

# Pravila o sukobu interesa i zahtjevi za prijavljivanjem sukoba interesa u nacionalnim kardiovaskularnim časopisima Europskog kardiološkog društva

## *Conflict of interest policies and disclosure requirements among European Society of Cardiology National Cardiovascular Journals*

Fernando Alfonso<sup>1\*</sup>, Adam Timmis<sup>2</sup>, Fausto J. Pinto<sup>3</sup>, Giuseppe Ambrosio<sup>4</sup>, Hugo Ector<sup>5</sup>, Piotr Kulakowski<sup>6</sup>, Panos Vardas<sup>7</sup>, on behalf of the Editors' Network European Society of Cardiology Task Force

<sup>1</sup>Chairman Editors' Network, <sup>2</sup>Heart, <sup>3</sup>Revista Portuguesa de Cardiologia, <sup>4</sup>Nucleus Member Editors' Network, <sup>5</sup>Acta Cardiologica, <sup>6</sup>Kardiologia Polska, <sup>7</sup>Hellenic Journal of Cardiology

**Editors' Network members:** Loizos Antoniades<sup>1</sup>, Mansoor Ahmad<sup>2</sup>, Eduard Apetrei<sup>3</sup>, Kaduo Arai<sup>4</sup>, Jean-Yves Artigou<sup>5</sup>, Michael Aschermann<sup>6</sup>, Michael Böhm<sup>7</sup>, Leonardo Bolognese<sup>8</sup>, Raffaele Bugiardini<sup>9</sup>, Ariel Cohen<sup>10</sup>, Istvan Edes<sup>11</sup>, Joseph Elias<sup>12</sup>, Javier Galeano<sup>13</sup>, Eduardo Guarda<sup>14</sup>, Habib Haouala<sup>15</sup>, Magda Heras<sup>16</sup>, Christer Höglund<sup>17</sup>, Kurt Huber<sup>18</sup>, Ivan Hulin<sup>19</sup>, Mario Ivanuša<sup>20</sup>, Rungroj Kittayaphong<sup>21</sup>, Chi-Tai Kuo<sup>22</sup>, Chu-Pak Lau<sup>23</sup>, Victor A. Lyusov<sup>24</sup>, Germanas Marinskis<sup>25</sup>, Manlio F Márquez<sup>26</sup>, Izet Mašić<sup>27</sup>, Luiz Felipe Pinho Moreira<sup>28</sup>, Alexander Mroček<sup>29</sup>, Rafael G. Oganov<sup>30,31</sup>, Dimitar Raev<sup>32</sup>, Mamanti Rogava<sup>33</sup>, Olaf Rodevand<sup>34</sup>, Vedat Sansoy<sup>35</sup>, Hiroaki Shimokawa<sup>36</sup>, Valentin A. Shumakov<sup>37</sup>, Carlos Daniel Tajer<sup>38</sup>, Ernst E. van der Wall<sup>39</sup>, Christodoulos Stefanadis<sup>40</sup>, Jørgen Videbæk<sup>41</sup>, Thomas F. Lüscher<sup>42</sup>

<sup>1</sup>Cyprus Heart Journal, <sup>2</sup>Pakistan Heart Journal, <sup>3</sup>Romanian Journal of Cardiology, <sup>4</sup>Avances Cardiológicos, <sup>5</sup>Archives des maladies du cœur et des vaisseaux Pratique, <sup>6</sup>Cor et Vasa, <sup>7</sup>Clinical Research in Cardiology, <sup>8</sup>Giornale Italiano Di Cardiologia, <sup>9</sup>Journal of Cardiovascular Medicine, <sup>10</sup>Archives of Cardiovascular Diseases, <sup>11</sup>Cardiologia Hungarica, <sup>12</sup>Heart News, <sup>13</sup>Journal of the Paraguayan Society of Cardiology, <sup>14</sup>Revista Chilena de Cardiologia, <sup>15</sup>Cardiologie Tunisienne, <sup>16</sup>Revista Española de Cardiología, <sup>17</sup>Svensk Cardiologi, <sup>18</sup>Journal für Kardiologie, <sup>19</sup>Cardiology Letters / Kardiología, <sup>20</sup>Kardio list, <sup>21</sup>Thai Heart Journal, <sup>22</sup>Acta Cardiologica Sinica, <sup>23</sup>Journal of the Hong Kong College of Cardiology, <sup>24</sup>Russian Cardiology Journal, <sup>25</sup>Seminars in Cardiovascular Medicine, <sup>26</sup>Archivos de Cardiología de México, <sup>27</sup>Medical Archives, <sup>28</sup>Arquivos Brasileiros de Cardiologia, <sup>29</sup>Cardiology in Belarus, <sup>30</sup>Cardiovascular Therapy and Prevention, <sup>31</sup>Rational Pharmacotherapy in Cardiology, <sup>32</sup>Bulgarian Cardiology, <sup>33</sup>Cardiology and Internal Medicine XXI, <sup>34</sup>Hjerteforum, <sup>35</sup>Archives of the Turkish Society of Cardiology, <sup>36</sup>Circulation Journal, <sup>37</sup>Ukrainian Journal of Cardiology, <sup>38</sup>Revista Argentina de Cardiologia, <sup>39</sup>Netherlands Heart Journal, <sup>40</sup>Hellenic Journal of Cardiology, <sup>41</sup>Cardiologisk Forum, <sup>42</sup>Kardiovaskuläre Medizin.

U inicijativu zajedničke i istodobne objave ovog članka uključeni su svi zainteresirani članovi skupine nacionalnih i pridruženih kardiovaskularnih časopisa Europskog kardiološkog društva.

*This is a joint simultaneous publication initiative involving all interested National and Affiliated Cardiovascular Journals of the European Society of Cardiology.*

**SAŽETAK:** Biomedicinski časopisi prijavljivanje sukoba interesa (COI — prema engl. *conflict of interest*) koriste kako bi jamčili vjerodostojnost i transparentnost znanstvenih postupaka. Međutim, časopisi se s prijavljivanjem COI ne bave niti sistematski niti dosljedno. Nedavna zajednička nastojanja urednika su utrla put prema implementaciji jedinstvenih načina prijave COI. Ovaj dokument pruža sveobuhvatni urednički stav o klasičnim problemima vezanim za COI. Raspravlja se o novim uvidima u trenutne smjernice COI i prakse nacionalnih kardiovaskularnih časopisa Europskog kardiološkog društva koji su izvedeni iz presječnog anketnog istraživanja primjenom standardiziranog upitnika.

**KLJUČNE RIJEČI:** sukob interesa, prijavljivanje sukoba interesa, urednička etika, časopisi.

## Uvod

Znanstveni proces oslanja se na povjerenju i vjerodostojnosti<sup>1-5</sup>. Znanstvena zajednica zahtjeva visoke etičke standarde za biomedicinska istraživanja i objavu znanstvenih sadržaja<sup>1-5</sup>. Prijavljivanje sukoba interesa (COI) (koji se također naziva konkurentna lojalnost, konkurentni interes ili dvojna obveza) je tijekom prošlog desetljeća smatrano ključnim za jamčenje vjerodostojnosti znanstvenog procesa<sup>6-10</sup>. Pristranost kod kreiranja, analize i interpretacije studija može se pojaviti u slučajevima kada autori ili sponzori imaju stečene interese<sup>6-10</sup>. Stoga bi COI trebao biti jasno objavljen čitateljima kako bi se olakšala njihova vlastita prosudba i interpretacija o njegovoj važnosti i potencijalnim implikacijama. Autori su odgovorni u potpunosti prijaviti potencijalni COI<sup>6-10</sup>. Ukoliko se to ne učini, smanjuje se povjerenje javnosti, zdravstvenih djelatnika i znanstvenika u recenziranu medicinsku literaturu<sup>6-10</sup>.

Prema Međunarodnom udruženju urednika medicinskih časopisa (ICMJE) COI postoji kada autor (ili autorova institucija), recenzent ili urednik imaju financijski ili osobni odnos koji neprimjereno utječe (pristranost) na njegove ili njezine postupke<sup>1,11,12</sup>. Potencijal za COI postoji bez obzira vjeruje li pojedinac da odnos utječe na njegovu ili njezinu prosudbu. Osim financijskih odnosa, COI se može izroditi i iz osobnih odnosa, akademskog natjecanja i intelektualne strasti. Kako bi spriječili dvosmislenost, autore bi trebalo izričito pitati da izjave postoji li COI ili ne. Urednici bi tu informaciju trebali objaviti ako vjeruju da je važna za prosudbu teksta<sup>1,11,12</sup>.

