, or diagnostic tools are promoted by industry, the primary motive is commercial. When industry is supporting medical educational activities or scientific meetings, whether directly or indirectly, communication may lack objectivity. Concerns that vested interests may distort education and then clinical decision-making have led to increasing public scrutiny of the relationships between industry, the medical profession, and medical societies.[1-5]

The links between industry, health-care professionals, and medical associations must be reviewed critically to ensure that these relationships are ethical and transparent. For a professional medical association such as the European Society of Cardiology (ESC), this is particularly important within the field of scientific communication and continuing medical education (CME). The purpose of this paper is to address these issues and to describe the policy of the ESC.

Scientific communication and continuing medical education

The results of medical research are communicated and disseminated by many different providers of CME using a variety of educational tools (**Table 1**). Educational programmes are often delivered by combinations of organizations acting in partnership (**Figure 1**).

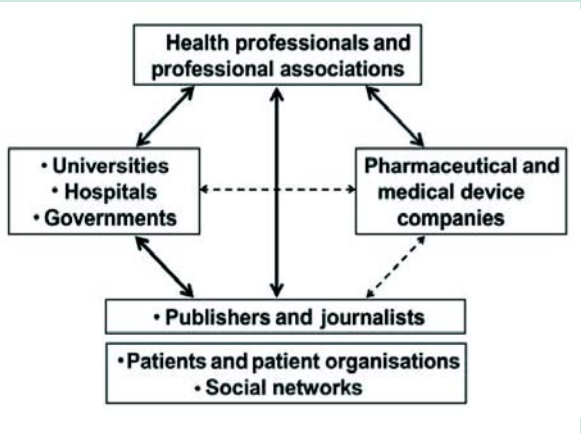

Figure 1. *Links between providers of continuing medical education and scientific communications. Solid arrows indicate the preferred channels of communication; dotted arrows are those links where an added impartial expert commentary could be useful.*

Stručne udruge: pristup Europskog kardiološkog društva

Obrazovne aktivnosti ESC, kao i slične aktivnosti ostalih medicinskih udruga, zadovoljavaju važne društvene i stručne potrebe. ESC ima misiju "smanjiti rizik kardiovaskularnih bolesti u Europi". Stručnjacima će pružanje uravnoteženih i neutralnih edukacijskih izvora i znanstvene komunikacije pomoći unaprijediti njihove profesionalne standarde.

Godišnji ESC kongres okuplja je oko 25.000 stručnjaka iz oko 140 zemalja. Znanstvene i edukativne konferencije, kao i one vezane uz kliničku praksu, organizirane su potpuno neovisno od Programskog odbora kongresa kojeg čini 50 članova, bez ijednog zaposlenog u industriji. Dostavljeno je približno 10.000 znanstvenih sažetaka te je nakon sistematskog i anonimnog postupka recenzije odabrano oko 40% koji se prezentiraju.

ESC također organizira pet simpozija, sastanaka posvećenih osnovnim istraživanjima i kliničkim tečajevima vezanim uz SMU. Internet stranice ESC (www.escardio.org) omogućuju i edukaciju u obliku e-učenja, webcasts, arhive prezentacija te online pristup znanstvenim sažecima ESC kongresa. Također, ESC objavljuje sedam recenziranih općih i specijalističkih kardioloških časopisa iz kojih se godišnje s interneta elektronički preuzme oko 4,5 milijuna znanstvenih radova.

U cilju optimalnog zbrinjavanja pacijenata, ESC razvija smjernice vezane uz kliničku praksu temeljem sveobuhvatnog pregleda objavljenih dokaza. Ovaj postupak uključuje procjenu utemeljenosti dokaza prednosti i rizika liječenja kao i stručne rasprave u cilju usuglašavanja stavova. Od 2005. do 2010. godine objavljeno je ili ažurirano 26 smjernica ESC vezanih uz kliničku praksu. Ostala znanstvena tijela u okviru ESC su tijekom 2009. i 2010. godine objavila dodatnih 50 znanstvenih izvješća sa stručnim usuglašenim dokumentima o više fokusiranih tema, a od ESC objavljeni su također i rezultati nekoliko zapisa i istraživanja.

Iako su ove aktivnosti organizirane neovisno od ESC, njihovi troškovi su neizravno i djelomično pokriveni iz financijskih sredstava koje ESC primi od zdravstvene industrije. Izlaganja na godišnjem ESC kongresu omogućava kardiolozima pristup najnovijim informacijama vezanim uz dijagnostičke i terapijske proizvode o čijoj bi se primjeni u kliničkoj praksi moglo razmisliti. Važno je da satelitski simpoziji koje organizira i potpomaže industrija budu jasno naznačeni u okviru programa i odvojeni od znanstvenih sekcija koje organizira Programski odbor kongresa.

Zdravstvene tvrtke

Privatne tvrtke imaju budućnost samo ako će biti profitabilne. U tržišnoj ekonomiji one imaju zakonsko pravo promovirati svoje proizvode i trebaju to činiti na način da ostanu uspješne. Zdravstvene tvrtke nisu nikakva iznimka, a ciljevi marketinške promidžbe uključuju prikaze rezultata istraživanja i novih proizvoda liječnicima, kao i promet isporučenih proizvoda. Dugoročni interes zdravstvenih tvrtki je bolje zastupati putem objektivnog i nepristranog usavršavanja kliničkog osoblja umjesto ponude komercijalnih proizvoda. Kada bi se u pravo vrijeme primijenila ispravna terapija postigao bi se maksimalni učinak i za pacijenta i za tvrtku.

Sve promotivne i edukacijske aktivnosti industrije ograničene su strogim propisima. U Zapadnoj Europi nužno je pridržavati se pravila koja uključuju pravila Europske federacije farmaceutskih industrija i udruga (EFPIA)[6] i Međunarodne

Professional associations: the ESC approach

The educational activities of the ESC, and similar activities by other medical associations, meet important societal and professional needs. The mission of the ESC is 'to reduce the burden of cardiovascular disease in Europe'. By providing balanced and neutral educational resources and scientific communication, it assists specialists to improve their professional standards.

The annual ESC Congress is attended by about 25 000 professional delegates from -140 countries. Scientific, educational, and clinical practice sessions are organized in total independence by the Congress Programme Committee, which has about 50 members; none of these being an industry employee. Roughly 10 000 scientific abstracts are submitted and ~40% are selected for presentation after a systematic and anonymous peer-reviewed process.

The ESC also organizes five subspeciality congresses, meetings dedicated to basic research, and clinical CME courses. Its website (www.escardio.org) offers educational resources such as e-learning programmes, webcasts, slide archives, and online access to the scientific abstracts of its congresses. The ESC publishes seven peer-reviewed general and specialist cardiology journals, from which around 4.5 million electronic downloads of scientific papers are made each year.

