Pouzdanost znanstvenih publikacija u biomedicini

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POUZDANOST ZNANSTVENIH PUBLIKACIJA U BIOMEDICINI

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Mentorica: prof. dr. sc. Ana Marušić

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„Vjerojatno ne postoji užasniji trenutak prosvjetljenja
od onoga u kojem otkrijete da je vaš otac čovjek – od ljudskog mesa.“
Frank Herbert: Dina

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2. POPIS OZNAKA I KRATICA

CC	bibliografska baza Thomson Reuters-a (engl. Current Contents)
CENTRAL	Cochrane registar istraživanja (engl. Cochrane Central Register of Controlled Trials)
CI	raspon pouzdanosti (engl. confidence interval)
CMJ	časopis Croatian Medical Journal
CROSBI	hrvatska bibliografska baza (engl. CROatian Scientific BIbliography)
DOAJ	zbirka znanstvenih i stručnih časopisa u otvorenom pristupu (engl. Directory of Open Access Journals)
EMBASE	bibliografksa baza biomedicinskih radova izdavačke kuće Elsevier (engl. Excerpta Medica dataBASE)
EQUATOR	Međunarodna inicijativa za uporabu izdavačkih smjernica u biomedicini (engl. Enhancing the QUAlity and Transparency Of health Research)
FDA	Agencija za kontrolu hrane i lijekova (engl. Food and Drug Administration)
HRČAK	Portal znanstvenih časopisa Republike Hrvatske
ICMJE	Međunarodni odbor urednika medicinskih časopisa (engl. International Committee of Medical Journal Editors)
IF	čimbenik odjeka (engl. impact factor)
IQR	interkvartilni raspon (engl. interquartile range)
MEDLINE	bibliografska baza američke Nacionalne medicinske knjižnice
ORCID	javni broj znanstvenika (engl. Open Researcher and Contributor IDentity)
PLoS	Javna znanstvena knjižnica (engl. Public Library of Science)
PRC	Međunarodnim kongresi o biomedicinskim publikacijama i postupcima recenzije (engl. International Congress on Peer Review and Biomedical Publication)
PubMed	pretraživač MEDLINE baze (engl. PUBlic MEDline)
SCOPUS	bibliografska baza izdavačke kuće Elsevier
SPSS	statistički paket za obradu podataka (engl. Statistical Package for the Social Sciences)
WoS	bibliografska baza Thomson Reuters kuće (engl. Web of Science)

3. PREGLED OBJEDINJENIH RADOVA

Ova doktorska disertacija temelji se na trima objedinjenim znanstvenim radovima:

1. Malički M, Jerončić A, Marušić M, Marušić A. Why do you think you should be the author on this manuscript? Analysis of open-ended responses of authors in a general medical journal. BMC Med Res Methodol. 2012;12:189.

   Indeksiran u CC-u, IF (za 2011.): 2,668

2. Malički M, von Elm E, Marušić A. Study design, publication outcome, and funding of research presented at the International Congresses on Peer Review and Biomedical Publication. JAMA. 2014;311:1065-1067.

   Indeksiran u CC-u, IF (za 2013.): 30,387

3. Malički M, Marušić A, OPEN Consortium. Is there a solution to publication bias? Researchers call for changes in dissemination of clinical research results. J Clin Epidemiol. 2014;67:1103-10.

   Indeksiran u CC-u, IF (za 2013.): 5,478

3.1. UVOD

„Pouzdamo se u Boga, svi ostali donesite podatke.“
William Edwards Deming

Znanost u svojoj težnji istini počiva na istraživanjima čiji bi se postupci ili rezultati trebali moći ponoviti ili potvrditi drugim istraživanjima.[1] Time se osigurava znanstvena objektivnost, naglašava odgovornost provođenja i objave istraživanja, te poziva na „napad sa svih strana“ i najmanjih detalja navedenih u znanstvenim publikacijama.[2]

3.1.1. Znanstvene publikacije

Prvi znanstveni časopis *Journal des Sçavans* izašao je u siječnju 1665. g. u Parizu, a drugi *Philosophical Transactions,* u ožujku iste godine u Londonu. Prvi medicinski znanstveni časopis *Medical Essays and Observations* izlazi 1731. u Edinburghu, te do kraja 19. stoljeća časopisi postaju glavni način komunikacije među znanstvenicima.[3] Prvi hrvatski medicinski časopis *Slovinski prvenci o naravi i zdravlju* izlazi 1860. u Beču,[4] a ubrzo nakon toga danas najprestižniji opći znanstveni časopisi *Nature* (1869.) i *Science* (1890.). U 20. stoljeću, razvojem računala, nastaju i prvi elektronički časopisi: *New horizons in adult education,* 1987., te 1990. *Postmodern culture*.[5] Nakon uspostave svjetske računalne mreže (engl. *World Wide Web*) 1994. godine, naglo se povećava broj elektroničkih časopisa, a mnogi tiskani časopisi počinju izlaziti i u elektroničkom obliku. *PubMed*, besplatni i javno dostupan pretraživač *MEDLINE* baze, pušten je u rad 1997.; 2003. osniva se *PLoS* (od engl. Public library of Science), 2004. *Scopus* i *Google Scholar*, te 2006. *Hrčak*, hrvatski portal znanstvenih i stručnih časopisa. Danas, 2015. godine, ukupno postoji više od 36 000 znanstvenih časopisa u svijetu, od kojih je trećina biomedicinskih, te više od 55 milijuna objavljenih znanstvenih radova.[6, 7]

Prema hrvatskoj bibliografskoj bazi CROSBI (engl. Croatian Scientific Bibliography), do 2015. g., hrvatski autori objavili su 143 672 znanstvena rada, od kojih je 20 478 (14,3%) biomedicinskih.[8] Od ukupno 376 hrvatskih znanstvenih časopisa indeksiranih u *Hrčku*, 127 indeksirano je i u bibliografskoj bazi *Scopus* (od toga 35 iz područja biomedicine), te 54 u *Web of Science* (WoS) bazi (13 iz područja biomedicine, tablica 1).[9]

Tablica 1. Hrvatski biomedicinski znanstveni časopisi indeksirani u bazi Web of Science.

Ime časopisa	**Čimbenik odjeka za 2014. g.**
Biochemia Medica	2,667
Croatian Medical Journal	1,563
Psychiatria Danubina	1,301
Arhiv za higijenu rada i toksikologiju	0,932
Food Technology and Biotechnology	0,920
Acta pharmaceutica	0,912
Chemical and Biochemical Engineering Quarterly	0,802
Croatica Chemica Acta	0,728
Acta Dermatovenerologica Croatica	0,431
Veterinarski arhiv	0,362
Acta Clinica Croatica	0,342
Signa Vitae	0,200
Periodicum biologorum	0,139

Izvorni znanstveni članci danas najčešće imaju ustaljenu strukturu: uvod, metode, rezultate i raspravu (IMRaD, od engl. introduction, methods, results and discussion), koja se razvila krajem 19. stoljeća, i potpuno prevladala biomedicinskim publikacijama 1980-tih.[10] Danas, ovisno o vrsti istraživanja, postoje i specifične smjernice za pisanje radova, koje pomažu i pri prikazu podataka potrebnih za njihovu procjenu, repliciranje ili metaanalizu.[11] Rukopis rada, napisan nakon provedenog istraživanja, obrade i interpretacije rezultata, znanstvenici najčešće šalju u časopis, i on biva podvrgnut uredničkom i recenzijskom postupku, od kojih potonji najčešće obuhvaća 2-3 nepristrana recenzenta.[12] Ovisno o ocjeni recenzenta i uredničkog odbora, rukopis se prihvaća za objavu, odbija, ili se traže ispravci i dodatna pojašnjenja. Naposljetku, nakon objave, rad postaje ili javno dostupan, ili dostupan na uvid, kupnju ili posudbu.

Učinkovitost recenzijskog postupka je upitna, i često mu se zamjera predugo trajanje (prosjek 15 tjedana, iako recenzenti u prosjeku potroše 3-6 sati na recenziju),[6, 13] prevelika skeptičnost prema inovativnim istraživanjima,[14] mala mogućnost otkrivanja prijevara ili propusta,[15] te činjenica da odbijanje rada često samo znači da će autori isti poslati u drugi ili n-ti časopis dok se on ipak ne objavi.[14] Unatoč tome, postupak recenzije ipak predstavlja prvu obranu znanstvene zajednice od nekvalitetnih istraživanja ili rukopisa u čiji je nastanak uloženo premalo truda ili znanja.[16] Pridonosi kvaliteti i diskursu među znanstvenicima, i jedan je od uvjeta indeksiranja časopisa u najpoznatije bibliografske baze.[17, 18]

U ovoj disertaciji pojam pouzdanosti ne odnosi se na postupak recenzije, već na informacije u publikacijama ili sažetcima, njihov izostanak te mogućnost njihova pronalaska. U narednim poglavljima slijedi prikaz svih (ne)pouzdanosti znanstvenih publikacija.

3.1.2. Pouzdanost autorstva

Autorstvo znanstveniku donosi prestiž, predstavlja njegovo postignuće, uvjet je za akademsko napredovanje, te omogućuje usporedbu s drugim znanstvenicima i natjecanje za financiranje daljnjih istraživanja.[19] Radovi objavljeni do 1920. imali su skoro isključivo samo jednog autora; da bi 1981. 66%, te 2011. 89 % svih objavljenih radova imalo više od jednog autora[20] (trenutno u *MEDLINE* bazi najveći broj autora na jednom članku iznosi 3172).[21] Utvrđivanje zasluga, tj. udjela obavljenog posla ili sposobnosti znanstvenika u radovima s tako velikim brojem autora predstavlja problem, te se u biomedicini najviše cijeni prvo ime na popisu autora, ili zadnje (koje najčešće predstavlja mentora ili voditelja istraživanja), tj. ime navedeno za kontakt osobu, tzv. dopisni autor (što najčešće opet biva ili prvi ili zadnji autor).[19] Zbog toga je, u zadnjem desetljeću, naglo porastao i broj dvostrukog prvog autorstva (engl. equal contribution or shared first authorship).[22] Iako je Međunarodni odbor urednika medicinskih časopisa (ICMJE prema engl. International Committee of Medical Journal Editors) prve kriterije autorstva izdao 1978.,[23] te njihovu zadnju izmjenu 2013. g.,[24] prethodna istraživanja pokazala su da se velik broj časopisa njih ne pridržava, te da biomedicinu obilježavaju prakse poklanjanja autorstva (engl. guest or honorary authorship),[25] prisilnog dopisivanja, autorskog kartela,[26] nepriznavanja ili oduzimanja zasluženog autorstva (engl. ghost authorship),[27] nepriznavanja angažiranja profesionalnih pisaca (engl. ghost writing),[28] te manipulacije redoslijedom autora.[29] Uz to su znanstvenici, ponekad i iz zabave, kao autora na svojim radovima navodili i kućne ljubimce (npr. psa,[30] mačku,[31] zamorca[32]), izmišljali imena,[33] upotrebljavali pseudonime,[34] ili proste riječi.[35] Većina spoznaja zlouporabe autorstva proistekla je iz razotkrivenih pojedinačnih slučajeva, a učestalosti takvih pojava iz upitnika kojim su znanstvenici pitani jesu li se susreli s nekim od takvih radnji. Prvi sustavni pregled istraživanja autorstva objavila je sa suradnicama moja mentorica, profesorica Ana Marušić, te pokazala da je 23% (95% CI 18% do 28%) znanstvenika u Americi ili Engleskoj iskusilo ili čulo za zlouporabe autorstva, te 55% (95% CI 45% do 64%) izvan tih zemalja.[19] Osim osvješćivanja o temi i objave smjernica i savjeta (prvenstveno dogovora oko autorstva na samom početku istraživanja),[36] dosad ne postoje istraživanja učinkovitih metoda smanjenja učestalosti zlouporabe autorstva.

Nadalje, iako mogu imati veliku ekonomsku cijenu te posljedice na nezadovoljstvo znanstvenika, same manipulacije autorstva se često smatraju manjim zlom od manipulacija ili modifikacija podataka na osnovi kojih se donose odluke o zdravlju ljudi.[37]

3.1.3. Pouzdanost rezultata i analize podataka

Izmišljanje ili promjenu podataka priznalo je, prema metaanalizi iz 2014. g., 1,7% (95% CI 1,2% do 2,4%) istraživača, dok je 30% (95% CI 17% do 46%) izjavilo da znaju za kolege koji su to počinili.[38] U trenutnim bazama, međutim, samo 0,02% svih radova povučeno je zbog takvih radnji.[39] Glavnim uzrokom manipulacije podatcima najčešće se smatra klima „publiciraj ili nestani“ (engl. publish or perish), zbog koje mladi, ali i iskusni istraživači pokleknu pod pritiskom usporedbe s kolegama.[40] Takve radnje, mogu imati negativne posljedice na ljudsko zdravlje, narušavaju povjerenje ispitanika koji pristanu sudjelovati u istraživanjima,[41]te mogu imati značajne novčane posljedice. U Sjedinjenim Američkim Državama prosječno je na jedno istraživanje, za koje su poslije dokazane nečasne radnje, bilo potrošeno 250 000 dolara.[37] Nakon što se manipulacije otkriju, najčešće posljedice su suspenzije znanstvenika, novčane kazne, rad pod strogim nadzorom ili nemogućnost prijave za financiranje istraživanja tijekom određenog razdoblja. Međutim, prestanak karijere znanstvenika je rijedak, i dio istraživača uspije održati istu produktivnost ili čak povećati broj objavljenih radova.[37] Dijelu istraživača sam čin istrage i mogućnost kazne ipak predstavlja preveliki pritisak i grižnju savjesti, te su zabilježeni i slučajevi oduzimanja vlastitoga života.[42]