Tradicionalno su biomedicinski časopisi slijedili standardni postupak kako bi se osigurala prijava COI. Mnoge organizacije su u zadnje vrijeme predložile daljnja nastojanja da se poboljša transparentnost i zaštiti integritet istraživanja, uključujući specifične preporuke i smjernice za prijavljivanje COI<sup>10</sup>. Međutim, zbog sve složenijih mehanizama financiranja osiguravanje odgovarajućeg izvještavanja o svim izvorima financijske potpore postaje sve izazovnije za urednike. Nadalje, časopisi imaju različite smjernice o prijavljivanju COI koje mogu uzrokovati zbunjenost jer isti autor u različitim časopisima može iznijeti različite informacije te tako može ugroziti povjerenje čitatelja<sup>11,12</sup>. Kako bi se savladali ovi problemi, ICMJE je predložio upotrebu jedinstvenog načina za prijavljivanje COI te je u listopadu 2009. godine pokrenuo "jedinstveni" elektronički format za prijavljivanje COI<sup>11,12</sup>.

Mreža urednika Europskog kardiološkog društva (ESC) je predana u promociji širenja i implementacije visokokvalitet-

**SUMMARY:** Disclosure of potential conflicts of interest (COI) is used by biomedical journals to guarantee credibility and transparency of the scientific process. COI disclosure, however, is not systematically nor consistently dealt with by journals. Recent joint editorial efforts paved the way towards the implementation of uniform vehicles for COI disclosure. This paper provides a comprehensive editorial perspective on classical COI-related issues. New insights into current COI policies and practices among European Society of Cardiology National Cardiovascular Journals, as derived from a cross-sectional survey using a standardised questionnaire, are discussed.

**KEYWORDS:** Conflict of interest, disclosure, editorial ethic. journals.

**CITATION:** *Cardiologia Croatica*. 2012;7(5-6):146-157.

## Introduction

The scientific process relies on trust and credibility<sup>1-5</sup>. The scientific community demands high ethical standards in biomedical research and the publication of scientific content<sup>1-5</sup>. During the past decade, disclosure of conflicts of interest (COI) (also called competing loyalties, competing interests or dual commitments) has been considered as key to guaranteeing the credibility of the scientific process<sup>6-10</sup>. Biases in design, analysis and interpretation of studies may arise when authors or sponsors have vested interests<sup>6-10</sup>. Therefore, COI should be made clear to the readers to facilitate their own judgement and interpretation of their relevance and potential implications. Authors are responsible for fully disclosing potential COI<sup>6-10</sup>. Failure to do so has shaken the confidence of the public, health professionals and scientists in the peer-reviewed medical literature<sup>6-10</sup>.

According to the International Committee of Medical Journal Editors (ICMJE) COI exist when an author (or the author's institution), reviewer or editor have financial or personal relationships that inappropriately influence (bias) his or her actions<sup>1,11,12</sup>. The potential for COI exists regardless of whether the individual believes that the relationships affect his or her scientific judgement. Aside from financial relationships, COI may emerge from personal relationships, academic competition and intellectual passion. To prevent ambiguity, authors should be explicitly asked to state whether COI exist or do not exist. Editors should publish this information if they believe it is important in judging the manuscript<sup>1,11,12</sup>.

Traditionally, biomedical journals have followed standard practices to ensure COI disclosure. Further efforts to improve transparency and protect the integrity of research, including specific recommendations and guidelines to disclose COI, have been recently proposed by many organisations<sup>1-10</sup>. However, ensuring adequate reporting of all sources of financial support is becoming increasingly challenging for editors as a result of the growing complexity of funding mechanisms. Furthermore, journals have different policies about COI disclosure which can cause confusion as the same author may report different information in different journals which, in turn, might jeopardise the confidence of the readers<sup>11,12</sup>. To overcome these problems, the ICMJE proposed the use of a common vehicle to report COI and, in October 2009, launched an electronic 'uniform' format for COI disclosure<sup>11,12</sup>.

The Editors' Network of the European Society of Cardiology (ESC) is committed to promoting the dissemination and im-

nih uredničkih standarda među nacionalnim kardiovaskularnim časopisima ESC (ESC NSCJ)<sup>13-16</sup>. Ovo izvješće preispituje problem COI s globalne i didaktičke perspektive te osigurava nove uvide u trenutne smjernice i prakse među ESC NSCJ.

## Upitnik i anketa o sukobu interesa

Kako bi utvrdili status COI i zahtjeva za prijavljivanjem među ESC NSCJ, osmišljen je poseban opsežan, strukturirani i standardizirani web upitnik. Upitnik je bio iscrpan te je obrađivao sve relevantne uredničke teme koje su vezane za COI. Prethodne publikacije o COI (od 2005. do 2010. godine) su dobivene pretraživanjem baze PubMed (u pretrazi Medline-a su korišteni izrazi: "sukob interesa", "konkurentni interesi" i "prijavlivanje") te su potom pažljivo pregledane analizirani kako bi se identificirali problemi relevantni za COI. Stavke koje su uključene u upitnik su naposljetku utvrđene nakon interne rasprave među glavnim članicama Mreže urednika. Neke povezane stavke i zbunjujuće ili suvišne teme su naposljetku uklonjene iz konačnog upitnika. Naposljetku je u anketu uključeno ukupno 48 stavki. Pitanja su grupirana u tri glavna interesna područja: (1) autori; (2) recenzenti; (3) urednici. Nadalje, također su izričito zatražene i dodatne povratne informacije o interesu koji je generirala ICMJE inicijativa o "jedinstvenom" prijavljivanju COI. Ostavljeni su prostori za proizvoljne tekstualne komentare za svako glavno interesno područje.

U lipnju 2010. godine iz Europske kuće srca poslana je web anketa svim glavnim urednicima ESC NSCJ, a naknadno (u srpnju 2010.) kardiološkim društvima povezanim s ESC. Poslan je poseban zahtjev da glavni urednici ispune anketu. Poziv je predlagao da se organizira sastanak između glavnog urednika, pridruženih urednika i pratećeg osoblja časopisa, kako bi se prije vraćanja upitnika raspravilo o rezultatima traženih informacija. U pozivnom pismu je naveden URL link na web anketu koji je urednicima omogućavao da pristupe anketi. U slučajevima kada nije bilo povratnog odgovora, izravno je kontaktirano nacionalno kardiološko društvo. Prema potrebi je također korištena i klasična pošta. Tijekom godine je poslano do pet zasebnih zahtjeva, a nakon toga su časopisi čiji odgovori su nedostajali bili klasificirani kao časopisi koji nisu odgovorili na zahtjev.

Konačni elektronički podaci su pažljivo analizirani od strane osoblja ESC u Europskoj kući srca te od strane nukleusa Mreže urednika ESC. Posebna pažnja je posvećena detektiranju podataka koji nedostaju, većim nedosljednostima ili pogreškama. Prema potrebi su od urednika zatražena dodatna pojašnjenja. Podaci su prezentirani kao globalni rezultati te su anonimni za pojedinačne časopise.

## Rezultati ankete o sukobu interesa

Ukupno 46 časopisa je odgovorilo na anketu. Od njih je 35 pripadalo ESC NSCJ, a ostalih 11 časopisima bilo je od pridruženih kardioloških društava. Ovo predstavlja odziv od 83% (35/42) od strane poznatih NSCJ i 58% (11/19) od strane pridruženih kardioloških društava. ESC NSCJ su iznimno heterogeni u pogledu ciljeva, formata i znanstvenog sadržaja<sup>13</sup>. Sukladno tome, neki urednici su odbili odgovoriti na našu anketu pošto su smatrali da se COI smjernice ne odnose na njihove časopise (nedostatak originalnih članaka, kratki bilteni, sadržaj s isključivo lokalnim vijestima, itd.) (podaci nisu prikazani).

plementation of high-quality editorial standards among ESC National Societies Cardiovascular Journals (NSCJ)<sup>13-16</sup>. This report examines the issue of COI from a global and didactic perspective and provides new insights into current policies and practices among ESC NSCJ.