The ESC develops clinical practice guidelines for optimal patient care based on a comprehensive review of the published evidence on a topic. This process involves assessment of the strength of evidence of the benefits and risks of treatments and debate among experts to achieve consensus. Between 2005 and 2010, 26 ESC Clinical Practice Guidelines were published or updated. During 2009 and 2010, other scientific bodies within the ESC published another 50 scientific statements and expert consensus documents on more focused topics and the results of several registries and surveys have also been published by our society.

While these activities are organized independently by the ESC, their costs are offset indirectly and in part by funding that the ESC receives from the health-care industry. The exhibition at the annual ESC congress allows attending cardiologists to receive up-to-date information on diagnostic and therapeutic products which they might consider using in clinical practice. Importantly, satellite symposia organized and supported by industry are clearly identified in the programme as being separate from the scientific sessions organized by the Congress Programme Committee.

Health-care companies

Private companies have a future only if they are profitable. In a market economy, they have a legitimate right to promote their products and they need to do so to remain successful. Health-care companies are no exception, but the goals of marketing initiatives include introducing research results and new products to physicians as well as delivering sales. It can be argued that the long-term interests of a medical company will be served better by providing education for clinicians that is accurate and impartial, instead of offering promotion that is commercial. If the correct treatment is applied to the right patient at the right time, then the maximum benefit may be achieved for both the patient and the company.

All promotional and educational activities of industry are bound by strict regulations. The rules that must be adhered to in Western Europe include those from the European

federacije udruga farmaceutskih proizvođača[7] te nacionalne preporuke[8]. Međunarodni zakoni protiv mita i korupcije uključuju Konvenciju protiv mita Organizacije za ekonomsku suradnju i razvoj objavljenu 1997., a revidiranu 2009. god.[9] Sve međunarodne zdravstvene tvrtke koje rade u SAD moraju također ispunjavati uvjete američkog Zakona protiv korupcije u inozemstvu iz 1977. godine. Prema svim spomenutim propisima, tvrtka je obvezna preuzeti svu odgovornost za potpunu usklađenost s odgovarajućim zakonima, kodeksima ili smjernicama vezanim uz sve promidžbene aktivnosti i materijale.[7] Osim toga, sve financijske veze između farmaceutskih tvrtki i liječnika pojedinaca trebale bi se objaviti sukladno "Sunshine" zakonu. Marketinške inicijative kao što su satelitski simpoziji podliježu istim propisima kao i ostali programi.[6-8] EFPIA također propisuje kodekse ponašanje kojima se reguliraju svi vidovi sudjelovanja zdravstvene tvrtke na izlaganju na medicinskom kongresu u Europi. U promidžbu proizvoda dozvoljeno je isključivo "razumno i razmjerno" ulaganje. Postupa li se u skladu s tim ocjenjuje nasumična kontrola vanjskih procjenitelja.

Komercijalne tvrtke za stalno medicinsko usavršavanje

Posljednjih godina osnovane su tvrtke za SMU koje liječnicima nude edukacijske skupove koji nisu organizirani od strane farmaceutike ili tvrtki koje se bave medicinskim uređajima. One često organiziraju takve skupove uz pokroviteljstvo industrije, međutim njihova profitabilnost kao treće strane koja organizira SMU, može ovisiti o tome koliko zadovoljavaju očekivanja industrije. Čak i kada te nove tvrtke organiziraju skupove za sveučilišne ili stručne udruge, moguće je zatražiti financijsko sponzorstvo od zdravstvenih tvrtki. Izvješće Macy iz SAD vezano uz medicinsku edukaciju savjetuje da je takvu podršku potrebno prekinuti.[10]

Za skupove koje organiziraju profitne tvrtke za SMU ne može se jamčiti da nisu pod takvim utjecajima odnosno da su objektivni. Izravno sponzorstvo stručnim udrugama od strane industrije u obliku neograničene edukacijske potpore čak može biti transparentnije od neizravnog sponzorstva nekog sličnog događaja kojeg vodi tvrtka za SMU. Nacionalne akreditirane organizacije u SAD za SMU su tijekom 2007. godine primile 1,2 milijarde dolara komercijalnih poticaja, a veći dio od toga je vjerojatno poslužio za oblike SMU koje su relativno neučinkovite za promjenu kliničkog postupka i poboljšanje liječenja pacijenata.[11]

Širi kontekst: aktualna zabrinutost

Svjedoci smo zabrinutosti unutar medicinske struke i medija o utjecaju zdravstvene industrije na propisane obrasce i uporabu medicinskih uređaja od medicinskih djelatnika. Temeljna zabrinutost je da povezanost s industrijom dovodi do stvarnih ili uočenih etičkih sukoba.[12,13] To može utjecati na propisivanje obrazaca i odabira lijekova za bolničke liste odobrenih lijekova,[14-16] a može neobjektivno utjecati na publikacije[17-20] ili sadržaj SMU aktivnosti koje financira industrija[3]. Kako bi se smanjila mogućnost da komercijalna industrija utječe na kliničke odluke stručna društva su pozvana na financiranje iz članarina, subvencija i fundacija, a ne putem poticaja iz industrije.[12,13,21] Nije neobično da autori iz različitih krugova imaju sasvim različite stavove.[22]

Ako se dijagnostički i terapijski napredak u medicini ne može komercijalizirati, vjerojatno se neće naširoko promovirati te se možda neće moći implementirati. Spomenuto je da bi

Federation of Pharmaceutical Industries and Associations (EFPIA)[6] and the International Federation of Pharmaceutical Manufacturers Associations[7], as well as national recommendations[8]. International anti-bribery and anti-corruption laws include the Antibribery Convention of the Organisation of Economic Cooperation and Development, published in 1997 and revised in 2009.[9] All international medical companies that operate in the USA must also meet the requirements of the US Foreign Corrupt Practices Act of 1977. According to all these regulations, a company should ensure and take responsibility for full compliance with all relevant laws, codes, or guidelines regarding all promotional activities and materials.[7] In addition, all financial relationships between a company and an individual physician will now be made public following the "Sunshine" Legislation. Marketing initiatives such as satellite symposia are subject to the same regulations as other programmes.[6-8] All aspects of the participation of a medical company in an exhibition at a medical congress in Europe are also governed by the codes of practice published by EFPIA. Only 'reasonable and proportionate' expenditure on promotion of a product is permissible. Compliance is subject to random inspections by external assessors.