Kada u pitanju nisu nečasne radnje, već slučajne pogrješke ili previdi, ispravci netočnih podataka se objave za čak 4% svih objavljenih publikacija, i u 24% takvih slučajeva dolazi do drastične promjene rezultata i zaključaka istraživanja.[43] Uz to, zbog današnjeg načina publiciranja i indeksiranja radova, sitnije pogrješke, poput onih pravopisnih, najčešće se i ne poprave. Nadalje, velik broj objavljenih radova nije moguće reproducirati,[44] bilo zbog nedovoljno jasnih i detaljnih opisa istraživanja, ili zbog selektivnog publiciranja rezultata, te nekritičnog uzorkovanja.[16] Uz to, prikupljeni „sirovi“ podatci (engl. raw data) često ne budu objavljeni, niti dostupni nakon traženja od autora, bilo da se radi o istraživanjima financiranim od strane industrije ili onih provedenih bez financiranja tj. čiji su autori sveučilišni profesori ili drugi znanstvenici.[45, 46] Time ostali znanstvenici najčešće ne mogu provjeriti ispravnost obrade ili prikupljanja podataka.[47]

Današnju biomedicinu također krasi i nepovezanost statističke i kliničke značajnosti,[48] selektivan izbor praćenih ili objavljenih ishoda,[49, 50] lažno predstavljanje tuđih radova ili ideja kao svojih, te praksa dvostrukog publiciranja zbog povećanja vlastitoga prestiža.[39] I dok su te i slične aktivnosti sve brojnije, nema dokaza da je taj porast posljedica većeg nepoštenja, već je moguće da su današnje metode otkrivanja napredovale zbog sve veće povezanosti međunarodnih i lokalnih medija, te bibliografskih baza.[51]

3.1.4. Pouzdanost referencija

„Koji grozan čas, kada prvi puta spoznamo potrebu skrivanja nečega.“
Frank Herbert: Odredište: Bezdan

Referencije su način obavještavanja čitatelja o izvorima iz kojih su preuzete informacije, te služe odavanju zasluga ili divljenja i unaprjeđenju znanstvenoga diskursa. U znanosti se koriste i za procjenu odjeka i utjecaja časopisa, te kao mjera inovativnosti i produktivnosti znanstvenika, sveučilišta i istraživačkih centara.[52] Iako je u većini časopisa odabir referencija isključivo pravo i odgovornost autora, neki časopisi ograničavaju broj referencija koje autori smiju upotrijebiti, ili izvore koje smiju koristiti.[53] Zbog velikog utjecaja koje referencije imaju na prestiž pojedinih autora i časopisa, sve više se otkrivaju i slučajevi njihovih manipulacija.[54] Izdavačka kuća Thomson Reuters zbog sustavnih manipulacija referencija 2011. g. kaznila je 34 časopisa, 2012. 51 časopis, 2013. 66 časopisa i 2014. 38 časopisa, te im odbila izdati čimbenik odjeka.[55, 56] Uz to, zbog još uvijek učestalog ručnog pisanja referencija, autori često krivo navode imena autora, volumen ili stranice časopisa, te se medijan pogrješaka pisanja referencija u literaturi procjenjuje na 38%, a neispravnog citiranja izjava na 20%.[57] Nadalje, praksa učestalosti neprovjeravanja izvora informacija, već njihovo preuzimanje od drugih autora (pogotovo kada se radi o izvorima preuzetih ih knjiga) pojavljuje se u čak 70-90% radova.[58]

Uz navedeno, kao i za autorstvo, postoje i pritisci od starijih kolega, recenzenta, urednika časopisa ili članova povjerenstva za ocjenu diplomskih ili doktorskih disertacija, za uvrštavanjem određenih referencija u pojedini rad ili disertaciju.[59, 60] Osim toga, zbog velikog broja naknadno objavljenih ispravaka, pa čak i slučajeva povlačenja članaka, te slabe obilježenosti takvih promjena, autori često citiraju članke ili podatke koji više ne vrijede ili za koje je dokazano da su izmišljeni.[61] Nadalje, zbog želje za većim odjekom, neki članci, poglavito smjernice, deklaracije i sl., publiciraju se u više časopisa odjednom (engl. simultaneous or concurrent publication), ali se često ne odredi „originalni“ izvor koji bi autori trebali citirati, te postoje i prakse sugeriranja autorima da citiraju upravo onu verziju koja je objavljena u časopisu u koji znanstvenici šalju svoj rad.[53, 62]

3.1.5. Pouzdanost objave, pohrane i pronalaska publikacija

Iako su časopisi glavni izvor informacija znanstvenicima, praksa njihova čitanja se u zadnjih dva desetljeća, razvojem računala, uvelike promijenila. Danas, znanstvenici većinom ne čitaju cijele brojeve časopisa, već se ili služe pretraživačima bibliografskih baza da pronađu one publikacije koje pišu o temi koja ih zanima,[63] ili koriste društvene mreže za njihovu razmjenu.[64] Današnja im tehnologija također omogućava odabir ključnih riječi te primanje obavijesti (engl. auto alert) putem e-pošte kada se objavi svaka nova publikacija na određenu temu.[65] Međutim, verzija objavljena u časopisu, ona u repozitoriju podataka ili bibliografskoj bazi, tj. na mrežnim stranicama izdavača ili autora, nije uvijek ista, i često nema jasno označenih promjena koje su se dogodile nakon objave rada.[66, 67] Nadalje, pogrješke u označavanju radova u bibliografskim bazama mogu uzrokovati njihovo neprikazivanje tijekom pretraga. [68, 69] Zbog toga, te razlika u pokrivenosti područja i časopisa, pri izradi sustavnih pregleda i metaanaliza, današnje detaljne strategije pretraživanja uključuju pretragu nekoliko bibliografskih baza (u biomedicini najčešće MEDLINE, EMBASE, CENTRAL, DOAJ).[70] Ali i unatoč tome, još uvijek veliki problem predstavljaju neobjavljeni rezultati ili sažetci istraživanja, tzv. siva literatura (engl. grey literature) koja često nije zastupljena u bibliografskim bazama; i čiji je pronalazak otežan, a učinak na rezultate i zaključke ponekad vrlo značajan.[71] Istraživanja su također pokazala da znanstvenici u prosjeku u 50% slučajeva ne objave rezultate svojih istraživanja, pogotovo kada rezultati nisu statistički značajni,[49, 72] te da se uvelike razlikuju mjere ishoda koje su planirane u istraživanju od onih koje su naknadno objavljenje, tj. postupci opisani u protokolima istraživanja od stvarne provedbe istraživanja.[50] Analiza 57 kliničkih istraživanja, za koje je američka Agencija za hranu i lijekove (FDA, prema engl. Food and Drug administration) pronašla manipulacije podatcima za vrijeme provođenja istraživanja, ili nepoštivanja kriterija uključenja i isključenja, tj. zasljepljivanja pacijenata, pokazala je da su samo u 3 primjera izvješća inspektora o takvim radnjama bila spomenuta u publiciranim radovima, te da ne postoje mehanizmi kojima FDA obavještava javnost ili urednike o svojim nalazima, kao ni mehanizmi kojima se traži od autora da se takve otkrivene radnje prijave tijekom slanja rukopisa za objavu.[73] Nadalje, ostala popratna dokumentacija o biomedicinskim istraživanjima (financijska izvješća, obavijesni pristanci, kodovi analize podataka) najčešće nije dostupna na uvid, što dodatno povećava sumnju u pouzdanost onoga što je objavljeno. U 2010., čak 58% građana Europe izjavilo je da ne mogu vjerovati izjavama istraživača o kontroverznim pitanjima u svijetu, jer smatraju da previše ovise o novcu ulagača.[74]

3.1.6. Ciljevi objedinjenih radova

Potaknuti prethodno navedenim, glavni ciljevi naših istraživanja bili su proširiti saznanja o (ne)pouzdanosti biomedicinskih publikacija, poglavito autorstva i cjelovitosti objave istraživanja. Pošto su prethodna istraživanja pokazala da obrasci koje časopisi koriste za deklariranje i potvrdu autorstva nisu pouzdan način njegova dokazivanja,[75, 76] te da autorstvo nije samo normativno pitanje koje se može odrediti dogovorenim kriterijima, već i vrlo osobno stajalište, osnovano na važnosti i vrijednosti doprinosa u pojedinom istraživanju,[77] u prvom istraživanju pretpostavili smo da će se doprinosi autora zamoljenih da vlastitim riječima opišu zašto zaslužuju autorstvo, razlikovati od navedenih kriterija za koje časopisi najčešće zahtijevaju od autora da ih prilikom slanja svojih rukopisa potpisom potvrde.

Cilj drugog istraživanja bio je analizirati pouzdanost autorstva i cjelovitosti objave istraživanja, te analizirati razvoj područja recenziranja i objavljivanja znanstvenih radova u biomedicini, i to na primjeru istraživanja predstavljenih na međunarodnim kongresima o biomedicinskim publikacijama i postupcima recenzije (PRC, prema engl. International Congress on Peer Review and Biomedical Publication). Kongresi PRC osnovani su s idejom podvrgavanja recenzijskih postupaka onim provjerama kojima urednici i recenzenti podvrgavaju znanstvenike prilikom recenzije njihovih radova, i od 1989. g. održavaju se svake četiri godine. Budući da na tim kongresima svoja istraživanja prezentiraju urednici najprestižnijih medicinskih časopisa, istraživači uključeni u izradu smjernica za pisanje članaka (engl. reporting guidelines), te znanstvenici najsvjesniji posljedica neobjavljivanja radova, htjeli smo utvrditi drže li se oni onoga što promiču; objavljuju li u cijelosti sva svoja prezentirana istraživanja, te postoje li promjene broja ili redoslijeda autora između njihovih prijavljenih sažetaka i naknadno objavljenih istraživanja.

Cilj trećega istraživanja bio je na većem uzorku utvrditi učestalost izostanka objave ili selektivne objave istraživanja, te ustanoviti mišljenja autora kliničkih ispitivanja i Cochrane sustavnih pregleda o razlozima i mogućoj prevenciji tih pojava, kao i njihova mišljenja o cjelokupnom procesu registracije i objave istraživanja koji obilježava današnju biomedicinu.

3.2. PREGLED METODOLOGIJE OBJEDINJENIH RADOVA

3.2.1. Istraživanje pouzdanosti autorstva

U istraživanje smo uključili sve autore (n=1425) koji su od ožujka 2009. do srpnja 2010. bili poslali svoje rukopise (n=345) časopisu *Croatian Medical Journal* (CMJ). Prilikom slanja rukopisa autori su bili zamoljeni da ispune obrazac koji je sadržavao kontakt informacije, izjavu o sukobu interesa i autorskom pravu, te sljedeću definiciju autorstva: „Autor je ona osoba koja je napravila značajni doprinos u poslanom istraživanju.“ Nakon navedene definicije, od autora je bilo traženo da opišu svoj doprinos istraživanju tako da odgovore na sljedeće pitanje: „Zašto smatrate da zaslužujete autorstvo na ovom radu?“ Budući da je potpuna obaviještenost o cilju istraživanja mogla utjecati na odgovore ispitanika, u obrascu se od ispitanika tražio općeniti pristanak na sudjelovanje u istraživanju uredničkog i recenzentskog postupka, bez navođenja detalja samog istraživanja. Istraživanje je bilo dobrovoljno i odluka o sudjelovanju nije utjecala na prihvaćanje ili odbijanje rukopisa. Samo istraživanje odobrilo je etičko povjerenstvo Medicinskoga fakulteta Sveučilišta u Zagrebu (broj 108-1080314-0140). Pojedinačni obrasci svakog autora rukopisa poslani su putem e-pošte dopisnom autoru, koji je zamoljen da ih proslijedi svojim koautorima. Ispunjene i potpisane obrasce koautori su vraćali individualno, ili preko dopisnog autora. Odgovori autora prepisani su u Excel-bazu, zajedno s rednim brojem autora u rukopisu i šifrom rukopisa, te uspoređeni s kriterijima ICMJE prema kojima autori moraju značajno pridonijeti svim trima sljedećim stavkama: 1) konceptu i ustroju istraživanja, ili prikupljanju podataka, ili analizi i interpretaciji podataka; 2) pisanju članka ili ispravaka presudnih za intelektualni sadržaj članka; 3) odobrenju zadnje verzije članka za objavu. Odgovore autora koji nisu sadržavali navedene kriterije posebno smo klasificirali.

Razlike u kategorijama navedenih kriterija prema redoslijedu autorstva usporedili smo χ^2-testom, a razlike u broju navedenih kontribucija prema broju autora na članku, zbog odstupanja raspodjele podataka od normalne, Mann-Whitney U testom. Medijane smo popratili s 95% intervalima pouzdanosti (CI, prema engl. confidence interval) i interkvartilnim rasponima (IQR), te rezultate potvrdili računalnom simulacijom uzorkovanja (engl. bootstraping) s 2000 ponavljanja. Razina značajnosti postavljena je na 0,05 za sve statističke testove. Podatci su analizirani verzijom 19 statističkog paketa SPSS (prema engl. Statistical Package for the Social Sciences 19,0; Chicago, Illinois, SAD).

3.2.2. Istraživanje pouzdanosti autorstva i cjelovite objave istraživanja

Uspostavili smo retrospektivnu kohortu svih predstavljenih istraživanja na 7 kongresa PRC od 1989. do 2013. godine. Popis i sažetke istraživanja pronašli smo na stranicama kongresa i u objavljenim knjigama sažetaka. Koristeći imena i prezimena autora navedenih na sažetcima i plakatima (posterima) za prvih 6 kongresa, pretražili smo mrežne stranice kongresa, te WoS i MEDLINE (putem pretraživača PubMed) za sve radove objavljene do kolovoza 2013. godine. Pronađene radove usporedili smo s podatcima prezentiranim na kongresima, i za one radove za koje smo se suglasili da predstavljaju cjelovitu objavu istraživanja, izvadili podatke o broju i redoslijedu autora, vrsti istraživanja, financiranju, dostupnosti u slobodnom pristupu (engl. open access), te citiranosti u bazi WoS. Također, izmjerili smo vrijeme (u mjesecima) od prezentiranja rada na kongresu do njegove objave u znanstvenom časopisu, te utvrdili je li došlo do promjene broja ili redoslijeda autora između sažetka ili postera predstavljenih na kongresu i istraživanja objavljenih u znanstvenom časopisu. Vrstu istraživanja neovisno su klasificirali Ana Marušić i Erik von Elm, i to sa zadovoljavajućom suglasnošću (vrijednost Cohenovog koeficijenta kappa, $\kappa = 0{,}78$). Prvobitne razlike u klasificiranju istraživanja dogovorno su usuglašene.