## Conflict of Interest questionnaire and survey

To determine the status of COI and disclosure requirements among ESC NSCJ a web-based, comprehensive, structured and standardised questionnaire was specifically devised. The questionnaire was exhaustive and dealt with all relevant editorial topics related to COI. Previous publications on COI (from year 2005 to 2010) were retrieved from PubMed (Medline search terms: 'conflict of interest', 'competing interest' and 'disclosure') and carefully reviewed to identify issues relevant to COI. Items included in the questionnaire were eventually determined after an internal discussion among the nucleus members of the Editors' Network. For the sake of simplicity some related items and confusing or redundant topics were subsequently removed from the final questionnaire. Eventually, a total of 48 different items were included in the survey. Questions were grouped into three main areas of interest: (1) authors; (2) reviewers; (3) editors. Furthermore, additional feedback about the interest generated by the ICMJE 'uniform' COI disclosure initiative was also explicitly requested. Spaces for free text comments were made available for each main area of interest.

In June 2010 the web-based survey was sent from the ESC European Heart House to all editors-in-chief of the ESC NSCJ and, in a second wave (July 2010), to the ESC Affiliated Cardiac Societies. A specific claim was made for the editor-in-chief in person to complete the survey. The invitation suggested that a meeting between the editor-in-chief, associated editors and corresponding journal staff should be organised, to discuss the results of the requested information, before returning the questionnaire. A URL link to the web-based survey was provided in the invitation letter to allow editors to enter the survey. When no answer was obtained the corresponding National Cardiac Society was contacted directly. Conventional mailing was also used as required. Up to five separate requests were sent over the year and thereafter missing journals were classified as non-responders.

The final electronic records were carefully analysed by ESC personnel at the European Heart House and by the nucleus members of the ESC Editors' Network. Attention was paid to detecting missing data, major inconsistencies or errors. Additional clarifications were requested from the corresponding editors as needed. Data are presented as global results and anonymised for individual journals.

## Conflict of Interest survey results

A total of 46 journals answered the survey. Of these, 35 belong to the ESC NSCJ and 11 to journals of Affiliated Cardiac Societies. This represents a response of 83% (35/42) of known NSCJ and 58% (11/19) for Affiliated Cardiac Societies. ESC NSCJ are highly heterogeneous in objectives, format and in scientific content<sup>13</sup>. Accordingly, some editors declined to answer the survey because they felt that COI policies did not apply to their journals (lack of original articles, small bulletins, contents with just social news, etc) (data not shown).

**Tablica 1** sažeto prikazuje osnovne podatke koji se odnose na COI autora. Gotovo polovica časopisa je imala posebne smjernice vezane za COI autora. U većini slučajeva je naglasak bio isključivo na financijski COI i COI izravno povezan s predanim tekstom. Nekoliko časopisa je dostavilo definicije ili primjere COI. U gotovo svim slučajevima u kojima je zahtjevan COI ove smjernice su utjecale na različite predate članke. Često je bila tražena pismena potvrda od strane autora. Međutim, postupci provjere točnosti prijave autor-skog COI su rijetko primjenjivani, iako je, u posebnim okolnostima, većina urednika kontaktirala autore kako bi razjas-nili pitanja vezana za COI. Pravila o postupanju s autorima koji ne objave COI rijetko su bila utvrđena. U većini časopisa urednici su odlučivali kad se COI autora treba objaviti, no u nekim časopisima ove su informacije bile sustavno publi-cirane (**Tablica 1**).

**Table 1** summarises the main data regarding authors' COI. Nearly half of the journals had a specific policy on authors' COI. In most cases, emphasis was only on financial COI and on COI directly related to the submitted work. Few journals provided definitions or examples of COI. In nearly all cases where COI were requested this policy affected all kinds of submitted articles. Written attestation by the authors was widely requested. However, procedures to verify the accu-racy of authors' COI disclosure were rarely implemented, although, under special circumstances, most editors eventu-ally contact authors to clarify COI related issues. Policies to deal with authors who fail to disclose COI were seldom in place. In most journals the editors decided when authors' COI should be published but, in some journals, this informa-tion was systematically published (**Table 1**).

**Table 1.** Journals policies on authors' conflicts of interest.

1) The journal has a specific policy on authors' COI:	20/45 (44%)
If yes:	
a. Described in the instruction for authors:	19/20 (95%)
b. Described in dedicated forms required for manuscript submission:	12/19 (63%)
2) The journal provides definition of different types of COI:	6/45 (13%)
3) The journal provides examples of different COI:	5/45 (11%)
4) COI are detailed by items and specified according to journals' definition:	9/45 (20%)
If yes:	
a. Financial COI are specifically considered:	8/9 (89%)
b. Non-financial COI are specifically considered:	2/9 (22%)
5) Editors recommend an "inclusive" policy where all potential COI (even those minor and vaguely related) should be disclosed:	13 /44 (30%)
6) Editors favour a "restrictive" policy where only potential COI that are relevant and directly related to the submitted work, should be disclosed:	19/42 (45%)
7) Resources from third parties received via the authors' institution are considered:	8/42 (19%)
8) Financial relationships involving family members are specified:	4/44 (9%)
9) COI are just disclosed as free text directly by the authors:	29/40 (73%)
10) Authors must submit a written attestation of potential COI:	18/44 (41%)
If yes:	
a. Signature is required only from the corresponding/responsible author:	10/18 (55%)
b. Every author should sign the form:	6/18 (33%)
11) Authors' COI disclosures apply to "all" submitted articles:	23/44 (52%)
12) Specific procedures are followed to verify that authors' COI disclosures are accurate:	6/44 (14%)
13) Under specific circumstances efforts are made to contact authors owing to concerns about disclosed or undisclosed COI (e.g. complaint by reviewers/readers):	27/41 (66%)
14) Specific policies to deal with authors who fail to disclose COI of published papers:	11/45 (24%)
15) Specific policies to "restrict" author publication of articles with a stated COI:	10/44 (23%)
16) The journal "publishes" all the authors' COI disclosures in all submissions:	13/40 (33%)
17) The editors decide, on an individual basis, when authors' COI should be "published":	23/43 (53%)
18) If authors' COI are not published, the information is made available upon request:	21/46 (46%)

Data from the 46 journals answering the questionnaire (number of journals answering each question is presented). Not all journals responded to all questions. COI = conflicts of interest.

**Tablica 2** navodi podatke vezane za COI recenzenata. Samo jedna četvrtina časopisa je imala smjernice za COI recenzenata. U više od polovice časopisa je od recenzenata traženo da odbiju poziv da preispitaju postoji li potencijalni COI. Međutim, diskvalificiranje recenzenata zbog potencijalnog COI je bilo rijetko.

**Table 2** discloses data related to reviewers' COI. Only one-quarter of the journals had policies for reviewers' COI. In more than half of the journals reviewers were asked to decline the invitation to review if potential COI existed. However, refusal of reviewers due to potential COI was rare.

**TABLE 2.** Journals policies on peer-reviewers' conflicts of interest.

1) The journal has a specific policy on reviewers' COI:	11/43 (25%)
2) Reviewers are required to explicitly state whether they have potential COI:	10/43 (23%)
3) Reviewers must submit a written attestation of potential COI:	7/43 (16%)
4) Frequency of request to disclose potential COI:	
only first invitation:	7/46 (15%);
always:	10/46 (22%);
yearly:	5/46 (11%)
5) Specific procedures are followed to verify that peer-reviewers' COI disclosures are accurate:	5/44 (11%)
6) It is suggested to reviewers that they "decline" the invitation if potential COI exists:	21/39 (54%)
7) There is a policy for "recusal" of reviewers with a declared COI:	6/42 (14%)
8) Peer-reviewers' COI are always published:	1/44 (2%)
9) Editors decide, on an individual basis, when reviewers' COI should be published:	20/44 (45%)
10) If reviewers' COI are not published, the information is made available upon request:	15/46 (33%)
COI = conflicts of Interest..	

**Tablica 3** prikazuje stanje COI urednika među dotičnim časopisima. U većini slučajeva nisu primjenjivana pravila koje se odnose na ove slučajeve. Nadalje, rijetki časopisi su imali smjernice za delegiranje odluka drugim urednicima ili pozvanim gostima urednicima. U trenutku zaprimanja poziva za anketu, samo jedna trećina urednika bila je upoznata s novom inicijativom ICMJE-o "Jedinstvenom obrascu za prijavljivanje sukoba interesa". Međutim, 90% urednika je smatralo da prijedlog ICMJE za COI ima potencijalnu vrijednost za njihove pojedinačne časopise te je većina izjavila da su ga voljni implementirati u relativno kratkom vremenskom razdoblju (**Tablica 4**).