For-profit continuing medical education companies

In recent years, CME companies have been founded to provide educational meetings for doctors which are not organized by pharmaceutical or device companies. They frequently organize meetings on behalf of industry, however, and their profitability as third-party providers of CME may depend on how well they satisfy the expectations of industry. Even when these new companies organize meetings for universities or professional associations, financial sponsorship may be sought from health-care companies. The Macy report in the USA recommended that such support should be discontinued.[10]

Meetings organized by for-profit CME companies are not guaranteed to be free of influence or bias. Direct sponsorship by industry to professional associations, in the form of unrestricted educational grants, might be more transparent than indirect sponsorship of a similar event run by a CME company. In the USA, nationally accredited CME organizations received $1.2 billion in commercial support during 2007, and much of this was probably used for types of CME that are relatively ineffective in changing clinical behaviour and improving patient outcomes.[11]

The wider context: current concerns

There is disquiet both within the medical profession and in the media about the influence of the health-care industry on prescribing patterns and on the use of medical devices by health-care professionals. The fundamental concern is that ties with industry lead to real or perceived ethical conflicts.[12,13] This may affect prescribing patterns and the selection of drugs for hospital formularies,[14-16] and it might bias publications[17-20] or influence the content of industry-funded CME activities.[3] To minimize the chance that commercial influences might affect clinical decisions, there have been calls for medical societies to be funded from membership dues, subsidies, and foundations rather than through grants from industry[12,13,21]. Unsurprisingly, authors from different perspectives have widely divergent views.[22]

If a diagnostic or therapeutic advance in medicine cannot be commercialized, then it is unlikely to be widely promoted

uvođenje novih kardiovaskularnih postupaka liječenja u svakodnevnu klinički praksu bilo puno sporije ako bi zdravstvena industrija radila "u vakuumu", bez kontakta s praksom.[23] U tom kontekstu neke aktivnosti koje su istovremeno edukativne i promotivne još uvijek mogu koristiti bržem širenju i usvajanju novih originalnih dostignuća.

and it may not be implemented. It has been suggested that the introduction of new cardiovascular treatments into routine clinical practice would have been much slower if the health-care industry had operated in a vacuum.[23] In this context, some activities that are both educational and promotional may yet lead usefully to the more rapid dissemination and adoption of genuine advances.

Table 2. *Sources of bias in scientific communication and education.*

Context	Examples of possible bias
Teacher in university or hospital	Limited depth and range of knowledge or understanding of lecturer Disproportionate presentation of material of greatest interest to lecturer Failure to keep content up-to-date
Lecturer at an educational meeting or course	Inadequate preparation Lack of objectivity—presentation of personal view as consensus on topic
Invited lecturer at a professional congress	Concentration on lecturer's own research, without acknowledging precedence or results from other research groups Favourable references to studies performed by friends and acquaintances Failure to disclose holding of patents, or other financial interests, relating to topic
Lecturer at a sponsored satellite symposium	Selective presentation of topic, without reference to alternative products from other manufacturers Omission of material critical of products of sponsoring company
Medical textbook	Dogmatic simplification of topic Space constraints limiting detailed discussion of background, controversies, and unanswered questions relating to topic
Clinical guidelines	Non-systematic review of topic Consensus rather than meta-analysis
Scientific abstract presentation	Premature and selective reporting of results using preliminary data, which may not be confirmed by final analysis
Scientific manuscript in peer-reviewed journal	Scientific fraud Selective statistical analysis and/or presentation of results Preferences or prejudices of reviewers Publication bias

Opasnost od pristranosti u medicinskoj edukaciji nije ograničena samo na aktivnosti koje podržava industrija. Ona može utjecati na bilo koju vrstu znanstvene komunikacije, pa čak i na edukacijski simpozij kojeg neovisno organizira fakultet ili stručna udruga (**Tablica 2**). Bez obzira na sadržaj, liječnik bi pri interpretiranju neke edukacijske ili znanstvene prezentacije trebao uvijek biti skeptičan. Pojava pristranosti kod novih dostignuća može se prikazati na neprekidnoj skali nijansama sjene među stupnjevima i različitim kombinacijama mogućeg intelektualnog (ili "akademskog") i komercijalnog utjecaja na ista (**Slika 2**). Teško je utvrditi precizne granice između prihvatljive i neprihvatljive pristranosti prikazanih primjera; neki prezentirani primjeri (npr. **c** na **Slici 2**) mogu se ocijeniti neprihvatljivim, a ostali (kao **a** i **e** na **Slici 2**) mogu zadovoljavati aktualne etičke standarde, iako i dalje još uvijek nose neke opasnosti pojave pristranosti.

Može se tvrditi da su sukobi interesa neizbježni i teško prepoznatljivi te ih je nemoguće eliminirati putem objave ili kroz edukaciju.[24] Moguća je primjedba da "interes konkurencije" mogu biti korisniji pokazatelji moguće pristranosti nego što su to "sukob interesa"[25], i da samo uska povezanost pojedinca može diskvalificirati iz neke edukacijske uloge.[26] Europski regulatori za lijekove su ustanovili da iako je nemoguće eliminirati sukob interesa, moguće je upravljati opasnošću pojave neobjektivne pristranosti.[27]

Američka udruga medicinskih učilišta izriče stav da je korisno učinkovito partnerstvo između industrije i sveučilišnih medicinskih centara.[28] To je pokrenulo sveučilišta da po-

The risk of bias in medical education is not restricted to activities that are supported by industry. It can affect any type of scientific communication, even an educational meeting organized independently by a university or medical association (**Table 2**). Whatever its context, a physician should always be sceptical when interpreting any educational or scientific presentation. The chance of bias can be represented on a continuous scale with subtle shading between grades and with varying combinations of possible intellectual (or 'academic') and commercial influence (**Figure 2**). It is hard to identify where precise boundaries could be drawn between what would be acceptable and what would not; of the examples presented, some (e.g. **c**) would be judged unacceptable but others (such as **a** and **e**) would meet the current ethical standards yet still carry some risk of bias.

It has been argued that conflicts of interest are unavoidable and difficult to recognize and that they cannot be abolished either by disclosure or by education.[24] Others have suggested that 'competing interests' may be a more helpful indicator of potential bias than 'conflicts of interest'[25], and that only 'significant' relationships might disqualify an individual from particular educational roles.[26] European drug regulatory agencies have determined that although conflicts of interest cannot be eliminated, the risk of bias can be managed.[27]

The Association of American Medical Colleges has stated that there are benefits from effective partnerships between industry and academic medical centres[28]. Basic and clinical scientists are now exhorted by their universities to protect

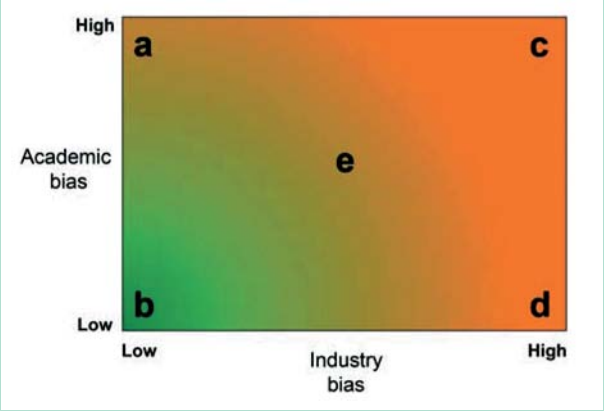

Figure 2. *Interaction of academic and industry bias in scientific communication. The risk of intellectual or 'academic' bias can be represented on a continuous scale from 'Low' (an impartial and objective presentation) to 'High' (a partisan or subjective presentation). The chance of bias resulting from sponsorship or involvement by industry ranges from none ('Low') to probable ('High'). Any scientific communication can be evaluated on both scales. Those plotted in the green zone are highly reliable; those in the orange zone must be interpreted with caution. Examples of activities judged to fall at the limits of these scales might be as follows:*