Podatke smo prikazali s popratnim 95% rasponima pouzdanosti, a promjene vrste istraživanja s obzirom na godinu održavanja kongresa analizirali χ^2_i testom za trend. Razlike u broju autora s obzirom na godinu održavanja kongresa usporedili smo Kruskal–Wallis testom zbog raspodjele podataka koja je odstupala od normalne. Razina značajnosti postavljena je na 0,05 za sve statističke testove. Svi podatci obrađeni su s pomoću statističkog paketa MedCalc (MedCalc Software verzija 12,0, Ostend, Belgija).

3.2.3. Istraživanje učestalosti i načina prevencije neobjavljivanja istraživanja

Na temelju prethodnih istraživanja o selektivnoj objavi istraživanja,[78] razvili smo upitnik o učestalosti i načinima prevencije otklona u publiciranju. Upitnik smo zatim testirali i prepravili prema komentarima osam iskusnih istraživača, te postavili na mrežne stranice projekta OPEN (engl. Overcome failure to Publish nEgative fiNdings, www.open-project.eu). Ujedno smo ga, s pomoću platforme SurveyMonkey, poslali na 1299 e-adresa autora koji su od 2010. do 2012. objavili klinička ispitivanja u najprestižnijim biomedicinskim časopisima ili u nacionalnim europskim časopisima, te onima koji su u istom razdoblju objavili Cochrane sustavni pregled. Od ekstrahiranih e-adresa 35 je bilo nevažećih, a 45 je izabralo opciju neprimanja upitnika poslanih platformom SurveyMonkey. Ispitanicima nije ponuđena nikakva nagrada za sudjelovanje u istraživanju, osim informacija o konačnim rezultatima.

Odgovore na pitanja s ponuđenim kategorijama odgovora prikazali smo za svaku skupinu pojedinačno, te postotke izračunali s obzirom na broj ispitanika koji je odgovorio na pojedino pitanje (ispitanici su mogli slobodno preskočiti svako pitanje na koje nisu željeli dati odgovor). Upitnik je ujedno sadržavao 7 pitanja s odgovorima otvorenoga tipa, u kojima su ispitanici mogli obrazložiti svoje odgovore, komentirati trenutno stanje u znanosti i znanstvenom izdavaštvu, te predložiti metode prevencije i smanjenja otklona u publiciranju. Zbog toga što su se odgovori ispitanika na jedno otvoreno pitanje često nadovezivali na ono prethodno, i zbog istog broja odgovora na otvorena pitanja između ispitanika sa i bez iskustva provođenja kliničkih istraživanja, tj. sudjelovanja u izradi sustavnih pregleda (P vrijednosti 0,139 do 0,938, χ^2 testovi), sve odgovore otvorenog tipa analizirali smo prof. Ana Marušić i ja kao da pripadaju jednoj skupini ispitanika, te smo ih, svatko ponaosob, razvrstali u tri kategorije: 1) razlozi postojanja otklona u publiciranju; 2) važnost otklona u publiciranju; 3) načini smanjenja i prevencije otklona u publiciranju.

Nadalje, 12. listopada 2012., za vrijeme kongresa EQUATOR (engl. Enhancing the QUAlity and Transparency Of health Research) koji se održavao u Freiburgu, u Njemačkoj, organizirali smo fokus-skupinu o otklonu u publiciranju. Sudionike fokus-skupine prikupili smo javnim pozivom za vrijeme plenarnog predavanja, te širenjem informacija o fokus-skupini za vrijeme stanki između radionica i predavanja.

Na početku fokus-skupine, sudionike smo zamolili da ispune anonimni upitnik koji se sastajao od sociodemografskih podataka i pitanja o iskustvu provođenja kliničkih istraživanja. Nakon kratkog uvoda, sudionicima smo postavili sljedeća tri pitanja: 1) *Koji su mogući razlozi neobjavljivanja istraživanja?;* 2) *Koji su načini identifikacije i prevencije otklona u publiciranju?*; 3) *Koji su vaši stavovi i razmišljanja o javnoj dostupnosti registra istraživanja, rezultata istraživanja, doktorskih disertacija i prijava istraživanja etičkom povjerenstvu?* Drugo i treće pitanje postavljeno je tek kada su ispitanici završili s nadopunjavanjem odgovora sudionika, tj. kada su zaokružili svoja razmišljanja o prethodnom pitanju. Sve odgovore snimili smo diktafonom i pretipkali u bazu Excel, te ih analizirali, primijenivši isti postupak kao i za otvorena pitanja poslanog upitnika. Snimku fokus-skupine pohranili smo na računalo Medicinskoga fakulteta u Splitu, gdje je ona dostupna drugim istraživačima, uz prethodno kontaktiranje prof. Ane Marušić ili mene.

3.3. PREGLED REZULTATA OBJEDINJENIH RADOVA

3.3.1. Rad 1. Zašto smatrate da zaslužujete autorstvo na ovom radu?

Ukupno je 1282 (90%) autora svojim riječima opisalo zašto zaslužuju autorstvo na rukopisu (n=335) koji su poslali u CMJ. Dodatnih 140 autora (9,8%) potpisalo je pristanak na sudjelovanje u istraživanju, ali nije odgovorilo na navedeno pitanje; 1 odgovor bio je nečitljiv, a dva odgovora odnosila su se na privitke koji nisu bili dostupni. Medijan broja autora na članku bio je 4 (IQR 3 do 6), a medijan broja navedenih razloga zasluge autorstva 2 (IQR 2 do 3). Razlozi 1116 (87%) autora bili su među onima opisanim kriterijima ICMJE, ali samo je 177 (16%) autora navelo sva tri potrebna kriterija; 474 (42%) dva od tri kriterija, te 465 (42%) samo jedan kriterij i to najčešće prvi (tablica 2).

Tablica 2. Broj (%) autora (n=1116) čiji su se odgovori podudarali s kriterijima autorstva Međunarodnog odbora urednika medicinskih časopisa (ICMJE)

Zadovoljen kriterij	Broj (%) autora*
Sva 3 kriterija	174 (15,6)
Kriterij 1 i 2 (ali ne i 3)	431 (38,6)
Kriterij 1 i 3 (ali ne i 2)	26 (2,3)
Kriterij 2 i 3 (ali ne i 1)	17 (1,5)
Samo kriterij 1:	355 (31,8)
koncept/ideja	12 (3,4)
ustroj	13 (3,7)
prikupljanje podataka	161 (45,3)
analiza podataka	24 (6,8)
interpretacija podataka	9 (2,5)
kombinacija navedenih kriterija	136 (38,3)
Samo kriterij 2:	105 (9,4)
pisanje rukopisa	45 (42,8)
ispravljanje rukopisa	49 (46,7)
pisanje i ispravljanje rukopisa	11 (10,5)
Samo kriterij 3	5 (0,5)
Odgovor: „Zato jer zadovoljavam kriterije ICMJE”	3 (0,3)

*Postotci pojedinog kriterija odnose se na udio unutar samog kriterija.

Izrazi koje su autori naveli pri opisu razloga bili su jako slični onima navedenim u opisu kriterija: 53% navelo je prikupljanje podataka (engl. data collection) te 98% ustroj studije (engl. study design). Autori čiji razlozi nisu odgovarali kriterijima ICMJE (n=166, 13%) najčešće su napisali da su jako pridonijeli istraživanju (94 od 166 autora, 56%, tablica 3).

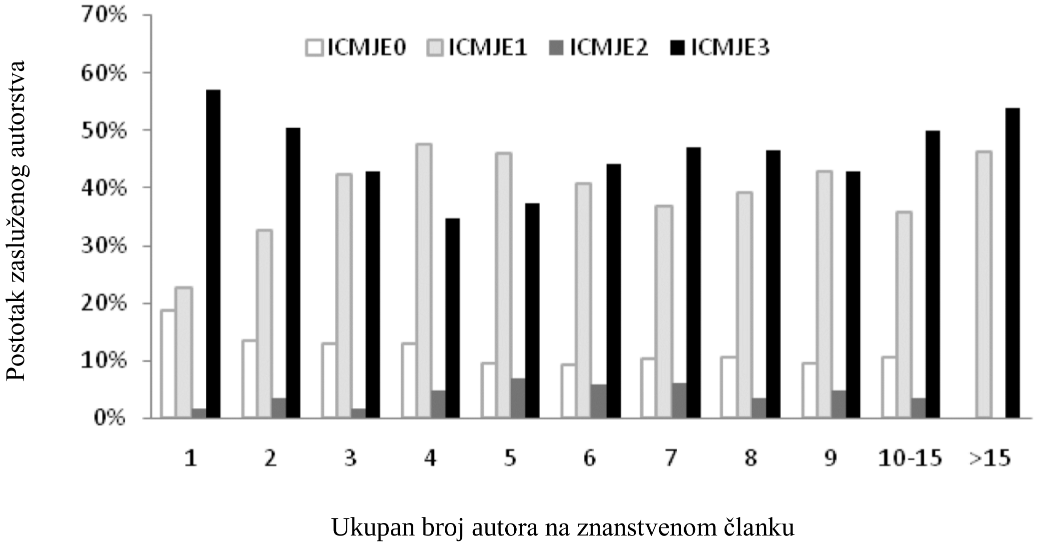
Tablica 3. Broj (%) autora (n=166) čiji se odgovori nisu podudarali s kriterijima autorstva Međunarodnog odbora urednika medicinskih časopisa (ICMJE)

Odgovor (razlog zasluge autorstva)	**Broj (%) autora (n=166)**
Zbog jakog doprinosa istraživanju	94 (56,6)
Da	9 (5,4)
Ovaj slučaj je zanimljiv	8 (4,8)
Mi radimo skupa	8 (4,8)
Ja sam specijalist/radim na odjelu za…	7 (4,2)
Zanima me ova tema	6 (3,6)
Ovo je moja disertacija	3 (1,8)
Jer su ovo važni rezultati	3 (1,8)
Pretražio sam literaturu	3 (1,8)
Jer preuzimam odgovornost za studiju	3 (1,8)
Jer sam šef odjela/instituta	3 (1,8)
Jer sam mentor	2 (1,2)
Jer sam koordinirao istraživanje	2 (1,2)
Pružio sam administrativnu/logističku potporu	2 (1,2)
Imam druge radove na istu temu kao biostatističar	2 (1,2)
Potpis autora kao odgovor	2 (1,2)
Jer sam pružio tehničku potporu	1 (0,6)
Jer sam preveo rukopis	1 (0,6)
Jer sam preveo rukopis i pretražio literaturu	1 (0,6)
Ovo je prvo istraživanje ovoga tipa	1 (0,6)
Na temelju prakse i kliničkog iskustva koje je dovelo do istraživanja	1 (0,6)
Jer želim prikazati način liječenja u ovoj ustanovi	1 (0,6)
Jer sam istraživač na projektu sa sličnim problemima	1 (0,6)
Jer smatram da je ovo najbolje liječenje za opisano stanje	1 (0,6)
Jer sam znanstveni savjetnik na ovom projektu	1 (0,6)

Razloge koji se nisu podudarali s kriterijima ICMJE navelo je i 98 (9%) autora čiji se ostatak odgovora podudarao s kriterijima ICMJE. Oni su, međutim, najčešće uz kriterij 1 ili 2 naveli kao razlog i pretragu literature (51 od 98 autora, 52%).

Većinom (n=869, 68%) je struktura odgovora na postavljeno pitanje bila u obliku pune ili djelomične rečenice koja je počinjala s „Ja…“ (n=655, 55%), s „Jer….“ (n=108, 8%), te s “Moj/a uloga/doprinos…” (n=15, 2%) slučajeva. Skoro trećina 401 (31%) odgovora bila je u obliku nizanja jednog ili više razloga.

Postotak autora čiji se razlozi nisu podudarali s kriterijima ICMJE bio je manji s većim brojem autora na radu i s redoslijednim mjestom bližim prvom autoru članka (slika 1).



Slika 1. Podudaranje odgovora autora s kriterijima autorstva Međunarodnog odbora urednika medicinskih časopisa (ICMJE): ICMJE 0 – autori čiji se odgovori ne podudaraju s kriterijima, ICMJE 1, 2 ili 3 – autori čiji se odgovori podudaraju s 1, 2 ili sva tri kriterija ICMJE.

Na radovima sa samo jednim autorom najčešće je odgovor sadržavao sva tri kriterija ICMJE (12 od 29, 41%). Samo jedan kriterij navelo je 8 (28%) autora, a razloge koji se nisu podudarali s kriterijima ICMJE 9 (31%) autora (najčešće značajan doprinos ili područje rada). Autori na radu s više od 8 autora naveli su više razloga za autorstvo od onih s 8 ili manje autora na radu (Mann Whitney U test, *P*=0,001).

3.3.2. Rad 2. Ustroj, cjelovita objava i financiranje istraživanja na PRC kongresima

U našem drugom istraživanju, od 504 prezentirana istraživanja tijekom 6 kongresa PRC, održanih od 1989. do 2009., 383 (76%) su bila opservacijska istraživanja, 81 (16%) pokusna istraživanja, te 40 (8%) mišljenja autora. Tijekom vremena smanjio se broj prezentiranih mišljenja autora (χ^2_1=47,3, P<0,001), a povećao broj kohortnih istraživanja (χ^2_1=10,7, P=0,002) i studija izvedivosti (χ^2_1=11,3, P<0,001). Medijan broja autora na istraživanju povećao se s 1 (95% CI, 1-1) od prvog kongresa 1989. na 4 (95% CI, 4-5) na posljednjem kongresu (Kruskal-Wallis test, P<0,001). Do kolovoza 2013., 305 (61%) prezentiranih istraživanja bilo je u cijelosti objavljeno (tablica 4), u obliku 294 znanstvenih članka (u 11 slučajeva 2 prezentirana istraživanja objedinjena su u jedan objavljeni rad).

Tablica 4. Ustroj i postotak cjelovite objave istraživanja predstavljenih na Međunarodnim kongresima o biomedicinskim publikacijama i postupcima u razdoblju od 1989. do 2009.