**Table 3** displays the status of editors' COI among the corresponding journals. In most cases, policies in this regard were not implemented. Furthermore, very few journals had policies for delegating decisions to other editors or to invited guest editors. Only one-third of the editors were familiar with the new 'Uniform Disclosure Form' ICMJE initiative when they received the survey invitation. However, 90% of the editors considered the ICMJE COI proposal of potential value to their particular journals and most of them declared that they were willing to implement it within a relatively short period of time (**Table 4**).

**Table 3.** Journals policies on editors' conflicts of interest.

1) The journal has a specific policy on editors' COI:	8/45 (18%)
2) Editors must submit a written attestation on potential COI:	6/8
3) Frequency to disclose potential COI:	
only when appointed:	5/6
yearly:	1/6
4) Specific procedures are followed to verify that editors' COI disclosures are accurate:	3/8
5) There is a policy for "recusal" of editors with a declared COI:	3/8
6) There is a policy for "delegating" handling decision to other (invited) editors:	4/7
7) Editors' COI are always published:	2/7
8) If Editors' COI are not published, the information is made available upon request:	5/6
COI = conflicts of Interest	

**Table 4.** Feedback on the ICJME “uniform disclosure form” initiative.

1) Editor was familiar with the ICMJE initiative “before” receiving the survey:	15/42 (36%)
2) The initiative was considered of value to the “particular” journal:	38/42 (90%)
3) Editors willing to implement the initiative within 3 years:	31/46 (67%)
4) Main perceived advantages of the initiative (top 5):	
a. Provides a common “uniform” platform for all journals:	42
b. All relevant information about COI is nicely presented and explained:	18
c. Allows easy update of the requested information:	12
d. Facilitates sequential submissions (if the paper is rejected by a journal):	11
e. Allows archiving of the requested information:	10
5) Main perceived disadvantages of the initiative (top 5):	
a. Increases the complexity of the submission process:	29
b. Publishing in the journal all potential COI of every author is not feasible:	17
c. Verification of the disclosed/undisclosed COI remains impossible:	17
d. Increases editorial bureaucracy:	15
e. Too detailed and exhaustive:	14
f. The meaning of some potential COI (travel grants to meetings, etc) might be perceived differently by American and European authors/journals/readers:	14

ICMJE = International Committee of Medical Journal Editors, COI = conflict of Interest.

## RASPRAVA

### Studije sponzorirane od strane industrije: prijatelj ili neprijatelj?

Istraživanja postaju sve složenija i standardi kvalitete sve zahtjevniji<sup>17-24</sup>. Stoga provođenje kliničkih studija postaje sve skuplje i uloga sponzora u osiguravanju održivosti istraživačkih projekata postaje ključna. Međutim, financiranje iz različitih izvora može izravno utjecati na istraživače i COI može neprimjereno utjecati na njihovo djelovanje ili prosudbu<sup>17-24</sup>. U slučajevima kada sponzor ima koristi od izvješća može se pojaviti suptilna pristranost u planu izvedbe i interpretaciji<sup>17</sup>.

Farmaceutske i tehnološke kompanije odgovorne su za najvažnije napretke medicinskog znanja<sup>17-24</sup>. Pacijenti, liječnici i društvo u cjelini imaju koristi od ovog jedinstvenog nastojanja te bi trebali biti zahvalni na predanosti industrije prema istraživanju. Više od 75% svih kliničkih studija financiraju farmaceutske kompanije<sup>25,26</sup>. Također, većina istraživanja se iz akademskih centara pomakla na izravne ugovore između sponzora i privatnih organizacija<sup>27,28</sup>. Profitabilne, ugovorne istraživačke organizacije trenutno troše više od 60% istraživačkih sredstava od industrije<sup>25-28</sup>. Ovo bi mogao biti rezultat njihove sposobnosti da ispitivanja provedu brže od akademskih institucija<sup>8,25</sup>. Ovaj fenomen objašnjava postupni gubitak utjecaja akademskih institucija na istraživačke programe<sup>25-29</sup>. Iako su najcitatirani članci i dalje pisani od strane autora s akademskim poveznicama, broj studija koje su financirane isključivo od strane industrije se povećao eksponencijalno<sup>30</sup>.

Ova promjena obrasca ima važne posljedice<sup>25-29</sup>. Prvo, sve je manja vjerojatnost da će se istražiti mnoga znanstveno relevantna pitanja (studije bez pokrovitelja). Također, mnoge studije<sup>8,31,32</sup> ukazuju da se, u usporedbi s ne-sponzoriranim istraživanjima, sponzorirane studije objavljuju rjeđe, što povećava zabrinutost oko pristranosti publikacije<sup>29</sup>. Iako je industrija okrivljavana za dominantno objavljivanje studija s pozitivnim ishodom, ovaj problem također pogađa i istraživanja financirana od strane države<sup>8,31-35</sup>. Kako bi umanjili utjecaj pristranosti, studije moraju biti registrirane u javno do-

## DISCUSSION

### Industry-sponsored studies: friend or foe?

Research is becoming progressively complex and quality standards increasingly demanding<sup>17-24</sup>. As a result, conducting clinical studies is becoming more expensive and the role of sponsors to ensure the viability of research projects is becoming critical. However, funding from different sources may directly affect investigators and COI may inappropriately influence their actions or judgement<sup>17-24</sup>. Subtle biases in design and interpretation may arise when a sponsor stands to gain from the report<sup>17</sup>.

Pharmaceutical and technological companies are responsible for most important advancements in medical knowledge<sup>17-24</sup>. Patients, doctors and society as a whole benefit from this unique effort and should be grateful for the research commitment by the industry. More than 75% of all clinical trials are funded by drug companies<sup>25,26</sup>. Likewise, the bulk of research has moved from academic centres to direct contracts between sponsors and private organisations<sup>27,28</sup>. For-profit, contract research organisations, currently consume more than 60% of research funding from industry<sup>25-28</sup>. This could be a result of their ability to complete trials more rapidly than academic institutions<sup>8,25</sup>. This phenomenon explains the gradual loss of the academic establishment's influence on the 'research agenda'<sup>125-29</sup>. Although the most cited articles continue to be generated by authors with academic affiliations, the number of trials financed exclusively by industry has increased exponentially<sup>30</sup>.

This paradigm shift has major consequences<sup>25-29</sup>. First, many scientifically relevant issues are decreasingly likely to be investigated (orphan studies). Second, many studies<sup>8,31,32</sup> suggest that, in comparison with non-sponsored research, sponsored trials are published less frequently, raising the concern of publication bias<sup>29</sup>. Although the industry has been blamed for preferential publication of studies with positive outcomes, this problem also affects government-funded research<sup>8,31-35</sup>. To reduce the effect of publication bias, trials

stupnim repozitorijima<sup>29</sup>. Istraživanja koja financira industrija su također povezana s višestrukim objavljivanjima studija s pozitivnim ishodima<sup>8,36</sup>. Ova praksa može utjecati na rezultate kasnijih recenzija, meta-analiza i čak smjernica za kliničku praksu. Alternativno, pokroviteljstvo od strane industrije je povezano s odlagama objave ili ograničenjima<sup>8</sup>.

Naposlijetku, studije sponzorirane od strane industrije imaju tri do četiri puta veću vjerojatnost dobivanja pozitivnih rezultata od studija bez sponzora<sup>8,31-33,37,38</sup>. Zanimljivo je da se čini da sve ove razlike nisu povezane s inferiornom metodologijom studija financiranih od strane industrije. Bekelman i sur.<sup>8</sup> su proveli sustavnu procjenu 1.140 originalnih studija te su dokazali statistički značajnu povezanost između pokroviteljstva od strane industrije i zaključaka koji idu u korist industrije. Studija je pokazala da su financijski odnosi između industrije, znanstvenih istraživača i akademskih institucija jako rasprostranjeni te da COI koji proizlazi iz ovih veza može značajno utjecati na biomedicinska istraživanja. Međutim, smatrano je mogućim da je, uzimajući u obzir ograničene resurse, industrija postala dostatno selektivna da financira isključivo potencijalno "uspješne terapije"<sup>38</sup>. Nedavno je provokativna studija, autora Ridker i Torres<sup>39</sup>, koja je uključivala 324 kardiovaskularnih istraživanja objavljenih u tri medicinska časopisa s najvišim čimbenicima utjecaja, analizirala vjerojatnost pozitivnih rezultata u skladu s izvorima financiranja. Studije financirane od strane industrije su češće dobivale rezultate koji su bili povoljni za lijek ili uređaj od onih koje su financirane od strane neprofitnih organizacija. Ovo je bilo posebice evidentno na studijama koje su koristile zamjenske ishode<sup>39</sup>.