a *1/4 A clinical scientist gives a lecture on his own research, referring to an invention which he has patented but not yet commercialized, but without disclosing his interest or reviewing alternatives.*

b *1/4 An academic cardiologist gives a balanced and critical lecture at an educational meeting in a university, which has been organized without commercial sponsorship.*

c *1/4 An interventional cardiologist presents the results of a nonrandomized, open study of a new device that was developed in his institution in collaboration with a company, at a sponsored symposium during a congress. He does not declare that the results of the intervention were analysed by the clinical research organization of which he is the principal shareholder or that he will receive a fee for speaking. A fee is paid by the company to the congress organizers but this is not disclosed.*

d *1/4 A clinical trialist reviews recent randomized trials of a new drug, at a special symposium organized by the company which sponsored the trials. All the participants have all their expenses paid by the company. The lecturer reviews alternative drugs produced by other companies and gives a balanced account, concluding with the recommendations from recent guidelines produced independently by a medical society.*

e *1/4 A clinical pharmacologist whose research group developed a new drug presents the results of its first randomized controlled trial, at a satellite symposium during an international medical congress. She discloses that she was the chairman of the steering committee. The results are presented fully and then reviewed critically by a discussant who has been given access to the database for independent statistical review. The manufacturers of the new drug sponsor clinicians to attend the congress.*

taknu svoje bazične i kliničke znanstvenike da patentiranjem izuma i otkrića zaštite svoje intelektualno vlasništvo te ih se hrabri da pokretanjem malih tvrtki iskoriste svoje patente ili komercijaliziraju svoje istraživanje. Europska komisija daje veliki značaj razvitku novih malih i srednjih poduzeća unutar zdravstvenog sektora kao poticaj gospodarskom razvoju; stav Europske komisije je da se "suradnja znanstvenog i poslovnog svijeta mora poboljšati".[29] Tako su, ironično, nedavne kritike upućene stručnim udrugama o povezanosti s industrijom dogodile istovremeno kada su se pojedini liječnici i istraživači da se više povežu sa zdravstvenom industrijom.

Čini se da javna zabrinutost nije usmjerena protiv postojanja komercijalnih aktivnosti, ali je nejasno na što točno cilja kritika te u kom slučaju je veza s industrijom prihvatljiva i poticana.

Može li se vjerovati malim tvrtkama, a biti sumnjičav prema velikima? Je li povezanost liječnika ili znanstvenika s malim tvrtkama prihvatljiva, dok s velikima nije? Nelogična je ta nedosljednost.

Aktualni oblici pružanja izobrazbe

Diljem Europe medicinski fakulteti organiziraju opsežne i cjelovite programe za dodiplomsku i poslijediplomsku medicinsku izobrazbu, no etabliranim kliničkim specijalistima ne

their intellectual property by patenting their discoveries or inventions, and they are encouraged to exploit them or commercialize their research by starting up small companies. The European Commission places great importance on the development of new small and medium enterprises within the health-care sector as a stimulus for economic development; its policy states that 'cooperation between the worlds of science and the world of business must be enhanced'.[29] Thus, ironically, recent criticisms of links with industry, which have been addressed to medical associations, have coincided with encouragements to individual physicians and researchers to become involved in industry.

It appears that public concerns are not about commercial activity per se, but it is unclear exactly where criticism is directed and when involvement with industry is acceptable or encouraged.

Are small companies trusted but large ones distrusted? Are links by physicians or academics with small companies acceptable, but links with large companies not so? Inconsistent standards are illogical.

Current patterns of provision

Throughout Europe, comprehensive programmes for undergraduate and postgraduate medical education are organized by university medical schools, but equivalent provision

pruža se jednaka izobrazba u obliku SMU u procesu stalnog stručnog napredovanja (CPD). Tu prazninu ispunjavaju stručne udruge i ponekad pružatelji SMU, često uz podršku industrije. Određena stručna udruga, kao što je ESC, vrlo je prikladno tijelo za pružanje SMU, budući da na takav način ispunjava svoju misiju i jer njezini članovi predstavljaju stručnjake u okviru svakog područja kardiovaskularne medicine.

Kada bi se ukinula pomoć institucija zdravstvene zaštite za edukacijske aktivnosti, tada bi teret pao na druge, poput vlade ili institucija zdravstvenog osiguranja ili poslodavce koji bi trebali osigurati financijsku potporu za trajnu izobrazbu liječnika. Konačno koji god model da se usvoji — bilo da se troškovi izobrazbe uključe u troškove lijekova i uređaja ili troškove zdravstvenih usluga ili budžete sveučilišta ili plaće i naknade liječnika, plaćat će društvo i bolesnici. Bilo bi neprihvatljivo ukinuti trenutne modele financiranja bez da ih se zamijeni alternativnim modelima, jer je SMU izuzetno bitan za održavanje visokih kliničkih standarda i kvalitete u zdravstvenoj zaštiti. Liječnici imaju etičku dužnost da poduzmu SMU i u najmanje 16 europskih država se ovo već zahtjeva za ponovnu validaciju njihove licence za rad.[30-32]

Postoje značajne razlike diljem Europe u tome kako se omogućuje SMU.[32,33] Detaljni podaci o troškovima farmaceutskih tvrtki i tvrtki koje se bave uređajima u Europi o SMU nisu dostupni[34], ali ta pomoć varira od oko 20% u Danskoj, do gotovo potpune poptpore za SMU u Italiji.[32]

U Francuskoj, ukupna sredstva predviđena budžetom za SMU iznose 64,9 mil. EUR godišnje. Budući da je 85% raspoređeno obiteljskim liječnicima, samo 9,7 mil. EUR je dostupno za podjelu između svih 95.000 specijalista;[31,35] to iznosi približno 100 EUR po specijalisti godišnje. U Ujedinjenom Kraljevstvu, Kraljevski liječnički zbor favorizira ukidanje povezanosti između industrije i medicinske edukacije oslanjajući se na Kraljevska udruženja i Ministarstvo zdravstva, koji će pružati pomoć za poslijediplomsku medicinsku edukaciju[36], ali nikakva formalna sredstva iz budžeta nisu raspoređena pojedinačnim liječnicima kod pružanja ovakve pomoći. U Njemačkoj liječnici obično moraju plaćati svoje vlastite aktivnosti SMU,[32] dok u Nizozemskoj svaki sveučilišni specijalist dobije 5.000 EUR godišnje iz budžeta za svoj CPD.[37] U Belgiji liječnici koji su akreditirani za CPD mogu tražiti i nešto veće naknade.[32] U Finskoj bi poslodavac svojim liječnicima trebao platiti 80% troškova za SMU, a vlada 20%.[32]

Iznos za SMU u SAD iznosio je od 2,3 milijarde dolara u 2008. godini uz 44% prihoda od komercijalnih sponzora.[38] Farmaceutske tvrtke i tvrtke koje se bave uređajima su potrošile oko 1 milijardu dolara za SMU, od čega je 45% je završilo kao dobit tvrtki koje se bave SMU, 22% sveučilištima, 19% stručnim društvima, 4% bolnicama, a 10% ostalim dobavljačima.[38] 2009. godine, iz budžeta koji je dosegnuo gotovo 700 milijun dolara, Američko udruženje za bolesti srca (AHA) potrošilo je 82 milijuna dolara na stručnu izobrazbu i usavršavanje.[39] Time bi si SAD mogao priuštiti ograničenje ili isključenje pomoći industrije za SMU kako bi se više oslonili na državne potpore.