Ustroj istraživanja	Prezentirana istraživanja Br. (% stupca)	Objavljeni Br. (% reda)
Opservacijska istraživanja:	383 (76,0)	239 (62,4)
Presječna istraživanja	238 (47,2)	149 (62,6)
Kohortna istraživanja	25 (5,0)	13 (52,0)
Istraživanja slučajeva i parova	5 (1,0)	2 (40,0)
Istraživanja ponovljenih mjerenja	19 (3,8)	14 (73,7)
Sustavni pregledi	17 (3,4)	13 (76,5)
Kvalitativna istraživanja	10 (2,0)	5 (50,0)
Druga opservacijska istraživanja (npr. ne-usporedna istraživanja)	69 (13,7)	43 (62,3)
Pokusna istraživanja:	81 (16,0)	47 (58,0)
Randomizirani pokusi	27 (5,3)	22 (81,5)
Nerandomizirani pokusi	25 (5,0)	11 (44,0)
Studije izvedivosti/pilot istraživanja	29 (5,7)	14 (48,3)
Mišljenja autora	40 (8,0)	19 (47,5)
Ukupno	504 (100,0)	305 (61,0)

Većina istraživanja 114 (38%) bila je objavljena u časopisu *Journal of American Medical Association*, koji je za prva 4 kongresa izdao tematski broj posvećen kongresu; 21 (7%) u časopisu *British Medical Journal*, 12 (4%) u časopisu *Annals of Emergency Medicine*, 8 (3%) u časopisu *Journal of Clinical Epidemiology*, te 8 (3%) u časopisu *PLoS ONE*. Sto članaka (34%) bilo je dostupno u slobodnom pristupu. Medijan vremena od prezentacije do objave istraživanja bio je 14 mjeseci (95% CI, 12-16). Redoslijed ili broj autora od prezentacije do objavljenog članka bio je istovjetan u 166 (56%) slučajeva, 83 (28%) istraživanja imala su promjene broja autora, a 45 (15%) njihova redoslijeda. Od objavljenih istraživanja, 284 (97%) su bila indeksirana u WoS bazi, od kojih je 265 (93%) imalo minimalno 1 citat, s medijanom od 20 (95% CI, 17-27). Tri najcitiranija istraživanja imala su više od 500 citata: 1798 – smjernice za objavu dijagnostičkih istraživanja,[79] 1016 – metodologija pronalaska istraživanja za sustavne preglede,[80] te 547 citata – istraživanje otklona u publiciranju (tablica 5).[81]

Tablica 5. Financiranje i citiranost istraživanja predstavljenih na Međunarodnim kongresima o biomedicinskim publikacijama i postupcima u razdoblju od 1989. do 2009.

			Citiranost prema WoS bazi	
Kongres	**Br. istraživanja**	**Financiranost***	**Ukupno za kongres**	**Medijan po članku (95% CI)**
Chicago ‘89	45	7	1955	42 (33 do 87)
Chicago ‘93	56	8	3136	32 (18 do 49)
Prague ‘97	93	14	2827	41 (29 do 54)
Barcelona ‘01	106	21	2501	22 (15 do 34)
Chicago ‘05	93	32	1859	18 (11 do 27)
Vancouver ‘09	111	26	633	6 (3 do 8)

*Podatci o financiranju istraživanja prikupljeni su iz objavljenih članka istraživanja; χ^2_1 za trend=15,2, P<0,001.

Financiranje je bilo navedeno za 106 (36%) objavljenih istraživanja. Najčešći izvori financiranja bili su državni/javni izvori (n=47, 44%), privatni izvori ili zaklade (n=25, 24%) te vlastito financiranje odnosno plaće (n=13, 13%). Ostali izvori financiranja bili su: časopisi ili izdavačke kuće (n=10, 9%), sveučilišta (n=9, 8%), industrija (n=2, 2%), te višestruki izvori (n=1, 1%).

3.3.3. Rad 3. Postoji li rješenje za otklon u publiciranju?

U našem trećem istraživanju dobili smo ukupno 182 odgovora: 8% odgovora (33 od 441) od autora koji su publicirali u najprestižnijim medicinskim časopisima, 7% (21 od 310) od autora nacionalnih europskih časopisa, 14% od autora Cochrane sustavnih pregleda (64 od 468), te 64 odgovora putem mrežnoga portala. Autori su bili iz 41 države, većinom muškoga spola (n=108, 59%), te zaposleni najčešće na sveučilištu (n=76, 42%), bolnici (n=69, 38%) ili istraživačkom institutu (n=20, 11%). Većinom su se bavili kliničkim istraživanjima (n=145, 80%), istraživanjima javnog zdravstva (n=36, 20%), te temeljnim medicinskim istraživanjima (n=14, 8%). Velik broj autora (n=77, 44%) objavio je više od 30 znanstvenih članaka, 57 autora (33%) objavilo je između 6 i 30 članaka, te 39 (23%) autora objavilo je 5 ili manje članaka (9 autora nije odgovorilo na ovo pitanje). Više od trećine autora (n=48, 36%) izjavilo je da nisu objavili sva svoja istraživanja, tj. da su objavili samo dio rezultata svojih istraživanja (n=40, 30%, tablica 6).

Tablica 6. Broj (%) autora sa spoznajom ili vlastitim iskustvom otklona u publiciranju

Pitanje	Broj (%) autora
Jeste li ikada sudjelovali u kliničkom istraživanju koje nije objavljeno u znanstvenom časopisu s postupkom recenzije?	
Ne, objavili smo sva naša klinička istraživanja	79 (60)
Da, objavili smo rezultate u časopisima bez recenzije	6 (4)
Da, imamo neobjavljenih rezultata iz kliničkih istraživanja	48 (36)
Broj neobjavljenih istraživanja (medijan, raspon)	2 (1-10)
Jeste li ikada sudjelovali u kliničkom istraživanju za kojeg svi prikupljeni podatci ili rezultati nisu bili u potpunosti objavljeni?	
Ne, objavili smo sve rezultate/podatke	93 (70)
Da, imamo neobjavljenih rezultata/podataka	40 (30)
Kao recenzent znanstvenog rukopisa, jeste li se susreli s problemom otklona u publiciranju?	
Da	72 (44)
Ne	66 (40)
Nisam nikada recenzirao/la rukopis za znanstveni časopis	27 (16)

Kao glavne razloge neobjavljivanja rezultata autori su naveli manjak vremena (n=21, 44%), metodološke probleme istraživanja (n=18, 38%), te statističku neznačajnost rezultata (n=12, 25%). Nešto više od trećine autora (n=61, 37%) izrazilo je zabrinutost da trenutna praksa registracije kliničkih istraživanja neće smanjiti otklone u publiciranju. Većina istraživača bila je za povećanje transparentnosti kliničkih istraživanja od objave rezultata istraživanja (n=132, 80%) do pristupa potpunom protokolu istraživanja (n=103, 63%). Međutim, samo četvrtina autora (n=45, 27%) bila je za objavu „sirovih“ podataka svakoga ispitanika.

Kvalitativna analiza odgovora autora pokazala je da ih je većina svjesna svoje krivice u neobjavljivanju rezultata, ali da smatraju da je za to odgovoran trenutan sustav objave i financiranja istraživanja koji preferira *„spektakularne rezultate“* i zbog kojeg istraživači *„ne žele trošiti svoje vrijeme na rezultate za koje znaju da neće biti objavljeni“.* Nadalje, istaknuli su da istraživači prikupe puno više podataka *„nego što trebaju ili mogu obraditi i objaviti“*. Izjavili su da je neobjavljivanje rezultata *„nemoralno“* jer *„izigra povjerenje i obvezu prema ispitanicima“*. Također su smatrali da obvezna registracija kliničkih istraživanja neće riješiti problem otklona u publiciranju, te da su uz povećanje svijesti o otklonu, uz poboljšanje obrazovanja istraživača, te uz odustajanje od pridavanja velike važnosti čimbeniku odjeka časopisa, potrebne i radikalne promjene cijelog trenutnog sustava objave znanstvenih istraživanja. Te promjene uključivale bi neobjavljivanje rezultata istraživanja u časopisima već isključivo u repozitorijima, zakonsku obavezu objavljivanja svih istraživanja, te inzistiranje na odgovornosti dionika, etičkih povjerenstava i financijera (tablica 7).

Tablica 7. Savjeti autora o načinima prevencije otklona u publiciranju.

Savjeti
Poboljšati trenutni sustav objave istraživanja
osigurati adekvatno obrazovanje istraživača i recenzenata
proširiti svijest o otklonu u publiciranju
osigurati obaveznu objavu protokola istraživanja s planom obrade podataka
osigurati obavezno korištenje smjernica za objavu rezultata i prijave sukoba interesa
smanjiti ovisnost o čimbeniku odjeka i njegovoj povezanosti s pozitivnim rezultatima
povećati transparentnost recenzentskog postupka i razloga (ne)prihvaćanja članaka
osigurati publikaciju komentara recenzenata zajedno s rezultatima istraživanja
osigurati ravnomjernu dobnu i spolnu zastupljenost članova uredničkih i drugih tijela
povećati važnost i ulogu komentiranja i recenziranja članaka nakon njihove objave
povezati registre i komentare istraživanja s pretraživačima i bazama znanstvenih članaka
povećati uporabu trenutnih registara i repozitorija podataka
uvesti obavezu objave godišnjih izvješća za sva klinička istraživanja
uspostaviti dodatne repozitorije rezultata
omogućiti javnosti dostupnost lokalnim i nacionalnim registrima istraživanja
omogućiti indeksiranje lokalnih i regionalnih časopisa u velikim bibliografskim bazama
uspostaviti sustave financiranja namijenjene pokrivanju troškova objave istraživanja
Ustrajati na odgovornosti dionika
etička povjerenstva i financijeri istraživanja trebali bi pratiti i odgovarati za istraživanja koja odobre
etička povjerenstva trebala bi odobriti samo ona istraživanja prijavljena u javnim registrima
glavni istraživači trebali bi odgovarati u slučaju neobjavljivanja rezultata istraživanja
Promijeniti trenutni sustav objave istraživanja
ukinuti postupak recenziranja članaka prije njihove objave
promijeniti ulogu časopisa u komentiranje rezultata objavljenih u repozitorijima podataka
omogućiti pristup cjelokupnoj dokumentaciji poslanoj etičkim povjerenstvima i financijerima
zabraniti financiranje i odobravanje istraživanja znanstvenicima koji imaju neobjavljene rezultate
Navedene savjete obvezati zakonom (uključujući kažnjavanje njihovog nepridržavanja)
Proširiti svijest javnosti i ispitanika i njihove uloge u nadgledanju i objavi istraživanja

Devet istraživača sudjelovalo je u organiziranoj fokus-skupini (4 muškarca i 5 žena), 8 ih je bilo zaposleno na sveučilištu, a 1 u javnozdravstvenoj organizaciji. Medijan objavljenih znanstvenih članaka sudionika bio je 7 (raspon 1-30). Među sudionicima 6 ih je imalo prethodno iskustvo registriranja kliničkog istraživanja u javno dostupnom registru. Odgovori sudionika bili su dosta slični prethodno opisanim odgovorima iz upitnika za autore (za glavne razloge neobjavljivanja rezultata naveli su, među ostalima, nedostatak vremena, dobivanje neželjenih rezultata, odbijanje rukopisa od nekoliko časopisa), ali su sadržavali i mnoge specifičnosti, posebice iskustva zemalja u razvoju. Istaknut je problem znanja engleskog jezika i objave istraživanja samo u lokalnim časopisima, te posljedice prirodnih katastrofa i ratova koji zaustave ili odgode publiciranje rezultata, tj. unište mjesta pohrane podataka. Također, istaknuta je nevidljivost sive literature i regionalne objave rezultata, te otklona koji zbog nemogućnosti pretrage sive literature nastaje prilikom sinteze rezultata. Predloženo je automatsko prevođenje ključnih riječi u pretraživačima literature, da bi se s većom vjerojatnošću obuhvatili rezultati istraživanja koji nisu objavljeni na engleskom jeziku. Uz to, spomenut je problem uspostave kontakta s dopisnim autorima, koji često promijene e-adrese, te nepostojanje sustava ili obveza zbog kojih bi istraživači morali obnoviti svoje kontakt informacije i u situacijama kada je prošlo i više od 15 godina od objavljivanja rada.

Jedan ispitanik istaknuo je da dio istraživanja često bude samo djelomice financiran (osigurano financiranje za početak studije), ali zbog nemogućnosti osiguranja dodatnog financiranja bude prekinut prije nego se istraživanje završi. Jedna ispitanica istakla je konflikte koji znaju nastati u uredničkim tijelima zbog različitog fokusa na važnost ili mogućoj citiranosti poslanog rukopisa, kao i razlika u mišljenju između starijih i mlađih članova odbora, odnosno razlika u spolu. Nadalje, budući da dio istraživanja provedu studenti magistarskih ili doktorskih studija, oni često nemaju vremena ili inicijative nakon obrane da svoju temu i objave. Među metodama za sprječavanje otklona u publiciranju sudionici su spomenuli ugovorne obaveze između sveučilišta ili institucija i istraživača, kojima bi ih se obvezalo na objavljivanje, te kojima bi se isplatio posljednji dio novca za istraživanje nakon objave rezultata. Jedan sudionik je naglasio da treba raditi i na promjeni klime publiciranja, te uvođenju poticaja i nagrada za one istraživače koji su objavili sva svoja istraživanja i držali se smjernica za njihovu objavu.