## Prethodne uredničke ankete o sukobu interesa

Krimsky i Rothenberg su 1997. godine ustanovili da svega 16% časopisa iz svih znanstvenih područja ima smjernice o COI<sup>40</sup>. Također, postojeća urednička pravila često nisu bile lako dostupna autorima koji prijavljuje članke<sup>41</sup>. Međutim, vremenom je registrirano značajno povećanje učestalosti prijave COI. U početku je većina časopisa od autora samo zahtijevala da prijave potencijalni COI. Kasnije su časopisi počeli poticati autore da potpišu izjave o prijavljivanju COI. Ako se od autora ne dobije potpisana izjava, ostaje mogućnost da je samo prvi autor pregledao smjernice časopisa o COI, što dovodi do sustavnog slabijeg prijavljivanja<sup>6</sup>. Interesantno, kad se kritički analiziraju neki časopisi koji teoretski poštuju preporuke ICMJE možemo ustanoviti da nemaju jasne smjernice o COI. Međutim, veća je vjerojatnost da su časopisi s najvišim čimbenikom utjecaja objavili smjernice o COI<sup>6,41</sup>.

Kako bi bolje okarakterizirali politiku COI, Cooper i sur.<sup>7</sup> su 2006. godine proveli presječnu web anketu na prikladnom uzorku od 135 urednika biomedicinskih časopisa čiju recenziju provode stručnjaci iz istog područja. Anketa je uključivala pitanja o postojanju specifičnih smjernica za autore, recenzente i urednike, posebna ograničenja koja se temelje na COI te javna dostupnost ovih objava. Devedeset i tri posto časopisa je izvijestilo da imaju smjernice za COI autora, no svega 82% je zahtijevalo pismenu potvrdu. Dok je 77% izvijestilo o prikupljanju COI informacija o svim predanim autorskim člancima, svega 57% je objavljivalo sve autorove prijave. Jedanaest posto časopisa je izvijestilo o ograničavanju autorovih podnesaka na temelju COI-a. Manji dio časopisa je izvijestio da ima smjernice za COI recenzenata (46%) ili urednika (40%); među kojima je 25% i 31% časopisa izjavilo da zahtijevaju diskvalifikaciju recenzenata i urednika ako prijave COI. Svega 3% ispitanika je objavljiva-

must be registered in publicly accessible repositories<sup>29</sup>. Industry-supported research has also been associated with multiple reporting of studies with positive outcomes<sup>8,36</sup>. This practice might affect results of subsequent reviews, meta-analyses and even clinical practice guidelines. Alternatively, industry sponsorship has been associated with publication delays or restrictions<sup>8</sup>.

Finally, industry-sponsored trials have a three- to four-fold greater probability of obtaining favourable results than their non-sponsored counterparts<sup>8,31-33,37,38</sup>. Interestingly, all these differences do not appear to be related to inferior methodology in industry-financed trials. Bekelman et al<sup>8</sup> performed a systematic review of 1,140 original studies demonstrating a statistically significant association between industry sponsorship and pro-industry conclusions. The study showed that financial relationships between industry, scientific investigators and academic institutions were widespread and that COI arising from these ties might significantly influence biomedical research. It was considered possible, however, that given limited resources, industry became selective enough to fund only potentially 'winning treatments'<sup>38</sup>. More recently, in a provocative study that included 324 cardiovascular trials published in the three medical journals with the highest impact factors, Ridker and Torres<sup>39</sup> analysed the probability of positive results according to the source of finance. Industry-financed trials more frequently obtained results favourable to drug or device than those financed by not-for-profit organisations. This was particularly evident in trials using surrogate end points<sup>39</sup>.

## Previous editorial surveys on conflicts of interests

In 1997, Krimsky and Rothenberg found that only 16% of journals across all scientific disciplines had COI policies<sup>40</sup>. In addition, existing editorial policies were often not readily available to submitting authors<sup>41</sup>. However, a substantial increase in the prevalence of COI disclosure occurred over time. Initially, most journals only required authors to disclose potential COI. Subsequently, journals encouraged authors to sign COI disclosure statements. If signed statements are not obtained from all authors, it remains possible that only the first author has reviewed the COI policy of the journal, leading to systematic under-reporting<sup>6</sup>. Interestingly, some journals that theoretically adhere to ICMJE recommendations do not have clear COI policies when critically analysed<sup>6</sup>. However, the journals with highest impact factors are more likely to have published COI policies<sup>6,41</sup>.

To better characterise COI policies, in 2006, Cooper et al<sup>7</sup> performed a cross-sectional web-based survey of a convenience sample of 135 editors of peer-reviewed biomedical journals. The survey included questions about the existence of specific policies for authors, peer reviewers and editors, specific restrictions based on COI and the public availability of these disclosures. Ninety-three per cent of journals reported having an author COI policy but only 82% of these required a written attestation. While 77% reported collecting COI information on all author submissions, only 57% published all author disclosures. Eleven per cent of journals reported restricting author submissions based on COI. A minority of journals reported having a policy on reviewers' COI (46%) or editors' COI (40%); among these, 25% and 31% of journals stated that they require refusal of peer-reviewers and editors if they report a COI. Only 3% of respondents published COI disclosures of peer reviewers and 12% publi-

lo prijave COI recenzenata, a 12% je objavljivalo prijave COI urednika, dok je 11% (za recenzente) i 24% (za urednike) izvijestilo da su ove informacije dostupne na zahtjev. U ovoj anketi su procjene izravno dali dopisni urednici no nikakve informacije nisu dobivene od samih publikacija<sup>7</sup>.

Druge studije su bile kritičnije te su analizirale informacije dostupne izravno od časopisa što je dalo drugačiju perspektivu. Interesantno je da su se neke od ovih studija usredotočile na prijavljivanje COI u kardiologiji. Weinfurt i sur.<sup>42</sup> su pretraživali bazu PubMed kako bi pronašli časopise na engleskom jeziku objavljene u 2006. koji bi pružili dokaze ili smjernice o korištenju koronarnih stentova. Kao pretpostavka, smatrano je razumnim očekivati da se u člancima na istu temu i u istom vremenskom razdoblju COI autora objavljuje na sličan način. Analizirano je ukupno 746 članaka od 2.985 autora objavljenih u 135 časopisa. Članci su pregledani kako bi se utvrdilo da li se dosljedno izvještava o financijskim interesima autora. Osamdeset i tri posto članaka nije imalo izjave o prijavi sukoba interesa za bilo kojeg autora, 72% nije identificiralo niti jedan izvor financiranja, a svega 6% autora je imalo članak s izjavom o prijavi sukoba interesa. Također, autorske izjave o postojanju sukoba interesa su se značajno razlikovale od članka do članka. Posebice, članci objavljeni u časopisima koji su podržali ICMJE smjernice imali su veće šanse prisutnosti izjave o prijavi sukoba interesa za sve autore. Slično, članci u kojima su svi autori imali izjave o prijavi sukoba interesa su imali veću šansu da se pojave u časopisima s višim faktorom utjecaja (srednji faktor utjecaja 11,6 nasuprot 3,1). Ovi istraživači su zaključili da čak i rijetko prijavljivani financijski interesi nisu prijavljivani dosljedno, što sugerira da postoje problemi s transparentnosti u kardiološkoj literaturi s potencijalnim implikacijama za skrb o pacijentima. Podaci su sugerirali da su zapažene nedosljednosti rezultat i smjernica časopisa i ponašanja autora<sup>42</sup>. Mnogi bi rekli da je nedosljedan sustav objave štetniji od potpunog izostanka objave.