Ukoliko bi Europa odlučila slijediti strategiju iz SAD, prekidajući veze između industrije i stručnih društava,[13] SMU bi se mogla jako ugroziti. Potpuno oslanjanje na državno financiranje nije održiva opcija za Europu u ovom trenutku. Odricanje od pomoći industrije za stručne udruge bi za posljedicu imalo povećanje naknada i smanjeno sudjelovanje na kongresima posebno od strane specijalizanata i mladih kolega. Stav je ESC da je, u nedostatku alternativnog financiranja, odnosno do uočavanja alternativnog financiranja, has not been made for the continuing professional development (CPD) of established clinical specialists in the form of CME. The gap is filled mostly by medical associations and sometimes by other CME providers, often supported by industry. A professional association such as the ESC is a very appropriate body to provide CME since it is a way to accomplish our mission and since its members include a critical mass of experts within each field of cardiovascular medicine.

If support from the health-care industry for educational activities was to be abolished then the onus would fall on others, such as governments or health insurance providers or employers, to provide financial support for the continuing education of physicians. Ultimately, whatever model is adopted — whether educational costs are included in the costs of drugs or devices, or health service charges, or university budgets, or individual doctors' salaries or fees — then society and patients will pay. To abolish the current models of funding without replacing them by an alternative would be unacceptable, as CME is critical for the maintenance of high clinical standards and quality of healthcare. Doctors have an ethical duty to undertake CME, and in at least 16 European countries, this is already required for the revalidation of their license to practice.[30-32]

There are considerable variations around Europe in how CME is provided.[32,33] Detailed data about the expenditure by pharmaceutical and device companies in Europe on CME are not available[34], but it can vary from about 20% of total provision in Denmark to almost complete support for CME in Italy.[32]

In France, the total governmental budget for CME is €64.9 m per year. Since 85% is allocated to family practitioners, only €9.7 m is available to be shared between all 95 000 specialists;[31,35] this works out at ~€100 per specialist per year. In the UK, the Royal College of Physicians favours cutting ties between industry and medical education, relying instead on the Royal Colleges and the Department of Health to support postgraduate medical education[36], but no formal budget has been allocated to individual physicians to support this. In Germany, doctors usually have to pay for their own CME activities[32], but in the Netherlands, academic medical specialists each receive a budget of €5000 per year for their CPD[37], and in Belgium, doctors who have been accredited for CPD can charge slightly higher fees[32]. In Finland, the employer should pay 80% of the expenses of CME for its physicians, and the government 20%.[32]

In the USA, CME was a $2.3 billion business in 2008 with 44% of income originating from commercial sponsors[38]. Pharmaceutical and device companies spent ~$1 billion on CME, of which 45% went to for-profit CME companies, 22% to universities, 19% to professional societies, 4% to hospitals, and 10% to other providers.[38] In 2009, from a budget approaching $700 million, the American Heart Association (AHA) spent $82 million on professional education and training.[39] Thus, the USA could perhaps afford to limit or exclude industry support for CME, in order to rely more heavily on public grants.

Should Europe choose to follow the strategy proposed in the USA, severing links between industry and medical societies,[13] CME could be severely compromised. Relying completely on public funding is not a viable option for Europe at the moment. The removal of industry support for medical associations would be followed by increased fees and reduced attendance at congresses especially by clinical trainees and young fellows. It is the view of the ESC that in the absence of alternative funding, or until alternative funding is identi-

održavanje veza s industrijom primjereno sve dok su obrazovni i znanstveni proizvodi i dalje neovisni, učinkoviti i nepristrani i sve dok su odnosi između stručnjaka ili glasnogovornika ESC i industrije transparentni i dok se objavljuju na odgovarajući način.

Preporuke

Pružatelji zdravstvene zaštite, edukatori, stručne udruge i industrija moraju djelovati zajednički i pojedinačno kako bi potvrdili i eliminirali stvarnu ili percipiranu pristranost. Buduća etičnost medicinske izobrazbe u Europi ovisi o osmišljavanju legitimne i etičke suradnje između pružatelja zdravstvene zaštite, akademskih ustanova, stručnih udruga, dobrotvornih zaklada i industrije.[25]

ESC se zalaže za principijelan i uravnotežen pristup koji prihvaća objave interesa između zdravstvenih stručnjaka i industrije, s ciljem osiguranja poštene i nepristrane izobrazbe zdravstvenih stručnjaka.[40]

Cilj SMU je razviti, održavati ili proširiti znanje, razumijevanje, proceduralne vještine i profesionalni rad liječnika kako bi mogli osigurati najvišu kvalitetu skrbi za svoje pacijente. Svi programi izobrazbe, bez obzira potječu li od ESC, organizatora SMU, industrije ili regulatornih tijela, bi se trebali uskladiti s temeljnim smjernicama i načelima. Trebali bi biti utemeljeni na dokazima, imati jasno definirane obrazovne ciljeve, jasno definiranu ciljnu publiku i ne sadržavati komercijalnu pristranost.

Edukacijski programi se moraju ocjenjivati na temelju njihove znanstvene vrijednosti, kvalitete, praktične korisnosti, uočenih dokaza, mogućih predrasuda, inovacije i nastavnih metoda. ESC traži akreditaciju svojih obrazovnih programa putem Europskog akreditacijskog vijeća za stalno medicinsko usavršavanje (EACCME)[41] i Europskog odbora za akreditaciju u kardiologiji (EBAC), pod pokroviteljstvom Europske unije liječnika specijalista (UEMS).

Organizatori SMU bi trebali nastojati osigurati obrazovne resurse i mogućnosti koje su prikladne i učinkovite. Tijekom vremena može se pojaviti potreba za kulturološkom promjenom uz manju ovisnost o tradicionalnim obrascima, uključujući predavanja[42] i sve više organiziranja praktičnih skupova u malim grupama s temama o kliničkim slučajevima, a što može učinkovitije utjecati na promjenu ponašanja liječnika.[43-45] Je li pitanje neograničene potpore za izobrazbu koje utječe na ponašanje liječnika vrijedna ove studije ili nije obzirom da ima malo empirijskih dokaza o mogućem utjecaju financiranja zdravstvenih udruga na učinkovitost njihovih edukacijskih programa.[5,46]

Suradnja između akademskih i privatnih sektora važna je za medicinska istraživanja te je u skladu sa pružanjem određenih kategorija SMU, dokle god postoje odgovarajuće mjere zaštite. Zajednički edukacijski programi mogu biti potrebni za usavršavanje liječnika i kirurga kod primjene novih medicinskih uređaja.[47] Posebno je važno da bilo koja suradnja između medicinske struke i industrije bude potpuno transparentna i da ciljevi izobrazbe budu od najveće važnosti.