3.4. ZNANSTVENI DOPRINOS OBJEDINJENIH RADOVA

Našim prvim istraživanjem potvrdili smo veliki nesrazmjer između trenutno najprihvaćenijih kriterija autorstva u biomedicini (kriterija ICMJE) i stvarnih razloga zbog kojih autori znanstvenih članaka smatraju da zaslužuju autorstvo. Ako i pretpostavimo da samim slanjem rukopisa autori potvrđuju treći kriterij ICMJE (odobrenje zadnje verzije članka), udio autora koji bi u našem istraživanju zaslužio autorstvo bio bi tek 54%. Taj udio sličan je rezultatima drugih istraživanja koja su koristila numeričke ljestvice ili dihotomne kategorije za označavanje doprinosa istraživanju.[82, 83] Također, u našem je istraživanju samo 65% autora kao razlog zasluge autorstva navelo pisanje ili revidiranje rukopisa, te samo 5% odobrenje zadnje (poslane) verzije. Zajedno, ti rezultati upućuju na potrebu revidiranja trenutnih kriterija autorstva, tj. na potrebu ispravnog i transparentnog navođenja uloge znanstvenika u opisanom istraživanju. Nadalje, pronašli smo detaljnije navođenje razloga zasluge autorstva u slučaju rukopisa s više od 8 autora, što je zacijelo posljedica veće potrebe za raspodjelom posla, a time i opravdanjem uloge u istraživanjima s velikim brojem suradnika. Iako se naizgled problem autorstva može riješiti prelaskom na navođenje doprinosa (kontribucija) tj. opisom doprinosa svakoga autora, nedovoljno detaljni ili isti razlozi navedeni su od više koautora istoga članka u našem istraživanju. Zato držim da opisi doprinosa kakvi se danas navode u biomedicinskim časopisima[84] ne omogućuju određivanje stvarne uloge pojedinih istraživača, niti nagrade koje bi iz njihovog rada trebale proisteći; pogotovo kada se radi o istraživanjima u kojima je sudjelovalo nekoliko desetaka, stotina ili tisuća istraživača.[36] Taj nesrazmjer između razloga autora, te očekivanja čitatelja, budućih poslodavaca, ili interesnih skupina kojima autorstvo označava često veoma različitu količinu sudjelovanja u istraživanju,[85] kao i otkrivene manipulacije autorstvom (opisane u poglavlju 2.2.1.) bile su najvjerojatnije povod proširenju kriterija ICMJE 2013. g. kada je uveden četvrti kriterij: preuzimanje odgovornosti od strane autora za sve aspekte rukopisa, uključujući i obvezu odgovaranja na sve upite o mogućoj neispravnosti ili pouzdanosti danoga istraživanja.[24] Nekoliko časopisa otišlo je već i korak dalje, i sada traži preuzimanje odgovornosti ne samo od strane autora, već i od ustanova zaposlenja tj. instituta gdje su se provela istraživanja.[86] Sukladno tome, upravo je potreba za većom ulogom i odgovornosti sveučilišta, instituta, etičkih odbora i financijera, jedan od savjeta istraživača koje smo dobili u našem trećem istraživanju.

Činjenica da je na pitanje: „*Zašto smatrate da zaslužujete autorstvo na ovom radu?*“ devet istraživača odgovorilo samo s *„Da“*, tj. 31% autora s nizanjem navoda, a ne cijelom rečenicom, vjerojatno reflektira trenutni proces slanja rukopisa preko mrežnih portala gdje se svi koraci doživljavaju istovjetnima obveznom pritisku na programske kućice kojima se potvrđuju brojna pravila časopisa ili izdavača, a bez kojih rukopis nije moguće poslati. Drugim riječima, traženje od autora da potvrde kriterije autorstva navedene od strane časopisa ili izdavača ne znači da ih autori i zadovoljavaju, već pruža urednicima osnove za rješavanje naknadnih otkrića zlouporabe. Naše prvo istraživanje nije imalo za cilj ponuditi rješenje pitanja autorstva u znanosti, ali dobiveni rezultati, zajedno s rezultatima istraživanjima koja su pokazala da prelazak na opis doprinosa nije smanjio broj koautora na člancima,[87, 88] te s rezultatima našeg drugog istraživanja u kojemu je redoslijed i broj autora između sažetaka tj. postera prezentiranih na kongresima i njihove posljedične objave bio istovjetan u samo 56% slučajeva, upućuju na važnost propitivanja pouzdanosti autorstva i praćenja autorskih trendova u znanosti, te ističu potrebu za mnogo većom transparentnosti u procesu dodjele i zasluge autorstva na znanstvenom članku. Poput registracije kliničkih istraživanja, možda je vrijeme da se sva planirana istraživanja registriraju u međunarodnim ili lokalnim registrima, uz točno navođenje planirane uloge, a time i redoslijeda autora na članku kada on bude objavljen. Takva bi registracija, naravno, omogućila i unošenje izmjena koje nastaju zbog životnih okolnosti, obveza, pa i smrti istraživača, ali bi praćenje takvih izmjena učinilo cijeli proces istraživanja mnogo transparentnijim, a vjerojatno i povoljnijim za mlađe znanstvenike, te pisce ili prevoditelje, čije bi se zasluge tada mnogo lakše moglo potvrditi i kontrolirati.[28]

Naše drugo istraživanje pokazalo je zanimljivu sliku kongresa na kojima svoja istraživanja predstavljaju urednici najprestižnijih časopisa u biomedicini i stručnjaci koji istražuju pouzdanost znanstvenih publikacija, drugim riječima oni najsvjesniji posljedica izostanka objave istraživanja, a čiji su radovi citirani više stotina i tisuća puta. Od svih prezentiranih istraživanja čak 39% nije bilo objavljeno u cijelosti ni nakon 4 (te u nekim slučajevima i nakon 24 godine) od njihova predstavljanja. Iako smo pokazali zastupljenost različitih vrsta istraživanja postupaka recenzije i pouzdanosti znanstvenih članaka, činjenica da je samo trećina istraživanja bila financirana, te da je udio pokusnih istraživanja iznosio 16%, upućuje na potrebu osnivanja kompetitivnih shema financiranja koje bi posljedično mogle privući veći broj istraživača u propitivanju i unaprjeđenju postupaka objave i otklona u publiciranju znanstvenih članaka, tj. u promicanju pouzdanosti znanstvenih članaka.

Učestalost izostanka objave istraživanja potvrdili smo i našim trećim istraživanjem, provedenim s autorima Cochrane sustavnih pregleda i kliničkih pokusa iz 41 različite zemlje, od kojih je 36% priznalo da ima neobjavljena istraživanja, tj. 30% da nije objavilo sve rezultate i prikupljene podatke. Sličnu učestalost izostanka objavljivanja (21-93%)

istraživanja tj. svih rezultata (40-62%) potvrdio je i nedavni sustavni pregled otklona u publiciranju.[49] No budući da je cilj našeg trećega istraživanja bio ponajprije istražiti mišljenja istraživača, prvi put smo pokazali da autori, uz prihvaćanje osobne odgovornosti, za uzroke izostanka tj. djelomične objave, krive ponajviše trenutni sustav provođenja, financiranja i objave istraživanja. To nezadovoljstvo današnjim sustavom, posredno su izrazili i putem radikalnih promjena koje su smatrali potrebnim današnjoj znanosti: od potpunog odustajanja objave rezultata u znanstvenim časopisima, do uključenja javnosti u praćenju i nadgledanju provođenja i objave istraživanja. Riječima jednog od istraživača: *„Važniji je pristup (informacijama ili podatcima) od objave znanstvenoga članka.“*

3.4.1. Nedostatci istraživanja

a) Istraživanje pouzdanosti autorstva

Naše prvo istraživanje, iako velikoga uzorka (n=1282), nije imalo dovoljnu zastupljenost radova s više od 8 autora (n=17). Pošto današnja istraživanja u biomedicini ponekad imaju i do tisuće navedenih autora,[21] potrebna su daljnja istraživanja da se utvrdi raspodjela i udio posla potreban za autorstvo, tj. napredci u karijeri koji su rezultat i priznanje suradnje u istraživanjima s tako velikim brojem suradnika. Nažalost, ni najnovije smjernice ICMJE tu ne pružaju rješenje, jer navode da bi istraživači trebali svim osobama koje su sudjelovale u prikupljanju podataka ponuditi (a time i osigurati) mogućnost sudjelovanja u onom opsegu koji zadovoljava priznanje autorstva.[24] Druga mana našeg prvoga istraživanja je analiza rukopisa samo jednog općemedicinskog časopisa, što u pitanje dovodi poopćivost rezultata. Međutim velika zastupljenost odgovora i sličnost rezultata s drugim istraživanjima na tu temu,[19, 82] potvrđuju poimanje autorstva onakvim kakvim su ga opisali naši ispitanici. Također, izvorno smo pokazali da jednostavnim upitom: „*Zašto smatrate da zaslužujete autorstvo na ovom radu?*“, bez navođenja kriterija koje bi istraživači trebali zadovoljiti, dobivamo razloge i razmišljanja istraživača o pitanju autorstva u biomedicini koja su jako slična onima kad se kriteriji autorstva prethodno definiraju.

b) Istraživanje pouzdanosti cjelovite objave istraživanja

Presječni ustroj našeg drugog istraživanja ne dopušta mogućnost utvrđivanja razloga izostanka objavljivanja radova prezentiranih na uglednom kongresu te, iako obuhvaća najprestižniji kongres o postupcima recenzije i publiciranja radova u biomedicini, rezultati se najvjerojatnije ne mogu poopćiti na druge znanstvene grane, gdje je postupak recenzije i utvrđivanja autorstva višestruko različit od onoga u medicini.[19] Međutim, našim trećim istraživanjem potvrdili smo razloge nepubliciranja objavljene u radovima drugih istraživača,[50] dok je ujedno postotak izostanka objave istraživanja koji smo pronašli u skladu s nedavno objavljenim sustavnim pregledom.[49]

c) Istraživanje učestalosti i metoda prevencije neobjavljivanja znanstvenih radova

Nedostatak našeg trećeg istraživanja je presječni ustroj istraživanja, te jako mali odaziv istraživača (8-14%). Međutim, učestalost odgovora na elektroničke upitnike u biomedicini često je jako slaba,[89, 90] te smo unatoč slabom odazivu uspjeli dobiti mišljenja istraživača iz 41 različite zemlje, te njima slična mišljenja potvrdili na provedenoj fokus-skupini. Pošto sam cilj istraživanja nije bio utvrditi prevladavajuće mišljenje svih istraživača u znanosti već istražiti moguće razloge neobjavljivanja radova, veličina uzorka višestruko nadmašuje potrebe eksplorativnih studija.[91]

Uz prethodno navedeno, snagu naših istraživanja potvrđuje i velika citiranost radova u kratkom roku nakon njihova objavljivanja (5, 4 i 6 u WoS-u, tj. 12, 4, 10 Google Scholar-u, te 3826 pristupa prvom istraživanju na mrežnim stranicama izdavača (do 1. prosinca 2015).

3.4.2. Osobni osvrt

„Danas je sve automatizirano – obavljeno računalima i ljudima koji su poput računala.“
Frank Herbert: Pod pritiskom

Svakom otkrivenom manipulacijom autorstva, referencija ili recenzentskog postupka, izmišljanjem ili manipulacijom podataka, te izostankom objave rezultata ili prikupljenih podataka povjerenje čitatelja i ispitanika biva izigrano. Ako još prevladava mnijenje iz 2010. kada je 58% anketiranih građana Europe izjavilo da ne vjeruje izjavama znanstvenika o kontroverznim pitanjima zbog njihove prevelike ovisnosti o novcu ulagača,[74] onda je znanost doista podbacila u transparentnosti i samokritičnosti na kojima se temelji. Nevoljkost istraživača za potpunom objavom prikupljenih izvornih podataka (27% u našem trećem istraživanju), 54% doista zasluženog autorstva u našem prvom istraživanju, 44% različitosti redoslijeda i broja autora između prezentacije na kongresu i cjelovite objave istraživanja (u našem drugom istraživanju), te 36%-39% neobjavljenih istraživanja (u našem drugom i trećem istraživanju) vjerojatno su posljedica okruženja, kompetitivnosti i nepovjerenja koji danas vladaju u znanosti, ali ujedno i manjka učinkovitih mehanizama sprječavanja takvih pojava. Međutim, kao što su sustavni pregledi postali najispravniji način davanja odgovora na konkretno pitanje o zdravlju, te kao što su registracije kliničkih ispitivanja na ljudima postale obveza bez kojih se danas istraživanja ne bi smjela započeti ili objaviti,[92] osobno smatram da su potrebni mehanizmi povećanja pouzdanosti znanstvenih publikacija danas dostupni, ali nažalost ne i univerzalno prihvaćeni. Sve veća suglasnost pacijenata da se njihovi podatci koriste za unaprjeđenje medicinskog znanja,[93, 94] kao i voljnost znanstvenika za objavom sirovih podataka,[95] zakonska obaveza objave u slobodnom pristupu onih istraživanja financiranih državnim sredstvima,[96] prijelazi na otvoreni tip recenzija,[97] objave „*živih*“ verzija znanstvenih članaka koje omogućavaju lakše popravljanje netočnih podataka,[67] zajedno sa širenjem masovnog kolaborativnog rada i javnih financiranja (engl. crowdsourcing),[98] mogu znanosti omogućiti da istinski ispuni svoju zadaću. Povezivanje tih praksi s *ORCID*-om znanstvenika, te sa sustavima poput *e-građani*, i društvenim mrežama (npr. *Facebook*, *ResearchGate*, *LinkedIn*) onemogućilo bi (ili bar uvelike otežalo) slučajeve lažnih identiteta, recenzija ili navoda u životopisima, te nemogućnosti kontaktiranja autora zbog promjene njihovih radnih mjesta. Već spomenuta registracija svih istraživanja, koju bi pratila objava cjelovitih protokola (uključujući i statističkoga plana obrade) omogućila bi puno bržu izmjenu podataka i možda prijelaz s inzistiranja da svi dijelovi istraživanja, od ideje preko provedbe i objave, moraju biti zaštićeni do same objave da bi se omogućilo ispravno priznanje zasluga. Uz to, automatizacija unosa prikupljenih podataka, mogućnost praćenja toga unosa uživo, automatiziran izračun rezultata pri dodatku svakoga pojedinog ispitanika, uz računalno generirane obrasce objave, smanjila bi mogućnost ljudske pogrješke te potrošnju vremena koju znanstvenici danas navode kao najčešći uzrok izostanka objave istraživanja. Osobno smatram da povezivanje svih prethodno navedenih mehanizama i sustava ne bi dovelo do ograničenja slobode ljudi, komunikacije u znanosti ili do nadgledanja poput Orwelijanskog *Velikog Brata,* što se ponekad zamjera povećanju transparentnosti,[99, 100] već bi postao standardni alat sličan mehanizmima samoispravljanja tekstualnoga unosa. Jaka (javna i zakonska) osuda zlouporabe podataka ili identiteta na znanstvenoj i međunarodnoj razni dodatno bi potvrdila klimu takve znanstvene komunikacije. Naposljetku, znanstvenici se moraju upitati što će znanost budućnosti reći o pouzdanosti današnje znanosti – s ustupanjem znanstvenicima (i javnosti) svih podataka prošlosti (poput rodnih listova, oporuka, umjetničkih djela, ali i privatnih pisama i snimaka),[101, 102] moguće je da će čovječanstvo u budućnosti pouzdanost znanstvenih publikacija 21. stoljeća procjenjivati i analizom arhiva, komunikacija, i bioloških uzoraka koje danas znanstvenici ne žele podijeliti.