Nedavno su Blum i sur.<sup>6</sup> analizirali COI smjernice 10% najvećih medicinskih časopisa prema njihovom čimbeniku utjecaja. Uputa za autore i dokumenti za predavanje rukopisa su pomoću standardiziranog obrasca pretraženi za izraze koji se odnose na COI. Analizirana su ukupno 262 časopisa. Od njih je 85% u uputama autorima tražilo prijavljivanje COI, a dodatnih 4% u drugim dokumentima za predavanje rukopisa. Linkovi na specifične smjernice o COI su u uputama za autore pronađeni u svega 25% časopisa. Iako je 77% časopisa dalo definicije COI, potpisanu izjavu o prijavljivanju sukoba interesa je tražilo svega 54% časopisa. Prijava potpore za putovanje je tražena u 12% časopisa. Interesantno je da je kategorija časopisa utjecala na zahtjeve za prijavu COI. Ovaj zahtjev je bio veći za časopise iz interne medicine nego za specijalizirane časopise, za časopise u gornjem kvartilu prema čimbeniku utjecaja i za časopise koji su podržavali ICMJE smjernice<sup>6</sup>.

Naši podaci o ESC NSCJ smjernicama za COI i zahtjevima za prijavljivanje sukoba interesa ukazuju da je ova tema i dalje sporna te joj časopisi ne posvećuju jednaku pažnju. Oslanjali smo se na samoizvještavanje od strane urednika časopisa. Međutim, uzimajući u obzir anonimnu narav ankete, ne vjerujemo da ima razloga sumnjati u točnost njihovih izvješća.

## Inicijativa ICMJE o jedinstvenom prijavljivanju sukoba interesa

ICMJE je u listopadu 2009. predložio "jedinstveni" elektronički format za prijavljivanje COI<sup>11</sup>. Obuhvaćena su četiri

shed editors' COI disclosures, while 11% and 24%, respectively, reported that this information was available upon request. In this survey, estimates were directly provided by the corresponding editors but no information was taken directly from the actual publications<sup>7</sup>.

Other studies were more critical and analysed the information available directly from the journals yielding a different perspective. Interestingly, some of these studies focused on COI disclosures in cardiology. Weinfurt et al<sup>42</sup> searched in PubMed for English-language articles published in 2006 that provided evidence or guidance about the use of coronary artery stents. As a premise, it was considered reasonable to expect that authors' COI were disclosed in similar ways in articles on the same topic published around the same time. A total of 746 articles with 2,985 authors published in 135 journals, were analysed. Articles were examined to determine whether authors' financial interests were consistently reported. Eighty-three per cent of the articles did not contain disclosure statements for any author, 72% did not identify any funding source and only 6% of authors had an article with a disclosure statement. Additionally, author disclosure statements varied significantly from article to article. Notably, articles published in journals that endorsed the ICMJE guidelines were more likely to have disclosure statements for all authors. Similarly, articles in which all authors had disclosure statements were more likely to appear in journals with higher impact factors (median impact factor 11.6 vs 3.1). These investigators concluded that even rarely disclosed financial interests were not disclosed consistently, suggesting that there are problems with transparency in the cardiac literature with potential implications for patient care. Data suggested that the observed inconsistencies were a result of both journals' policies and authors' behaviour<sup>42</sup>. Many would argue that an inconsistent system of disclosure is more harmful than no disclosure at all.

More recently, Blum et al<sup>6</sup> analysed COI policies of the top 10% of medical journals according to their impact factor. Instructions to authors and manuscript submission documents were electronically searched for phrases relating to COI using a standardised form. A total of 262 journals were analysed. Of these, 85% requested COI disclosure in the instruction to authors and an additional 4% in other submission documents. Links to specific policies on COI were found within the instruction for authors in only 25% of journals. Although 77% of journals provided definitions on COI, signed disclosure statements were required by only 54% of journals. Travel grant disclosure was requested by 12% of journals. Interestingly, journal category influenced COI disclosure requirements. This request was higher for internal medicine journals than for specialty journals, for journals in the top quartile according to impact factor and for journals endorsing the ICMJE guidelines<sup>6</sup>.

Our data on ESC NSCJ COI policies and disclosure requirements suggest that this topic remains controversial and is not uniformly addressed by journals. We relied on self-reporting by journal editors. However, given the anonymous nature of our survey, we do not believe there is any reason to question the accuracy of their reports.

## ICMJE Uniform Disclosure Initiative

In October 2009 the ICMJE proposed an electronic 'uniform' format for COI disclosure<sup>11</sup>. Four main areas were address-



glavna područja: povezanost autora sa subjektima koji su podržali predani rukopis (neograničeno vremensko razdoblje), veze s poslovnim subjektima koji imaju potencijalni interes u općem području članka (vremensko razdoblje 36 mjeseci), financijske veze njihovog supružnika ili djece te, naposljetku, nefinancijske veze koje su potencijalno važne za predani rukopis. Svaki autor bi trebao sam ili preko prateće institucije prijaviti izravno primljena sredstva koja su korištena za obavljanje istraživanja. Također, trebalo bi prijaviti sve izvore prihoda koji su relevantni za prijavljeni rad, a isplaćeni su od strane treće strane prije predavanja teksta te sve relevantne dugotrajne odnose, čak i ako su završili. Financijski prihodi bi trebali biti prijavljeni bez obzira na iznos. Upute za autore i ispunjeni uzorak su dani u PDF formatu. Obrazac za prijavu je na [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) bio dostupan za učitavanje, ispunjavanje i slanje u časopis<sup>11</sup>. Obrazac se može spremati i koristiti ponovo-dodajući ažurirane informacije-za novi rukopis. Svaki autor bi trebao predati zaseban obrazac te je odgovoran za točnost i cjelovitost predanih informacija<sup>11</sup>.

ICMJE je dozvolio razdoblje za pokusno testiranje do travnja 2010. u kojem se poticalo slanje prijedloga<sup>12</sup>. Obrazac je izmijenjen na osnovu povratnih informacija. Izražena zabrinutost je bila većinom tehničke i etičke prirode, a odnosila se na upite o nefinancijskim vezama. Sukladno tome je poboljšana jasnoća za ne-izvorne govornike engleskog jezika (uključujući rječnik pojmova). Također, zbog poteškoća utvrđenih kod definiranja nefinancijskog COI, ovaj dio je izmijenjen kako bi bio manje nametljiv (trenutno predstavljen kao proizvoljni upitnik) no da zadrži svoj smisao. Naposljetku, upitnici vezani za COI kod članova obitelji su uklonjeni iz ažuriranog obrasca<sup>12</sup>.

Ideja u pozadini ove inicijative je da se olakša i standardizira jedinstveno prijavljivanje COI te da se postupak učini jednostavnijim za autore i manje zbunjujućim za čitatelje. Ovo jedinstveno "univerzalno" sredstvo omogućava autorima da pohrane elektroničke obrasce koji se mogu ažurirati po potrebi te se na taj način otkloni potreba za ponovnim oblikovanjem informacija za prijavu COI za svaki novi prijavljeni tekst. Naposljetku, ovo će eliminirati očigledne nedosljednosti kod prijavljivanja COI koje su rezultat različitih smjernica u časopisima<sup>11,12</sup>.

## Dodatni urednički stavovi vezani za sukob interesa

Zabrinutost oko COI nije novost. Moliere je u svojoj komediji *Le Malade Imaginaire* satirizirao odnos između liječnika i apotekara koji su iskorištavali hipohondra Argana za svoju vlastitu financijsku dobit<sup>21</sup>. Biomedicinski časopisi su naročito osjetljivi na probleme koji su povezani s COI. Kao što je izjavio Richard Smith, bivši glavni urednik časopisa *British Medical Journal*, "kvaliteta časopisa će blagosloviti kvalitetu lijeka"<sup>43</sup>. Stoga je jednostavno shvatiti dodatnu pažnju koju istraživanjima sponzoriranima od strane industrije posvećuju recenzenti i urednici<sup>33</sup>. Neki urednici traže da autori istraživanja koja su povezana s industrijom moraju svoje podatke potvrditi od strane različitih izvora, a drugi čak traže da sirove podatke analiziraju nezavisni akademski statističari<sup>20,33</sup>. Neki urednici ne prihvaćaju editorijale ili recenzije od autora s potencijalnim COI jer bi isti mogli smanjiti objektivnost<sup>19,44,45</sup>. Ovi tekstovi osobito ovise o tumačenju i objektivnosti. Međutim, procjenjivanje COI u člancima koji iznose mišljenje može biti zahtjevno. Dilema je očigledna: oni autori koji imaju najveću stručnost su obično oni s jasnijim potencijalnim

sed: authors' associations with entities that supported the submitted manuscript (indefinite time frame), associations with commercial entities with potential interest in the general area of the manuscript (time frame 36 months), financial association of their spouse and children and, finally, non-financial associations potentially relevant to the submitted manuscript. Each author should disclose resources received directly, or via the corresponding institution, which were used to complete the investigation. Additionally, all sources of revenues relevant to the submitted work paid by any third party before the submission and any relevant long-term relationship, even if ended, should be disclosed. Financial revenues should be disclosed regardless of the amount. A guide for authors and a completed sample was provided in PDF format. The reporting form was made available at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) to be downloaded, completed and sent to the journal<sup>11</sup>. The form can be saved and used again — adding updated information — or a new manuscript. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information<sup>11</sup>.