Preporuke koje se tiču objavljivanja i upravljanja mogućim sukobima interesa su objavljeni u Europi, SAD i drugdje[16,48-54] te su uvelike prihvaćeni od strane ESC.

ESC je usvojio sljedeći specifični kodeks ponašanja. Time se osigurava pružanje nepristranog, na dokazima utemeljenog, i visokokvalitetnog SMU u kardiovaskularnoj medicini.

fied, maintaining links with industry is appropriate as long as educational and scientific products remain independent, effective, and unbiased and as long as the relationships between ESC experts or spokespersons and industry are transparent and appropriately disclosed.

Recommendations

Health-care providers, educators, professional associations, and industry must act collectively and individually to acknowledge and eliminate real or perceived bias. The future probity of medical education in Europe depends on devising legitimate and ethical collaborations between health-care providers, academic institutions, professional associations, charitable foundations, and industry.[25]

The ESC advocates a principled and balanced approach that acknowledges disclosures of interest between health-care professionals and industry, and aims to provide honest and unbiased education for health-care professionals.[40]

The goal of CME is to develop, maintain, or increase the knowledge, understanding, procedural skills, and professional performance of physicians, to enable them to provide the highest quality of care for their patients. All educational programmes, irrespective of whether they originate from the ESC, CME providers, industry, or regulatory bodies, should adhere to essential guiding principles. They should be evidence-based, have clearly defined educational objectives, have a clearly defined target audience, and be free of commercial bias.

Courses must be evaluated on the basis of their scientific merit, quality, practical utility, perceived evidence base, potential bias, innovation, and teaching methods. The ESC seeks accreditation of its educational programmes through the European Accreditation Council for Continuing Medical Education (EACCME)[41] and the European Board for Accreditation in Cardiology (EBAC), under the auspices of the European Union of Medical Specialists (UEMS).

The providers of CME should endeavour to provide educational resources and opportunities that are appropriate and effective. Over time, this may require a cultural change with less dependence on traditional formats including lectures[42] and increased provision of small-group practical sessions based on clinical cases, which may be more effective in changing physicians' behaviour.[43-45] Whether or not an unrestricted educational grant influences the behaviour of physicians would merit study, since there is little empirical evidence concerning the possible impact of funding to medical associations on the effectiveness of their educational courses.[5,46]

Cooperation between the academic and private sectors is important for medical research, and it is not incompatible with the provision of some categories of CME as long as appropriate safeguards are in place. Joint educational programmes may be needed for the training of physicians and surgeons in the use of new medical devices.[47] It is particularly important that any collaboration between the medical profession and industry is completely transparent and that educational objectives are paramount.

Recommendations concerning the disclosure and management of possible conflicts of interest have been published in Europe, the USA, and elsewhere[16,48-54] and these are broadly accepted by the ESC.

The ESC has adopted the following specific code of conduct. This assures the provision of unbiased, evidence-based, and high-quality CME in cardiovascular medicine.

Kongresi i edukacijski programi

(1) Svaki član odbora kongresnog programa mora ispuniti izjavu o postojanju interesa. Nijedan zaposlenik neke zdravstvene tvrtke ne može djelovati kao član programskog odbora.

(2) Predsjednik Odbora kongresnog programa ne bi trebao imati nikakve veze s industrijom što bi predstavljalo značajan sukob interesa u njegovom/njezinom mandatu.

(3) Zajednički odabir skupova od strane članova programskog odbora se mora temeljiti samo na znanstvenoj vrijednosti.

(4) Predavači bi trebali biti izabrani za skup kako bi se osigurao ujednačen stav ili usporedba među protagonistima uz izdvajanje vremena za pitanja i raspravu.

(5) Svi voditelji sjednica i predavači moraju izvršiti objavu interesa.

(6) Svi voditelji sjednica i predavači moraju prikazivati slajd sa svojom objavom interesa dovoljno dugo kako bi publika imala vremena za čitanje cjelokupnog sadržaja. To uključuje izjavu o mogućnim akademskim sukobima interesa kao i bilo koje veze s institucijama zdravstvene zaštite.

(7) Odgovornost je voditelja sjednice tijekom bilo kojeg skupa publici ukazati na bilo kakve jasne sukobe interesa koji nisu objavljeni, ili bilo koje očite velike pristranosti u sadržaju prezentacije.

(8) Svaki pojedinac koji sudjeluje u znanstvenom kongresu ili edukacijskom programu bi trebao dati svoje vlastito mišljenje kod ocjene integriteta i kvalitete svake prezentacije.

(9) Ove preporuke odnose se na godišnji kongres ESC, na subspecijalističke kongrese u organizaciji udruženja ESC i druge edukacijske programe u organizaciji ESC i njezinih konstitutivnih tijela, kao što su simpoziji Update i edukacijski programi u Europskoj kući srca.

(10) Akreditacija kongresa i edukacijskih programa za svrhu SMU bi se trebala tražiti od neovisne organizacije poput EACCME ili EBAC.

Satelitski simpoziji

(11) Satelitski skupovi bi se trebali biti jasno označiti kao sponzorirani skupovi od strane industrije i trebalo bi prepoznati komercijalni motiv i opasnost od utjecaja na takvim događajima. Ako su podaci uključeni u konferencijski program, onda isti trebaju biti navedeni u zasebnom i jasno prepoznatljivom dijelu (npr. na papiru u drugačijoj boji).

(12) Satelitski simpoziji bi se trebali održavati u posebnim terminima koji se ne poklaju s terminima znanstvenih sjednica.

(13) Proizvodi tvrtki se ne smiju reklamirati u predavaonicama, sobama za sastanke niti konferencijskoj sali.

(14) Pozvani akademski govornici su odgovorni za informacije koje su prikazane na njihovim slajdovima.

Trgovačke izložbe

(15) Bilo koja tvrtka koja sudjeluje na trgovačkoj izložbi na ESC kongresu mora ispuniti zahtjeve koji su uključeni u kodekse rada u industriji.

Neograničene potpore

(16) Dozvoljen je pojam 'neograničene edukacijske potpore' iz farmaceutske tvrtke ili tvrtke koja se bavi uređajima.

Congresses and educational courses

(1) Every member of a congress programme committee must complete a declaration of interests. No employee of a medical company can serve as a member of a programme committee.

(2) The Chairperson of the Congress Programme Committee should have no relation with industry which would represent a significant conflict of interest during his/her term of office.

(3) The joint selection of sessions by members of a programme committee must be based only on scientific merit.

(4) Speakers should be selected for a session to provide a balanced view or a comparison between protagonists, with time allocated for questions and discussion.

(5) All chairpersons and speakers must complete a disclosure of interests.

(6) All chairpersons and speakers must show a slide with their disclosure of interests, for long enough to ensure that the audience has time to read all of its contents. This should include a statement of possible academic conflicts of interest as well as any links with the health-care industry.