3.5. KRATKI SAŽETAK NA ENGLESKOM JEZIKU (SUMMARY)

Integrity of scientific publications in biomedicine

Introduction: Science pertains to be self-critical, self-correcting, and ultimately replicable. As 1.7% scientists admitted fabrication or modification of data, and instances of authorship, citation, publication and peer review manipulations have been discovered, we sought to explore the integrity of biomedical publications, especially regarding authorship, non-publication and means of reducing dissemination bias.

Methods: Using three observational studies we analyzed: a) answers to the question: “*Why do you think you should be the author on this manuscript?”;* b) funding, study type and differences between research presented at peer review conferences and their subsequent publication; c) opinions and experiences of clinical trialists and systematic reviewers regarding dissemination bias.

Results: Only 54% of authors in our first study satisfied international authorship criteria. We found differences in number and byline of authors in 44% cases in our second study, as well as 39% of non-publication between research presentation and full publication. In our third study, we confirmed the non-publication rate (36%), and showed that authors regard current publication practices as the main culprits for today’s state of science.

Conclusions: Our results indicate that current authorship criteria and publication practices in biomedicine need to be revised and restructured if science is to preserve its integrity.

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4. ŽIVOTOPIS

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2009. – 2009.	Socijalni radnik (engl. flexicarer/befriender), Westminster Mind and the Brain Injury Support Services Ltd, London, UK

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Projekti

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6. Radionica: Editorial research. 12.-13. Prosinca 2012. Barcelona, Španjolska.

Ostalo

Materinji jezik:	hrvatski
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Uporaba računalnih programa:	Microsoft Office, MedCalc, SPSS, R, End Note, Perl

5. PRESLIKE OBJEDINJENIH RADOVA

1. Malički M, Jerončić A, Marušić M, Marušić A. Why do you think you should be the author on this manuscript? Analysis of open-ended responses of authors in a general medical journal. BMC Med Res Methodol. 2012;12:189.

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Why do you think you should be the author on this manuscript? Analysis of open-ended responses of authors in a general medical journal

Mario Malički, Ana Jerončić, Matko Marušić and Ana Marušić*

Abstract

Background: To assess how authors would describe their contribution to the submitted manuscript without reference to or requirement to satisfy authorship criteria of the International Committee of Medical Journal Editors (ICMJE), we analyzed responses of authors to an open-ended question *"Why do you think you should be the author on this manuscript?"*.

Methods: Responses of authors (n=1425) who submitted their manuscripts (n=345) to the *Croatian Medical Journal*, an international general medical journal, from March 2009 until July 2010 were transcribed and matched to ICMJE criteria. Statements that could not be matched were separately categorized. Responses according to the number of authors or their byline position on the manuscript were analyzed using Mann–Whitney *U* test and Moses test of extreme reactions.

Results: The number of authors per manuscript ranged from 1 to 26 (median=4, IQR=3-6), with the median of 2 contributions per author (IQR=2-3). Authors' responses could be matched to the ICMJE criteria in 1116 (87.0%) cases. Among these, only 15.6% clearly declared contributions from all 3 ICMJE criteria; however, if signing of the authorship form was taken as the fulfillment of the third ICMJE criterion, overall fraction of deserving authorship was 54.2%. Non-ICMJE contributions were declared by 98 (7.6%) authors whose other contributions could be matched to ICMJE criteria, and by 116 (13.0%) authors whose contributions could not be matched to ICMJE criteria. The most frequently reported non-ICMJE contribution was literature review. Authors on manuscripts with more than 8 authors declared more contributions than those on manuscript with 8 or fewer authors: median 2, IQR 1–4, vs. median 2, IQR 1–3, respectively (Mann Whitney *U* test, p=0.001; Moses Test of Extreme Reactions, p<0.001). Almost a third of single authors (n=9; 31.0%) reported contributions that could not be matched to any ICMJE criterion.

Conclusions: In cases of multi-author collaborative efforts but not in manuscripts with fewer authors open-ended authorship declaration without instructions on ICMJE criteria elicited responses from authors that were similar to responses when ICMJE criteria were explicitly required. Current authorship criteria and the practice of contribution declaration should be revised in order to capture deserving authorship in biomedical research.

Keywords: Authorship, Guideline adherence, Contribution disclosure form, International Committee of Medical Journal Editors (ICMJE), Editorial policies, Croatia

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Background

Authorship is perhaps the most important aspect of research – it recognizes the credit for research and, what is important for individual scientists, it is the primary criterion for career advancement. Although it may seem that giving credit for research would be a straightforward decision, authorship is burdened by many problems in all research disciplines [1]. In biomedicine, there is ample evidence that the authorship criteria widely accepted by journals and publishers – those from the International Committee of Medical Journal Editors (ICMJE) [2] are not well understood or followed by both the medical students and experienced researchers [3-5], resulting in a high prevalence of authors of published articles who do not satisfy the ICMJE criteria [6-9].

Our research group has shown in a number of studies in our own and other journals that forms used by journals for contribution declaration for authorship are not a reliable way of judging authorship [8-12], and that authorship does not seem to be only a normative issue subjective to categorization into criteria, but also a very personal view of the importance and value of one's contributions [13]. Based on this body of evidence, we hypothesized that authors who were asked to describe in their own words why they think they deserve authorship on a submitted manuscript may differ in their contribution declaration then the authors who were instructed about standard authorship criteria or asked to declare authorship using checklists with ICMJE-eligible contributions.

Methods

Participants

All authors (n=1425) who submitted manuscripts (n=345) to the *Croatian Medical Journal* (CMJ) from March 2009 until July 2010 were included in the study. Individual forms with a question about authorship and other information (contact address, copyright and participation in editorial research) for each author of the manuscript were sent by e-mail to the corresponding authors, who were asked to distribute these to their coauthors. Completed and signed documents were returned to the editorial office by the individual or corresponding authors.

Ethical considerations

The participation in the study was voluntary and did not influence the editor's decision to accept or reject the articles submitted. As the full information on the study could influence the response of the authors, authors were asked to accept the participation in research of editorial and peer-review issues [9-12]. This information was provided in the authorship form and the authors were offered an opt-out option for the participation in the journal's research. The study was approved by the Ethics Committee of the Zagreb University School of Medicine under the grant from the Ministry of Science and Technology of the Republic of Croatia No. 108-1080314-0140 to MMar.

Authorship form

The form started with the general definition of an author: "An AUTHOR of a scientific article is considered to be someone who has made substantive contribution to the submitted work." There was no reference to any authorship criteria. We then asked the authors about their contribution to the submitted work in the following way: "The CMJ requests from the authors of submitted manuscripts to describe their contribution to the research described in the manuscript by answering the following question: Why do you think you should be the author on this manuscript?"

Analysis of responses

All responses were transcribed into an Excel spreadsheet, including the authors byline position in the submitted manuscript, and the manuscripts submission number. Wording the ICMJE used for defining authorship credit formed the basis of variables (criteria) to which the authors' statements were manually matched [2]: "Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3." Authorship statements that could not be matched to any of the above ICMJE criteria, such as translation of the article, supervision/mentorship or literature search, were separately categorized.

Statistical analysis

Frequencies and percentages were used for the description of qualitative variables. Depending on the distribution of data, following descriptors were used for quantitative variables: mean and standard deviation, median and interquartile range (IQR). Pearson's chi-square test was used to compare qualitative data frequencies. The distributions of total authors on paper according to identical responses by authors were contrasted using the Mann–Whitney *U* test and the Moses test of extreme reactions, to analyze differences in central tendency and dispersion, respectively. The same two tests were used to compare the number of declared contributions per author by total author count or by author's byline. A 95% confidence interval (CI) for median, estimated by the bias-corrected and accelerated bootstrapping method with 2000 replications, was also reported in order to complement hypothesis testing. The level of significance for all statistical tests was 0.05. Data were analyzed with SPSS statistical package 19.0 (SPSS; Chicago, Illinois, USA).

Results

We analyzed responses from 1282 (90.0%) authors of 335 submitted manuscripts; 140 (9.8%) authors signed their acceptance to participate in research but did not write an answer to the authorship question; 1 form was not readable, and 2 referred to attachments which were not available for analysis. The number of authors per article ranged from 1 to 26 (median=4, IQR=3-6). The median number of declared contributions per author was 2 (IQR=2-3).

Authors' responses could be matched to ICMJE criteria in 1116 (87.0%) cases (Table 1). Among these authors, only 15.6% clearly declared contributions from all three ICMJE categories, whereas 3 authors (0.3%) explicitly stated that they satisfied ICMJE criteria. More than a third (38.6%) satisfied the first two ICMJE criteria (research and writing), while the rest declared a single ICMJE contribution, either to research execution (31.8%) or writing (9.4%) (Table 1). Authors whose contributions could be matched to the ICMJE criteria used the wording that was similar to the terminology used in the ICMJE definition (Table 2). The frequency of the terminology identical to that from the ICMJE definition ranged from 52.8% for "data collection" to 98.0% for "study design". Other declarations used words or phrases that described the activity covered by the ICMJE criteria.

The responses of 166 (13.0%) authors could not be matched to ICMJE criteria (Table 3). Among them 56.3% stated that they made a significant contribution, without listing what that contribution was, while others declared the importance of the submitted case, employment in a health care institution, or just wrote "Yes". Some also reported mentorship/supervision, literature search and translation, administrative/technical/statistical support and other professional contributions as valid reasons for authorship. Three authors stated that the submitted work was a part of their master thesis – they were the first authors on manuscripts with 3 (2 manuscripts) and 6 authors. Non-ICMJE contributions were also declared by 98 (8.8%) authors whose other contributions could be matched to ICMJE criteria (Additional file 1: Table S1). Among these authors, additional contributions were declared most often by those who also declared contributions to the first two ICMJE criteria (50.0%), while the most frequently reported contribution was literature review, in 52.0% cases.

For all respondents, open-ended declarations were mostly in the form of a full or partial sentence: 655 authors (55.1%) used the sentence starting with "I ...", 108 (8.4%) authors started with "Because ...", and 15 (1.2%) with "My ...". The rest of the respondents (n=401, 31.3%) just listed their contributions (Additional file 2: Table S2).

Table 1 Number (%) of authors (n=1116) whose authorship statement could be matched to ICMJE criteria

Criteria	No. (%) of authors*
Full criteria (1 and 2 and 3)	174 (15.6)
Criteria 1 and 2 not 3	431 (38.6)
Criteria 1 and 3 not 2	26 (2.3)
Criteria 2 and 3 not 1	17 (1.5)
Criterion 1 only:	355 (31.8)
"conception"	12 (3.4)
"design"	13 (3.7)
"acquisition of data"	161 (45.3)
"analysis of data"	24 (6.8)
"interpretation of data"	9 (2.5)
any 2 contributions	92 (25.9)
any 3 contributions	34 (9.6)
any 4 contributions	9 (2.5)
all 5 contributions	1 (0.3)
Criterion 2 only:	105 (9.4)
"drafting of the article"	45 (42.8)
"revising of the article"	49 (46.7)
both contributions	11 (10.5)
Criterion 3 only	5 (0.5)
Statement: "Because I contributed to the submitted article as an author according to the ICMJE criteria"	3 (0.3)

*Percentages for contributions specified in an individual authorship criterion are to the total sum of responses within that criterion.

Table 2 Expressions used by authors (n=1116) in statements that could be matched to the ICMJE criteria

Expression categories	No. (%) of authors
Criterion 1 – Conception:	
“planned/planning”	129 (43.7)
“conception”	118 (40.0)
“my idea“	32 (10.1)
“organized research”	5 (2.0)
“hypothesis”	5 (2.0)
Other*	6 (2.2)
Criterion 1 – Design:	
“design/designing”	347 (98.0)
“chose proper methodology”	3 (0.9)
“experiment construction”	2 (0.5)
Other†	3 (0.6)
Criterion 1 – Acquisition of data:	
“data collection”	183 (31.1)
“data acquisition”	128 (21.7)
“did the experiments”	77 (13.1)
“conducted the study”	52 (8.8)
“treatment”	32 (5.4)
“diagnosis”	30 (5.1)
Other‡	87 (14.8)
Criterion 1 – Analysis of data:	
“analysis made/analyzed”	257 (73.7)
“statistical analysis”	87 (24.9)
“processed data”	5 (1.4)
Criterion 1 – Interpretation of data:	
“interpretation”	255 (91.8)
“presentation”	19 (6.8)
“draw conclusion”	3 (1.4)
Criterion 2 – Drafting of the article:	
“writing”	247 (46.9)
“drafting”	182 (34.5)
“manuscript preparation”	84 (15.8)
“wrote discussion”	7 (1.4)
Other§	7 (1.4)
Criterion 2 – Revising the article:	
“revision/revising”	219 (73.5)
“intellectual contribution”	54 (18.1)
“edited”	18 (6.0)
“made final copy/version”	5 (1.6)
“made corrections”	3 (1.0)
Other ‖	5 (1.6)
Criterion 3 – Final approval:	
“final approval”	215 (91.8)
“agree with the version published”	5 (2.1)

*Statements containing terms such as “inception”; “initiation”; “developed the project”.
†Statements containing terms such as “depicted the original scheme”; “protocol construction”.
‡Statements containing terms such as “obtained data”; “gathered data”; “did research”; “patient management”.
§Statements containing terms such as “wrote introduction”; “wrote results”; “wrote abstract”.
‖Statements containing terms such as “second draft”; ”completion”; “polishing”.