The ICMJE allowed a period of beta-testing until April 2010 when submission of suggestions was encouraged<sup>12</sup>. As a result of the feedback comments, the form was modified. Concerns raised were mainly technical and ethical regarding inquiries about non-financial associations. Accordingly, clarity was enhanced for non-native English speakers (including a glossary of terms). Additionally, owing to the difficulties detected in defining non-financial COI, this section was also modified to be less intrusive (currently presented as an open query) while keeping its locus. Finally, queries about COI in family members were removed from the updated form<sup>12</sup>.

The idea behind this initiative was to facilitate and standardise uniform disclosure of COI and to make the process easier for authors and less confusing to readers. This uniform 'universal' vehicle allows authors to save the electronic forms that can be updated as needed and eliminates the need for reformatting disclosure information for each new submission. Finally, this will eliminate apparent inconsistencies in the report of COI as a result of different journal policies<sup>11,12</sup>.

## Additional editorial perspectives regarding Conflicts of interests

Concerns about COI are not new. In his play *Le Malade Imaginaire* Moliere satirised the relationship between the doctor and the druggist as they exploited the hypochondriac Argan for their own economic benefit<sup>21</sup>. Biomedical journals are particularly vulnerable to COI-related problems. As Richard Smith, the former editor-in-chief of the *British Medical Journal*, stated "the quality of the journal will bless the quality of the drug"<sup>43</sup>. Therefore, it is easy to understand the extra scrutiny of industry-sponsored research by reviewers and editors<sup>33</sup>. Some editors require that authors of industry-associated research have their data analysis confirmed by a different source and others even ask for the raw data to be analysed by an independent academic statistician<sup>20,33</sup>. Some editors do not commission editorial or review articles from authors with potential COI as these may blur objectivity<sup>19,44,45</sup>. These pieces rely especially on interpretation and objectivity. However, assessing the importance of COI in opinion articles may be challenging. The dilemma is obvious: those authors with the greatest expertise are usually those with clearer potential COI<sup>44</sup>. Last, but not least, editors should

COI<sup>44</sup>. Na kraju, no ne i manje važno, urednici bi također u časopisima trebali izbjegavati marketing koji je zamaskiran kao edukacija. Važno je napomenuti da potpora industrije iznosi većinu sredstava koja se dodjeljuju programima trajne medicinske izobrazbe (CME)<sup>19</sup>. Neki sugeriraju da je CME postao podmuklo sredstvo za agresivnu promociju lijekova i medicinskih uređaja (čak i s indikacijama koje nisu službeno prihvaćene). Drugi CME smatraju marketinškim alatom i unosnim procesom — s prikrivenim isplatama liječnicima — što potkopava nezavisnost medicinskih društava<sup>19,46</sup>.

Ponekad se medicinska literatura proizvodi na opskurne načine. Profesionalni pisci, unajmljeni od strane industrije, mogu djelovati kao "pisci iz sjene" i stvarati radove čija vjerodostojnost će se kasnije povećati pozivanjem akademskih liječnika da djeluju u svojstvu "gostujućeg autora"<sup>33</sup>. Nažalost, ovi gostujući autori rijetko daju značajne doprinose dizajnu, analizi i tumačenju podataka<sup>33</sup>. Suprotno tome, mnogi zaslužni znanstvenici u industriji mogu biti uklonjeni iz popisa autora od strane sponzora. Povezanost s farmaceutskom kompanijom ne bi trebala biti smatrana dokazom prijestupa, kao što je ranije naglašeno, većina važnih medicinskih istraživanja je generirala farmaceutska industrija.

Časopisi obično koriste dva glavna oružja u borbi protiv COI: prijavljivanje i isključivanje<sup>44</sup>. Međutim, kao što je rečeno, smjernice za COI uvelike variraju među urednicima. Prijavljivanje se ne bi trebalo smatrati kao panaceja koja će riješiti COI već, sa stajališta urednika, rasvjetljivanje odnosa između liječnika i farmaceutskih kompanija predstavlja najbolji način poštovanja ovog Gordijskog čvora<sup>44</sup>. Urednici bi trebali odlučiti da li žele objaviti informacije koje su autori prijavili o potencijalnom COI. Urednici mogu po svojoj ocjeni odlučiti da li je potencijalni COI dovoljno važan za objavljivanje<sup>6</sup>. Međutim, nije jasno kako urednici odlučuju da li žele objaviti prijavu. Štoviše, mjera u kojoj takva "tajna prijava" može utjecati na integritet časopisa ili izdanog djela ostaje nepoznata<sup>7</sup>. Neki časopisi sistematski objavljuju sve prijavljene potencijalne COI<sup>6</sup>. Međutim, ova strategija troši velike uredničke resurse te je okrivljena za uvođenje predrasude u procjenu tekstova od strane čitatelja i degradiranje cijelog sadržaja članka. Vrijednost iscrpnog sistematskog objavljivanja svih potencijalnih COI ostaje iznimno kontroverzna. Ova praksa ne jamči da će čitatelji biti u mogućnosti utvrditi da li je COI značajan ili nije. Doista, ova praksa bi mogla navoditi na pogrešno mišljenje jer se može percipirati kao pristranost kada objava nije prisutna i propustiti kada je važna. Iako COI ne podrazumijeva nikakvo neprimjereno ponašanje, McCarthyjevska reakcija na izraz bi mogla pogrešno dovesti do pretpostavke krivnje dok se ne dokaže nevinnost<sup>23,33,47</sup>. Njihalo se njiše prema sve većem nadzoru, no odgovorni urednici bi trebali osigurati da njihovi čitatelji, bar za sada, uživaju u zlatnoj sredini.

Urednici su veoma zaposleni te ne mogu provoditi provjeru svake predane studije. Naša anketa je u skladu s prethodnim izvješćima<sup>7</sup> što sugerira da gotovi niti jedan časopis nema službene smjernice o "provjeri" prijave COI<sup>7</sup>. Urednici nisu policajci no, istovremeno, postaje jasno da je u slučaju otkrivanja neprimjerenog ponašanja potrebno određeno djelovanje. Mnogo puta se urednici prema COI ponašaju kao "psi čuvari bez zuba". Alternativno, drugi urednici predlažu da se tvrdnje o preslabom prijavljivanju COI-rigorozno istraže<sup>9</sup>. Međutim, urednici nemaju resurse potrebne za provođenje cjelovite istrage kako bi se razjasnila prevrtljiva i višeznačna pitanja vezana za COI. U većini slučajeva njihova konačna uloga je da problem upute odgovarajućem

also avoid the existence of marketing masquerading as education in their journals. Of note, industry support accounts for most of the funding of accredited continuing medical education (CME) programmes<sup>19</sup>. Some suggest that CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices (even with off-label indications). Others consider CME a marketing machine and a lucrative process-with concealed payments to doctors-that undermines the independence of medical societies<sup>19,46</sup>.

Sometimes medical literature is produced in obscure ways. Professional writers, hired by the industry, may act as 'ghostwriters' to produce papers for which credibility will be subsequently increased by inviting academic physicians to act as a 'guest author'<sup>33</sup>. Unfortunately, these guest authors rarely make significant contributions to the design, analysis and data interpretation<sup>33</sup>. Conversely, many deserving industry scientists may be removed from the byline directly by the sponsors. Affiliation with a drug company should not be viewed as evidence of wrongdoing because, as previously emphasised, most important medical discoveries are generated by the pharmaceutical industry.