(7) It is the responsibility of the chairpersons during any session to bring to the attention of the audience any clear conflicts of interest that have not been disclosed, or any apparent major bias in the content of a presentation.

(8) Each individual attending a scientific congress or educational course should exercise his or her own judgement when assessing the integrity and quality of each presentation.

(9) These recommendations apply to the annual Congress of the ESC, to the subspeciality congresses organized by the ESC Associations, and to other educational courses organized by the ESC and its constituent bodies, such as Update Meetings, and Educational Courses at the European Heart House.

(10) Accreditation of congresses and educational courses for CME purposes should be sought from an independent organization such as EACCME or EBAC

Satellite symposia

(11) Satellite symposia should be clearly marked as sponsored by industry and the commercial motive and risk of influence in such events should be recognized. If details are included in a conference programme, then they should be listed in a separate and clearly identifiable section (e.g. on differently coloured paper).

(12) Satellite symposia should be held at special times that do not coincide with any scientific sessions.

(13) Company products must not be advertised in the lecture theatre, meeting room, or conference hall.

(14) Academic invited speakers are accountable for the information presented on their slides.

Trade exhibitions

(15) Any company participating in a trade exhibition at an ESC congress must meet all the requirements included in industry codes of practice.

Unrestricted grants

(16) The concept of an 'unrestricted educational grant' from a pharmaceutical or medical device company is permissible.

Sredstva dobivena kroz neograničene edukacijske potpore će se isplatiti za aktivnosti SMU prema samostalnoj odluci ESC.

Webinari, e-učenje i učenje na daljinu

(17) Zahtjevi za transparentnošću su isti za programe učenja na daljinu i obrazovne aktivnosti temeljene na internetu kao i za kongrese i face-to-face edukacijske sastanke. Svi članovi fakulteta moraju izvršiti objavu interesa. Izravno sponzoriranje tvrtke nije dopušteno, ali je dozvoljena pomoć u obliku neograničene edukacijske potpore.

Smjernice kliničke prakse

(18) Akademska nezavisnost i integritet su osobito važni u razvoju kliničkih smjernica, pa su tako neophodni i posebno strogi standardi.

(19) Niti jedan zaposlenik farmaceutske tvrtke ili tvrtke medicinskih uređaja ili tehnološke tvrtke ne može biti član Odbora za smjernice.

(20) Nije dopušten bilo koji oblik izravne podrške tvrtke za izradu smjernice.

(21) Svi članovi odbora za kliničke smjernice te svi članovi pojedinih radnih skupina za smjernice moraju ispuniti obrazac o objavi interesa. U pojedinoj radnoj skupini Odbora za smjernice kliničkog rada ove objave se moraju podijeliti među Članovima. Objave interesa Članova radne skupine se spominju u objavi Smjernica i stavljaju na internet stranicu.

(22) Zbog bilo kojih sljedećih karakteristika će se pojedinac diskvalificirati iz rada odbora za smjernice: djelomično radno vrijeme ili plaća od povezane tvrtke, značajno dioničko vlasništvo, odnosno vlasništvo nad patentom kojim se ostvaruju značajni prihodi ili primanje značajnih naknada za autorska prava za intelektualno vlasništvo u svezi s temom smjernica. Ovo pravilo se primjenjuje od 1. rujna 2012. godine.

(23) Primanje konzultantskih naknada ili naknada za predavanja neće biti prepreka da određena osoba postane član odbora, ali te podatke mora u potpunosti objaviti.

(24) Dva predsjednika bi trebala supredsjedati svakom radnom skupinom za smjernice. Najmanje jedan od ovih predsjednika ne bi smio biti u sukobu interesa vezanog za temu tijekom razdoblja pripreme i sastavljanja smjernice. Ova mjera će se izvršiti za smjernice o kojima odluku donese Odbor za smjernice kliničkog rada 2012.—2014.

(25) Članovi Radne skupine za smjernice mogu imati povezane interese (kao što je sudjelovanje u upravnim odborima kliničkih istraživanja), ali se isti moraju u potpunosti objaviti.

(26) Slične preporuke se odnose na članove bilo kojeg stručnog odbora ili znanstvenu radnu skupinu koju imenuje bilo koje konstitutivno tijelo ESC. Objava interesa je obvezna.

(27) Ostali pojedinci i oni koji imaju interese koji ih onemogućavaju da budu u članstvu odbora za smjernice mogu biti pozvani da daju savjete zbog svog akademskog stručnog znanja. Zaposlenici odjela za istraživanje i razvoj medicinskih tvrtki mogu djelovati kao savjetnici za pojedina znanstvena ili tehnička pitanja za radne skupine, ali bilo kakvi takvi doprinosi se moraju objaviti.

Funds obtained through unrestricted educational grants will be disbursed for CME activities at the sole discretion of the ESC.

Webinars, e-learning, and distance learning

(17) The requirements for transparency are the same for distance learning courses and internet-based educational activities, as for congresses and face-to-face educational meetings. All faculty members must complete a disclosure of interests. Direct company sponsorship is not permitted, but support in the form of unrestricted educational grants is allowable.

Clinical practice guidelines

(18) Academic independence and integrity is especially important in the development of clinical guidelines, and so particularly rigorous standards are required.

(19) No employee of a pharmaceutical or medical device or technology company can be a member of a Guidelines committee.

(20) Any form of direct company support for the development of a guideline is not permitted.

(21) All members of the Clinical Practice Guidelines committee and all members of individual Guidelines Task Forces must complete a full disclosure of interests. In an individual Task Force of the Clinical Practice Guidelines Committee, these disclosures are shared between Members. Disclosures of interest of Task Force Members are mentioned in the publication of the Guidelines and put on the website.

(22) Any of the following characteristics disqualifies an individual from serving on a Guidelines committee: part-time employment or salary from a related company, significant stock ownership, or holding of a patent which generates significant revenues or receipt of significant royalties for intellectual property related to the topic of the guidelines. This rule will apply as of 1 September 2012.

(23) Receipt of consultancy fees or fees for lecturing would not debar an individual from being a member of a committee but must be fully disclosed.

(24) Each Guidelines Task Force should be co-chaired by two chairpersons. At least one of these chairpersons should have no conflict of interest related to the topic during the period of preparation and of production of the guideline. This measure will take place for guidelines decided by the Clinical Practice Guidelines Committee 2012-14.

(25) The members of a Guidelines Task Force may have related interests (such as participation in steering committees of clinical trials), but these must all be fully disclosed.

(26) Similar recommendations apply to the members of any expert writing committee or scientific task force, appointed by any constituent body of the ESC. Disclosure of interests is mandatory.

(27) Other individuals and those with interests which disbar them from membership of a Guidelines committee may be invited to give advice because of their academic expertise. Employees of the research and development departments of medical companies may act as advisers on specific scientific or technical issues to task forces, but any such contributions must be disclosed.