We separately analyzed the distribution of authors with ICMJE matching and non-matching contributions in relation to their position on the byline and the total number of authors on the submitted manuscript. Single authors on a manuscript (n=29) most often reported contributions that satisfied all 3 ICMJE criteria (n=12; 41.4%), while 8 (27.6%) of them reported a single ICMJE contribution. Almost a third of single authors (n=9; 31.0%) reported contribution(s) that could not be matched to any ICMJE criterion. The reasons for authorship they declared could be grouped into 2 distinctive sets: a) significant contribution to the reported work, without specification of contribution(s) and b) professional competence in the field from which the research was reported. Similar declarations were observed for manuscripts with 3 authors (31 out of 161 authors, 19.3%, declared non-ICMJE matching contributions). In manuscripts with 2 authors, authors whose contributions could not be matched to the ICMJE criteria (10 out of 66, 15.2%) reported significant (unspecified) contributions. The fraction of authors with ICMJE non-matching contributions decreased with more authors on a manuscript, as well as with the ascending position on the byline (Figure 1). Authors with all 3 ICMJE criteria fulfilled (considering their signature as the fulfillment of the third criterion) predominated in all manuscripts, regardless of the number of authors or of their position on the byline, except for authors on the 3rd to the 5th byline position, who more often reported a single ICMJE matching contribution (Figure 1). In relation to their byline position, there was no difference between ICMJE matching and non-matching contributions declared on manuscripts with 2 or 3 authors (p>0.05 for all comparisons, Pearson’s chi-square). We observed a difference in the number of contributions declared by ICMJE matching and non-matching statements. In general, authors on manuscripts with more than 8 authors declared more contributions than those on manuscript with 8 or fewer authors: median 2, IQR 1–4 (95% CI for median 2–3), vs. median 2, IQR 1–3 (95% CI 2–2), respectively (Mann Whitney *U* test, p=0.001; Moses

Table 3 Number (%) of authors (n=166) whose authorship statement could not be matched to ICMJE criteria for authorship

Stated contribution	No. (%) of authors*
Substantial/direct contribution	94 (56.6)
"Yes"	9 (5.4)
This (case) is interesting	8 (4.8)
We work/collaborate together	8 (4.8)
I am a specialist of/I work in the department for	7 (4.2)
"I am interested in this topic/field"	6 (3.6)
"It was my master degree thesis"	3 (1.8)
"The study carries scientific value"	3 (1.8)
Literature search	3 (1.8)
"I have participated sufficiently to take public responsibility for appropriate portions of the content"	3 (1.8)
Chief of the project/department	3 (1.8)
Supervisor	2 (1.2)
Coordinator	2 (1.2)
Bibliographical search, administrative and logistic support	2 (1.2)
"I have other related publications as a biostatistician"	2 (1.2)
Signature of the author	2 (1.2)
"My participation in the contribution was administrative and technical support."	1 (0.6)
"I was responsible for translation of the article."	1 (0.6)
"I have especially taken part in collecting the literature data, translation."	1 (0.6)
"This is the first study of its kind."	1 (0.6)
"On the basis of operational practice and clinical experience which led to this work."	1 (0.6)
"Because I want to present process of treatment in our institute."	1 (0.6)
"I am an investigator in scientific project with similar problems."	1 (0.6)
"Because I believe this is a proper treatment in this situation."	1 (0.6)
"I was scientific consultant of this research"	1 (0.6)

*Percentages do not add up to 100 because of rounding.

Test of Extreme Reactions, $p<0.001$). This difference was still observed in the subsequent analysis when we compared the number of ICMJE matching contributions by authors between manuscripts with more than 8 authors (median 3, IQR 2–4, 95% CI 2–3), and less or equal to 8 authors (median 2, IQR 1–4, 95% CI 2–2) (Mann Whitney *U* test, $p=0.061$; Moses Test of Extreme Reactions, $p<0.001$). The difference in the number of contributions in manuscripts authored by researchers whose contributions could not be matched to the ICMJE criteria was inconclusive as the analysis was underpowered (only 17 out of 166 authors (10.2%) were authors on manuscripts with more than 8 authors). The position of those authors on the byline was not associated with the number of contribution declarations. Those with the byline position higher than 8th had a median of 2 contributions, IQR 1–3 (95% CI 2–2), similar to authors with lesser or equal to the 8th byline position which also contributed a median of 2 contributions, IQR 1–3 (95% CI 1.5–3) (Mann Whitney *U* test, $p=0.762$; Moses Test of Extreme Reactions, $p=0.065$).

There were 95 manuscripts where contribution declarations had identical wording for 2 or more authors. Such manuscripts tended to have a greater total number of authors than the whole population of manuscripts (Additional file 3: Figure S1): whereas all manuscripts had median of 4 authors (IQR=4-6), manuscripts with identical declarations had a median of 6 authors (IQR=4-8). Significant differences were found both in the central tendency (Mann Whitney *U* test, $p<0.001$) and the dispersion (Moses Test of Extreme Reactions, $p<0.001$) between the two groups of manuscripts.

Discussion

Our study showed that authors, when asked about authorship in a non-instructional way, i.e. without reference to the ICMJE criteria as a standard in biomedicine [2], mostly declared contributions that could be matched to the first two ICMJE criteria (executing research and writing the manuscript), but not to the third ICMJE criterion (approving of the final manuscript version).

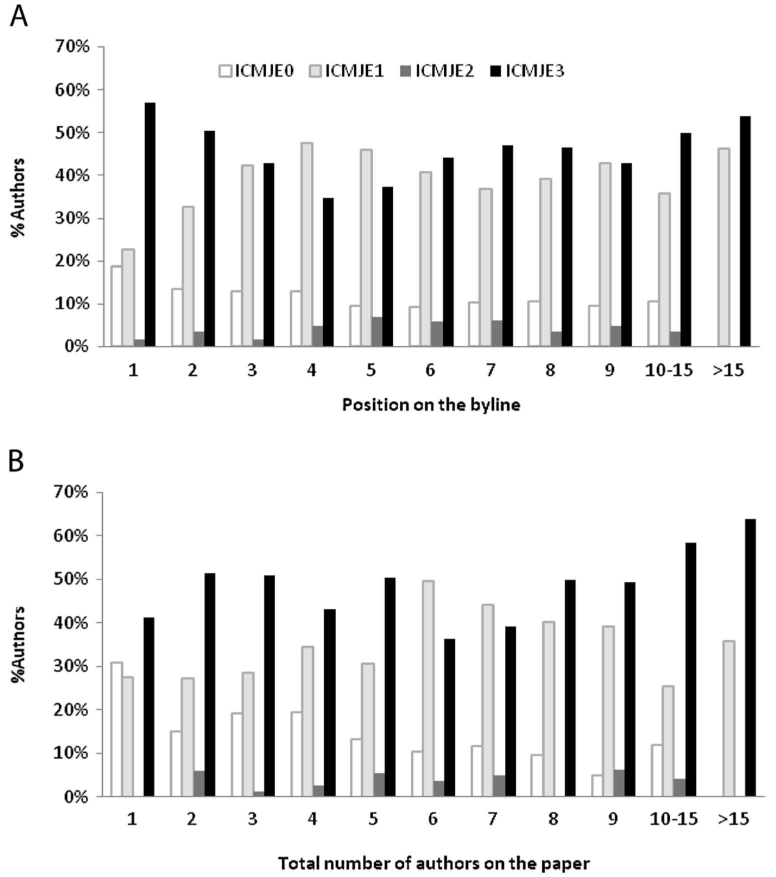

Figure 1 Distribution of authors' declared contributions according to their position on the byline (A) and the total number of authors on a manuscript (B). ICMJE 0 – authors whose contributions could not be matched to ICMJE criteria, ICMJE 1, 2 or 3 – authors whose contributions could be matched to one, two or all three ICMJE criteria, respectively.

The authors also most often used the wording of the ICMJE definition to describe their contributions. The declarations from 13% of the authors could not be matched to any ICMJE criterion. The fraction of such authors decreased with the increasing number of authors and their remoteness from the first byline position.

Our study is limited by its cross-sectional design, but our findings are strengthened by a high response rate, since filling out authorship forms is mandatory for manuscript processing in most science journals. Generalizability of the findings to other medical journals and research and academic settings can also be questioned as the study was performed in a single journal. However, the results are consistent with the previous finding from authorship studies in our journal, which included both survey and randomized study designs [9-12], as well as with studies from other journals or academic settings [3,4,6-8].

Despite the fact that we asked an open-ended question and did not provide instruction on ICMJE definition as accepted authorship criteria in biomedicine, most of the reported contributions matched those described in the ICMJE definition of authorship. However, only 15.6% of the authors whose contributions could be matched to ICMJE definition satisfied all three ICMJE criteria. Further 38.6% declared contributions exclusively to the first two ICMJE criteria (research and writing). As authors made this declaration on a signed statement after manuscript submission, it can be assumed that they gave approval to the manuscript submitted to the journal. If their signature is then taken as a fulfillment of the third ICMJE criterion, the overall fraction of deserving authorship according to the ICMJE increases to 54.2%, which is similar to the results of our previous studies (range from 39% to 75%) that were based on the ICMJE definition and which had different study designs [9-12]. Approval of the manuscript can be regarded as something that is outside of the creative effort of researchers, and it can even be impossible to obtain in cases when one of the researches dies before the final version of the manuscript is finished. Today many journals require contact e-mails from all of the listed authors, subsequently informing them that the corresponding author had submitted an article in their name. Consequently, this makes the final approval a procedural requirement, and not necessarily a criterion for authorship contribution.

The lack of regard for final approval as a criterion for deserved authorship observed in this study, which had a cross-sectional design and did not refer to the ICMJE criteria, confirms the results of our previous study where we showed in a randomized study design that the "final approval of the article" was an inherently different category from other contributions and that it should be considered rather as an administrative requirement similar to signing of a copyright transfer [11]. Furthermore, our recent analysis of journals from different research fields, including social sciences and humanities, also demonstrated that authorship definitions by journals, publisher and professional organizations or associations mostly addressed research and/or writing as contributions necessary for authorship [14]. In our study, authors who declared a single contribution that could be matched to an ICMJE criterion, declared research contribution more often (in 31.8% cases) than writing contribution (in 9.4% cases).

The "fractionation" of authorship into more contribution categories was evident in multi-authored articles, where the number of contributions declared increased in manuscripts with more than 8 authors and specifically in those where authors declared ICMJE matching contributions. Taken together with the finding that overall, non-ICMJE matching contributions were more frequent in manuscripts with few authors (1–3 per byline), this indicates that authors from smaller research collaborations do not see the need to elaborate on their contributions, as their role in research presented is clear. In larger collaborative groups, contribution declaration seems to require a coordinated effort, particularization and careful distribution of contributions. Our study was not designed to check whether each individual author really filled in the form (although each was separately signed by individual authors), but the finding that manuscripts with more than 6 authors had more declaration forms with identical wording of the declarations indicates that filling in the forms could either be a centralized effort to formally satisfy journal's requirements or that authors simply copied from each other, without engaging in truthful elaboration of their contributions. Different behavior in authorship declaration with increasing number of authors on manuscripts can also be related to the current publishing practices in biomedicine, where the number of authors was not perceived as an important issue for academic performance, in contrast to the position on the byline and the journal's impact factor, explaining at least in part the increase in the number of authors per publication [15].

Single authors or authors of manuscripts with 2 to 4 authors had most ICMJE non-matching contribution statements. These authors usually stated that they made a significant contribution, without any specification, or they disclosed their professional expertise in the field. These statements, however, cannot be taken to imply undeserved authorship; they rather suggest differences in perceptions of the authors to the established criteria for authorship and the means of their reporting.

Despite the fact that our authorship forms had a required line where the authors had to sign their name if they agreed to be listed as an author in the submitted manuscript; a small number of authors, who answered our authorship question with only a "Yes", most likely perceived that question as just another required confirmation of their authorship. Perception of authorship declarations as a form of external check-list necessary for manuscript submission is also supported by the finding that almost a third of the respondents in our study did not use full or partial sentences to a question that required an answer in the form of a sentence. Providing a list of contributions instead of a sentence may be the result of authors' experience and familiarity with the prevalent practice in biomedical journals to formulate their contribution declarations as checklists.

Conclusion

Based on our previous research into authorship [9-12], particularly our finding that authorship is not a normative issue subjective to categorization into criteria, but a very personal view of the importance and value of one's contributions [13], we hypothesized that journals should ask the authors a simple questions "Why do you think you deserve to be the author of this manuscript?" [9]. The current study demonstrated that such an open-ended authorship declaration without instructions on any available authorship criteria elicits responses from authors that are similar to responses when the ICMJE criteria are explicitly required. Contribution declaration is especially problematic in multi-authored collaborative research efforts. Taken together with the results of our recent systematic review on authorship research [1], particularly the disappointing findings that the practice of contribution declaration has not reduced the number of authors on the byline [16,17], there is enough evidence that current authorship criteria in medicine are not adequate and that they should be revised to capture those deserving authorship in biomedical research. We believe that obligatory inclusion of authorship issues in research education, as well as planning of authorship during the development of research protocols would enable fair recognition of all contributions to the research effort. The task of journal editors in this system would not be that of regulating authorship criteria and monitoring authorship eligibility, but that of maintaining public trust in the research enterprise by ensuring the transparency of the authorship decision process.

Additional files

Additional file 1: Table S1. Contribution declarations of authors (n=98) whose free text authorship statements included both ICMJE matching and non-matching contributions.

Additional file 2: Table S2. Sentence structure of authors' answers (n=1282) to the open-ended question: Why do you think you should be the author on this manuscript?

Additional file 3: Figure S1. Distribution of manuscripts with (closed bars) or without (open bars) identical contribution declarations from at least 2 authors according to the number of authors on the manuscript.

Competing interests

At the time of the study, A. Marušić and M. Marušić were Coeditors in Chief of the *Croatian Medical Journal*. The authors declare that they have no competing interest.