Journals typically use two main weapons to deal with COI: disclosure and exclusion<sup>44</sup>. However, as discussed, policies for COI vary widely among editors. Disclosure should not be considered as a panacea to deal with COI but, from an editorial perspective, casting daylight on the relationship between doctors and pharmaceutical companies represents the best way to untie this Gordian knot<sup>44</sup>. Editors should decide whether to publish the information disclosed by authors about potential COI. Editors have the 'discretion' to decide if the potential COI is important enough to be revealed<sup>6</sup>. However, it is unclear how editors decide whether to publish disclosures. Moreover, the extent to which such "secret disclosure" may affect the integrity of the journal or the published work remains unknown<sup>7</sup>. Some journals systematically disclose all reported potential COI<sup>6</sup>. However, this strategy consumes major editorial resources and has been blamed for introducing prejudice in the judgement of manuscripts by readers and for tainting the full content of the article. The value of an exhaustive systematic disclosure of all potential COI remains highly controversial. This practice does not guarantee that the readers will be able to determine whether COI are meaningful or not. Indeed, this practice may be misleading because bias may be perceived when not present and overlooked when relevant. Although COI do not imply any improper behaviour, a McCarthyesque reaction to the term would wrongly support the presumption of guilty until proven innocent<sup>23,33,47</sup>. The pendulum is swinging towards increased oversight, but responsible editors should ensure that their readers enjoy the sweet spot in the middle, at least for the time being.

Editors are very busy and cannot conduct a forensic check on every submitted trial. Our survey is consistent with prior reports<sup>7</sup> suggesting that almost no journal has a formal policy of 'verification' of COI disclosures<sup>7</sup>. Editors are not policemen but, at the same time, it becomes clear that some action is expected when misconduct is detected. Many times editors behave as a 'toothless watchdog' regarding COI. Alternatively, other editors suggest that allegation of under-reported COI should be rigorously investigated<sup>9</sup>. However, editors do not have the resources required to conduct a full investigation to clarify elusive and multifaceted COI-related issues. In most cases their final role is just to raise the issue with the corresponding dean. Notably, formal 'corrections' about COI are rarely published.

dekanu. Potrebno je naglasiti da se službeni "ispravci" vezani za COI rijetko objavljuju.

Svi autori ovog članka podržavaju važnost prijavljivanja potencijalnog COI kad se znanstveni rad preda na razmatranje bilo kojem ESC NSCJ. Štoviše, kada postoji sumnja, bolje je prijaviti više informacija i prepustiti urednicima da donesu odluku. Inicijativa ICMJE i o jedinstvenom prijavljivanju sukoba interesa predstavlja prekretnicu u tom pogledu te utire put daljnjoj transparentnosti u biomedicinskom izdavaštvu<sup>11,12</sup>. Stoga potičemo ESC NSCJ da postupno prilagode svoje smjernice kako bi mogli slijediti ovaj urednički prijedlog. Međutim, na ovom putu bi trebalo obratiti pozornost na neke potencijalne probleme. Prvo, iscrpno prijavljivanje višestrukih, manjih i slabo povezanih potencijalnih COI može "razvodniti" značaj stvarnih ozbiljnih COI s kojima bi većina čitatelja htjela biti upoznata. Drugo, neki relevantni institucionalni COI nisu otvoreno poznati svim uključenim istraživačima te bi, sukladno tome, iste bilo nemoguće prijaviti. Treće, mnogi veći časopisi učestalo dopuštaju starijim međunarodnim predvodnicima mišljenja s jasnim (utvrđenim i dobro poznatim) COI da sistematski prijavljuju da u njihovim radovima nema COI. Mladi znanstvenici ovo mogu shvatiti kao zbunjujuće i uznemirujuće dok će drugi ovu nedosljednost smatrati dokazom da je cijeli proces licemjerman. Naposljetku, u obzir bi trebalo uzeti glavne sociokulturalne razlike među zemljama. Većina europskih liječnika (uključujući većinu urednika u popisu autora ovog članka) učestalo prima povremene potpore za putovanja od različitih farmaceutskih kompanija kako bi mogli nazočiti skupovima medicinskih društava, a to do sada nije sustavno prijavljivano kao potencijalni COI. Međutim, situacija je drugačija s druge strane Atlantika gdje se takva praksa već niz godina smatra neadekvatnom ili čak nedoličnim ponašanjem. U Sjevernoj Americi je izravna potpora (uključujući putovanja) CME programa od strane industrije zabranjena dok se ista praksa u većini europskih zemalja smatra prihvatljivom<sup>19</sup>. Urednici NSCJ bi trebali biti upozoreni na potrebu suočavanja s ovim napornim problemima u svojim časopisima u skladu s lokalnim smjericama i praksama<sup>48</sup>. Trebalo bi poduzeti progresivne mjere kako bi se osigurao sustavni pristup ovim uredničkim problemima vezanima za COI. Međutim, zdrav razum i prosudba bi trebali prevladati kako bi se ostvarila ravnoteža između objektivnog i idealnog.

## Zaključne napomene

Korisnici medicinskih stipendija očekuju pouzdan sustav prijavljivanja sukoba interesa, prema kojem časopisi i autori prijave provode na odgovarajući i dosljedan način. Postoji stigma koja okružuje prijavljivanje COI koju bi trebalo postupno savladati. ESC je nedavno definirao općenite smjernice za COI<sup>49</sup>. Ovaj pregled daje još jedan okvir za bolje razumijevanje COI sa stajališta urednika. Ova anketa o ESC NSCJ COI smjericama i zahtjevima za prijavljivanje potvrđuje da se časopisi s ovom temom suočavaju na slab i nejednak način. Potrebne su daljnje aktivnosti kako bi se povisila svijest o važnosti prijavljivanja COI te kako bi se promovirale smjernice za poboljšanje transparentnosti biomedicinskih istraživanja.

Received: 5<sup>th</sup> Jan 2012

\*Address for correspondence: Cardiovascular Institute, Clinico San Carlos University Hospital, Plaza de Cristo Rey. Ciudad Universitaria. Madrid. Spain.

Tel: +34 91 549 4082, Fax: +34 91 330 3289

Email: falf@hotmail.com

All authors of this review support the importance of disclosing potential COI when a scientific paper is submitted for consideration to any ESC NSCJ. Moreover, when in doubt it is better to err on the side of over-disclosure and let the editors make the decision. The ICMJE Uniform Disclosure Initiative represents a milestone in this regard and paves the way for further transparency in biomedical publishing<sup>11,12</sup>. Therefore, we encourage ESC NSCJ to progressively adapt their policies in order to be able to adhere to this editorial proposal. However, in this journey, some potential caveats should be carefully heeded. First, exhaustive disclosure of multiple, minor and vaguely related potential COI might 'dilute' the relevance of real major COI that most readers would be interested to know. Second, some relevant institutional COI are not openly disclosed to all corresponding researchers and, accordingly, these may be impossible to declare. Third, many major journals frequently allow senior international opinion leaders with clear (definitive and well-known) COI to systematically declare the absence of COI in their papers. Young scientists may perceive this as confusing and disturbing while others will regard this inconsistency as evidence that the whole process is completely hypocritical. Finally, major sociocultural differences among countries should be also taken into account. Most European doctors (including most editors in the byline of this article) frequently receive occasional travel grants from diverse pharmaceutical companies to attend medical society meetings and, up to now, these have not been systematically disclosed as potential COI. The situation, however, is quite different on the other side of the Atlantic where such practices have been considered inadequate or even misconduct for a number of years. In North America, direct support (including travel) of CME programmes by industry is prohibited while this practice is considered acceptable in most European countries<sup>19</sup>. NSCJ editors should be alerted to the need to deal with these vexing problems in their respective journals in line with local policies and practices<sup>48</sup>. Progressive steps should be taken to ensure a systematic approach to these COI-related editorial issues. However, commonsense and reason should prevail in order to achieve a balance between the pragmatic and utopian.

## Final remarks

Consumers of medical scholarship expect a reliable system of disclosure, in which journals and authors make disclosures appropriately and consistently. There is a stigma surrounding the reporting of COI that should be progressively overcome. The ESC has recently defined a general policy for COI<sup>49</sup>. This review provides another framework to better understand COI from an editorial perspective. This survey on ESC NSCJ COI policies and disclosure requirements confirms that this topic is poorly and not uniformly dealt with by journals. Further actions are required to increase awareness of the importance of COI disclosure and to promote policies aimed at enhancing transparency in biomedical research.

**Disclosures:** None of the editors authors of this paper had any potential conflict of interest that needs to be disclosed in relation to this manuscript.

**Acknowledgements:** We are grateful for the support and assistance of Iris Chapuis, Lone Kristoffersen, Isabelle Collin and Muriel Mioulet from the ESC National Cardiac Societies Relations Department at the Heart House.

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