Kardiološki časopisi ESC

(28) Postupanje autora, recenzenata i urednika časopisa ESC treba biti u skladu sa standardima preporučenim od strane Međunarodnog odbora urednika medicinskih časopisa.[55] Obvezne su objave interesa pojedinih autora.

(29) Ako se dostavljaju kliničke studije uz potporu industrije, autori bi trebali navesti da su imali potpuni pristup bazi podataka i potpunu slobodu u tumačenju rezultata.

(30) Glavni urednik i urednici te redakcija svakog ESC časopisa moraju ispuniti cjelovitu izjavu o interesima. Glavni konkurentski interesi će onemogućiti pojedinca da postane urednik ESC časopisa.

(31) Svi rukopisi moraju podlijegati anonimnoj i neovisnoj recenziji. Trebalo bi osigurati neovisnu statističku recenziju za svaki prihvaćeni rukopis.

(32) Članovi uredništva i recenzenti trebaju odbiti bilo kakav poziv za uređivanjem ili recenzijom bilo kakvih rukopisa koji se odnose na teme, lijekove ili uređaje u kojima postoje značajni komercijalni ili akademski interesi.

(33) Urednici bi trebali dodijeliti vanjskog savjetodavnog urednika za bilo koji dostavljeni rukopis koji se odnosi na teme, lijekove ili uređaje kod kojih imaju značajan konkurentski interes.

ESC opservacijska istraživanja i registri

(34) Znanstvene registre u kliničkoj praksi i post-marketinški nadzor medicinskih uređaja treba provoditi u skladu s visokim etičkim standardima, odgovorno i te ih evaluirati.

(35) Opservacijska istraživanja mogu biti potpomognuta neograničenim edukacijskim potporama. Višestruko sponzorstvo je dozvoljeno, ali ne sponzorstvo od strane jedne tvrtke.

Donirana financijska sredstva bi se trebala ujediniti i upravljati centralno, a to ne bi trebalo utjecati na sadržaj ili vođenje programa.

Objave

Revidirana politika o otkrivanju interesa je usvojena od strane Odbora ESC 2010. godine. Svi članovi Odbora ESC, Odbora ESC udruga, Vijeća i Nukleusa radnih skupina ESC moraju ispuniti obrazac o objavi interesa svake godine jednako kao i više stalno osoblje. U obrascu za objavu se navodi svaka kategorija odnosa prema karakteru odnosa (potpore, naknade govornicima, konzultantski honorari; vlasnički udjeli, radni odnos u određenoj tvrtci itd.) i razina financijskih sredstava od umjerene do značajne.

Zaključci

Napredak u medicini ovisi o uspješnosti dijaloga strana uključenih u istraživanje i razvoj i strana koje pružaju zdravstvenu zaštitu. Česta razmjena ljudi između akademske zajednice i industrije (posebno znanstvenika i inženjera u tvrtkama) na obrazovnim skupovima i kongresima može dovesti do nekih od najboljih i najinovativnijih istraživačkih ideja. Prekidanje takvih veza kao rezultat uklanjanja pristranosti kod edukacijskih programa potpomognutih industrijom, može suzbijanjem novih ideja uzrokovati više štete za opće dobro, a iste u konačnici bi mogle pomoći kod poboljšanja kardiovaskularnog zdravlja bolesnika.

ESC cardiology journals

(28) The conduct of the authors, reviewers, and editors of ESC journals should comply with the standards recommended by the International Committee of Medical Journal Editors.[55] Open disclosures of interest of individual authors are mandatory.

(29) If clinical studies supported by industry are submitted, authors should state that they had full access to the database and total freedom in interpreting the results.

(30) The editor-in-chief, editors, and editorial board of each ESC journal must complete a full declaration of interests. Major competing interests would exclude an individual from becoming an editor of an ESC journal.

(31) All manuscripts must be subject to anonymous, independent peer review. There should be an independent statistical review of every accepted manuscript.

(32) Members of the editorial board and reviewers should decline any invitation to edit or review any manuscripts relating to topics, drugs, or devices, in which they have significant commercial or academic interests.

(33) Editors should assign an external consulting editor for any submitted manuscript relating to topics, drugs, or devices, in which they have significant competing interest.

ESC observational research and registries

(34) Scientific registries of clinical practice and post-marketing surveillance of medical devices should be conducted according to high ethical standards, accountable, and subject to peer review.

(35) Observational research may be supported by unrestricted educational grants. Multisponsorship is permissible but not sponsorship by a single company.

Donated funds should be pooled and administered centrally, and these should not influence the content or conduct of the programme.

Disclosures

A revised policy concerning disclosure of interests was adopted by the Board of the ESC in 2010. All members of the Board of the ESC, of the Boards of ESC Associations, and of the Councils and of the Nuclei of the ESC Working Groups must complete a disclosure of interests every year, as well as senior permanent staff. The disclosure form details each category of relationship by nature (grants, speaker fees, consulting honoraria, stockholder, employment by a company, etc.) and by financial level from modest to significant.

Conclusions

Medical progress thrives on a productive dialogue between those involved in research and development and those involved in the delivery of healthcare. Frequent exchanges between academia and industry (in particular, company scientists, and engineers) at educational meetings and congresses can result in some of the best and most innovative research ideas. Disruption of these links might cause more harm to the common good, by suppressing the generation of ideas that could ultimately improve patients' cardiovascular health, than might result from eliminating any bias associated with industry-funded educational programmes.

Stručna društva trebaju na transparentan, učinkovit i etični način, razviti konstruktivnu suradnju s industrijom. Da bi se to postiglo, mora se zadržati i poštovati povjerenje ne samo javnosti, nego i zdravstvenih djelatnika, vlade i regulatornih tijela. Ako bi se poslušali pozivi za zabranom industrijske podrške stručnim društvima prije nego se ponudi alternativno rješenje, tada bi se ozbiljno ugrozile mogućnosti za SMU. Znanstveno utemeljena suradnja između stručnih društava i industrije treba biti uzajamno korisna, etička i odgovarajuća. Odmah na početku takve suradnje potrebno je naznačiti osobne interese uključenih strana. U cilju zaštite krajnjeg korisnika — pacijenta, posebnu pozornost treba usmjeriti na uspostavljanje postupaka upravljanja i reguliranja.

Medical societies need to develop a constructive partnership with industry, in a transparent, productive, and ethical manner. To achieve that the trust not only of the public, but also of healthcare professionals, governments, and regulators must be retained and be respected. If the calls to ban industry support of medical associations were to be heeded, before alternatives were in place, then opportunities for CME would be severely compromised. Science-driven collaboration between professional societies and industry can be mutually beneficial, ethical, and appropriate. The personal interests of all parties involved must be stated clearly from the outset. Due care must be paid to ensure that governance and processes are in place to protect the ultimate beneficiary — the patient.

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*Address for correspondence: Presidential Office, European Society of Cardiology, The European Heart House, 2035 Route des Colles-Les Templiers, 06903 Sophia Antipolis, France.

Phone: +33-4-9294-7600, Fax: +33-4-9294-7608,

Email: escboard@escardio.org

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