Authors' contributions

MMal – Created the database, matched authors statements to ICMJE criteria, performed parts of descriptive statistics, interpreted results, drafted the abstract and tables, revised the initial draft of manuscript, and approved the final version of the manuscript. AJ – Helped create the database, performed statistical analysis, interpreted results, drafted the methods section and prepared figures, revised the initial draft of manuscript, and approved the final version of the manuscript. MMar – Conceived and designed the study, acquired data, coordinated coauthors, interpreted results, revised the initial draft of manuscript, and approved the final version of the manuscript. AM – Conceived and designed the study, reviewed matching of authors statements to ICMJE criteria, performed literature review, interpreted results, drafted the initial manuscript, revised the coauthors inputs and additions, and approved the final version.

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Study Design, Publication Outcome, and Funding of Research Presented at International Congresses on Peer Review and Biomedical Publication

The first International Congress on Peer Review and Biomedical Publication (PRC) was organized in 1989 to "subject the editorial review process to some of the rigorous scrutiny that editors and reviewers demand of the scientists whose work they are assessing."[1] Since then, peer review research was introduced as a Medical Subject Heading (MeSH),[2] and the number of indexed articles has been continuously increasing. To evaluate the development of peer review research in biomedicine, we analyzed research presented at all PRCs since 1989.

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Related articles pages 1045 and 1063

Methods | We established a retrospective cohort of PRC poster and podium abstracts and used author names to search the PRC's website, Web of Science (WoS), and PubMed for full articles through August 20, 2013. We collected data on authorship, time to publication, declared funding sources, article availability, and citation counts in WoS. Two authors classified study design independently, with acceptable agreement ($\kappa = 0.78$). Data were analyzed using MedCalc; 2-sided significance testing included χ^2 tests and Kruskal-Wallis test (type I error was set to $P < .05$).

Results | Of 614 presented abstracts, 75% described observational studies; 18%, intervention studies, and 7%, opinion pieces (**Table 1**). Over time, the number of opinion pieces decreased from 17 in 1989 to 1 in 2013 (χ^2_1 for trend = 47.3, $P < .001$). The number of cohort studies increased from 0 in 1989 to 8 in 2013 ($\chi^2_1 = 10.7$, $P = .002$). Feasibility studies increased from 1 in 1989 to 20 in 2013 ($\chi^2_1 = 11.3$, $P < .001$). The median number of abstract authors increased from 1 (95% CI, 1-1) in 1989 to 4 (95% CI, 4-5) in 2013 ($P < .001$). Of the 504 abstract presentations from the first 6 PRCs, 305 (61%) led to 294 published articles (**Table 2**). From abstract presentation to publication, there were no changes in the byline order or number of byline authors in 166 abstracts (56%), whereas 83 abstracts (28%) had changes in the number of authors listed and 45 (15%) had changes in the byline order. One hundred fourteen articles (38%) were published in *JAMA*, 21 (7%) in *BMJ*, 12 (4%) in *Annals of Emergency Medicine*, and 8 (3%) each in the *Journal of Clinical Epidemiology* and in *PLoS ONE* (Table 2). The median time to publication was 14 months (95% CI, 12-16), when excluding 110 articles in *JAMA* theme issues. One hundred articles (63%) were freely available online.

Funding was reported in 106 (36%) published articles that had been presented as abstracts at the 1989-2009 PRCs and in 45 abstracts (41%) presented at the 2013 PRC, most commonly from public or charity sources (Table 1). The absolute number and proportion of articles with declared funding increased over time, with a peak in 2005 (Table 2).

Two hundred eighty-four published articles (97%) were indexed in WoS; 265 (93%) of them received at least 1 citation, with a median of 20 (95% CI, 17-27) citations per article. Articles with the most citations were on a reporting guideline for health research[3] (published in 17 journals; n = 1798 citations), synthesis of evidence[4] (n = 1016), and publication bias[5] (n = 547).

Discussion | Peer review research uses various study designs and is published in a broad spectrum of journals. However, experimental studies aimed at improving methods of peer review and reporting of biomedical research are still underrepresented. Although the peer review research community is aware of the consequences of nonpublication of research,[6] 39% of studies presented at PRCs have not been fully published. In our cohort, we were unable to determine whether the underreporting was selective (eg, favoring positive results) and were not able to determine its causes. Lack of suitable journal outlets is an unlikely explanation because there was no decrease in publication output after *JAMA* ceased its PRC theme issues in 2005. Because our cohort represents research presented for more than 20 years at the discipline's major meeting, it may have limited generalizability to research presented elsewhere.

Peer review and other editorial procedures have the potential to significantly influence the knowledge base of health care. Despite their critical role in biomedical publishing, methods of peer review are still underresearched and lack dedicated funding. Systematic and competitive funding schemes

Table 1. Study Designs, Publication Proportion, and Funding Sources of Research Presented at International Congresses on Peer Review and Biomedical Publication (PRC), 1989-2013

	1989-2009 PRCs		2013 PRC[a]
Study Design	No. of Abstracts Presented (Column %)	No. of Abstracts Published as Articles (Row %)	Total No. of Abstracts (Column %)
Total	504 (100)	305 (61)	110 (100)
Observational studies	383 (76)	239 (62)	79 (72)
Surveys, of documents or persons	238 (47)	149 (63)	42 (38)
Cohort studies	25 (5)	13 (52)	8 (7)
Case-control studies	5 (1)	2 (40)	0 (0)
Time series studies	19 (4)	14 (74)	5 (5)
Systematic reviews	17 (3)	13 (77)	5 (5)
Qualitative studies	10 (2)	5 (50)	5 (5)
Other observational studies[b]	69 (14)	43 (62)	14 (13)
Intervention studies[c]	81 (16)	47 (58)	30 (27)
Randomized trials	27 (5)	22 (81)	5 (5)
Nonrandomized studies	25 (5)	11 (44)	5 (5)
Feasibility/pilot studies	29 (6)	14 (48)	20 (18)
Opinion pieces	40 (8)	19 (48)	1 (1)
Funding source[d]		No. of Abstracts Published as Articles (Column %)	No. of Abstracts (Column %)
Total		294 (100)	110 (100)
None declared		163 (55)	53 (48)
No funding		25 (9)	12 (11)
Funding received		106 (36)	45 (41)
Public/government		47 (16)	21 (19)
Private foundations/charity		24 (8)	13 (12)
Internal sources/salary		13 (4)	4 (4)
Publisher/journal		10 (3)	1 (1)
University		9 (3)	1 (1)
Industry		2 (1)	1 (1)
Multiple sources		1 (0)	4 (4)

[a] Data on studies presented at 2013 PRC were extracted from abstracts.

[b] Including noncomparative studies.

[c] Including before-after studies.

[d] Funding information for research presented at PCRs from 1989 to 2009 was available only from published articles; in 2013 funding was published in abstracts.

Table 2. Publication Output, Country of Origin, Declared Funding and Subsequent Citations of Studies Presented at International Congresses on Peer Review and Biomedical Publication, 1989-2013

			Articles Published[b]			WoS Citations to Articles[c]	
Congress	No. of Countries Represented[a]	Abstracts Presented	Theme Issue	Regular Publications	Declared Funding[d]	Total per Meeting	Median per Article (95% CI)
Chicago 1989	5	45	21	13	7	1955	42 (33-87)
Chicago 1993	9	56	24	17	7	3136	32 (18-49)
Prague 1997	20	93	34	16	14	2827	41 (29-54)
Barcelona 2001	21	106	31	27	21	2501	22 (15-34)
Chicago 2005	18	93		63	32	1859	18 (11-27)
Vancouver 2009	24	111		59	25	633	6 (3-8)
Chicago 2013	19	110			45		

Abbreviation: WoS, Web of Science.

[a] As stated in authors' affiliations in the abstracts.

[b] In 11 instances 2 presented abstracts were later published as a single article. Articles from Chicago 1989 were published either in a monograph[1] (n = 10), both in the monograph and a journal (*JAMA*, n = 21), or only in journals (n = 3). *JAMA* stopped publishing theme issues since Chicago 2005.

[c] Web of Science (WoS) was used as citation data source because it covered the whole period of the Peer Review Congresses. Searches were performed on August 19 and 20, 2013.

[d] Funding information was obtained from published articles for 1989-2009 Congresses and from abstracts for the 2013 Congress (χ_1^2 for trend = 22.2, $P < .001$).

are needed to build and sustain excellence, innovation, and methodological rigor in peer review research.

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Author Contributions: Dr Marušić had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: von Elm, Marušić.
Acquisition of data: all authors.
Analysis and interpretation of data: all authors.
Drafting of the manuscript: all authors.
Critical revision of the manuscript for important intellectual content: all authors.
Statistical analysis: Malički.
Administrative, technical, and material support: Malički, Marušić.
Study supervision: von Elm, Marušić.

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COMMENT & RESPONSE

Mortality in Patients With Hypovolemic Shock Treated With Colloids or Crystalloids

To the Editor The Colloids vs Crystalloids for the Resuscitation of the Critically Ill (CRISTAL) trial[1] found no difference in 28-day mortality but improved 90-day mortality in patients in the intensive care unit (ICU) with hypovolemic shock resuscitated using colloids (mainly hydroxyethyl starch solutions) vs crystalloids (mainly isotonic saline). The CRISTAL trial was unblinded and allocation of patients occurred by envelope randomization using fixed block size, which may not have ensured allocation concealment.

That adequate randomization may have failed and allocation of patients into the 2 intervention groups may have been skewed in the CRISTAL trial is supported by marked baseline imbalance in the numbers of patients that received crystalloids and colloids in the 12 hours prior to randomization. In a large trial like CRISTAL, such differences are unlikely to occur by chance. Lack of allocation concealment and blinding can introduce bias, which often leads to overestimation of intervention effects.[2]

Bias is also suggested because the results of the CRISTAL trial contrast with those of other recent trials with low risk of bias[3,4] and a systematic review[5] that showed increased use of renal replacement therapy, increased mortality, or both, with hydroxyethyl starch.

Interpretation of the CRISTAL trial[1] is further complicated by the variety of colloid and crystalloid solutions used in the 2 intervention groups. In addition, randomization may not have been preserved in the subgroup analyses by type of fluid received because the allocation to different types of fluids may have depended on trial site in addition to randomization.

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To the Editor The CRISTAL trial[1] requires scrutiny because its results contradict other high-quality evidence.[2] The CRISTAL trial was stopped for futility based on no difference in 28-day

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ORIGINAL ARTICLES

Is there a solution to publication bias? Researchers call for changes in dissemination of clinical research results

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Abstract

Objectives: To explore opinions of authors of published reports of clinical trials and Cochrane systematic reviews on the causes and methods of preventing publication bias.

Study Design and Setting: An online questionnaire was developed and sent to researchers publishing in high-impact or national general medical journals, authors of Cochrane systematic reviews, and a general population of researchers. Open-ended questions about publication bias were qualitatively analyzed. We also held a focus group with experienced researchers and/or Cochrane reviewers.

Results: Publication bias was common: 48 (36%) respondents had own unpublished trials and 40 (30%) admitted selective outcome reporting; but researchers felt strongly that blame rested also with the system that promotes and augments publication bias practices. Qualitative analysis of both survey responses and focus group discussion identified possible ways of reducing publication bias through increased transparency, improvements to trial registries, search engines and databases, enhancement of the role of institutional review boards, positive encouragement of scientists, and policy changes.

Conclusion: Although well aware of the problem, clinical researchers knowingly contribute to problems of selective reporting and nonpublication of trials. They call for changes in current practices of journal-based communication of trial reporting and for systematic evaluation of measures to decrease publication bias.

Keywords: Publication bias; Clinical trials; Guideline adherence; Questionnaires; Focus groups; Information dissemination

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1. Introduction

Results from clinical trials are necessary to provide unbiased information for making decisions about medical therapies and diagnostic procedures. Yet, despite the need for greater transparency of clinical research and recent strong initiatives to increase this transparency, for example, mandatory registration and posting of results from clinical trials [1,2], there is still a long way to go before 100% of studies are published [3]. Recently updated systematic review on biases in clinical trials [4] confirmed that the extent of publication bias remains unchanged and that studies with significant or positive results are more likely to be published. The blame has been put on investigators as "*almost all failure to publish is due to the failure of investigators to submit reports for publication*" [5]. Even Cochrane Collaboration researchers—experts acutely aware of publication bias—publish only about a third of results presented at annual meetings [6].

Despite a number of studies investigating the prevalence and causes of nonpublication [7−11], investigators have not been asked about possible solutions. To address this knowledge gap and contribute to the discussion on how to achieve full transparency of clinical research [3], we used an online survey to assess how clinical researchers and Cochrane systematic reviewers explain the reasons behind publication bias and propose methods to prevent it. We further explored the themes that emerged in the survey in a focus group discussion held at a research conference on transparency in health research.

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What is new?

- Clinical researchers from 41 countries reported high rates of nonpublication of their own trials (36%) and admitted to selective reporting of trial results (30%), confirming that publication bias remains a serious problem.
- Researchers are aware of being the main culprits for publication bias but feel strongly that the blame rests with the system that allows such practices — from research funders and institutions to journals and trial registries.
- To preserve the integrity and transparency of clinical research, researchers call for radical changes in the process of communicating the trial results to the professional and general public, including legal actions and alternatives to journals.

2. Methods

2.1. Survey development and data collection

A questionnaire (Appendix A at www.jclinepi.com) was developed based on previous surveys on publication bias [7]. The term "clinical trial" used in the survey was defined as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." The types of publication bias addressed in the survey were "publication or nonpublication of research findings, depending on the nature and direction of the results; duplicate publications from the same patient data sets; and selective reporting of outcomes."

The questionnaire was piloted for content and face validity among a convenience sample of eight experienced researchers and revised according to comments and suggestions.

The questionnaires were sent out using the SurveyMonkey platform. The survey was performed using the total design method for mailing procedure [12]. No incentives other than information on the results of the surveys and on the OPEN (Overcoming the failure to Publish nEgative fiNdings) project were offered for completing the surveys.

2.2. Survey respondents

Four target groups were identified: (1) researchers who had published their trial(s) in high-impact journals ($n = 452$), (2) researchers who had published in European national medical journals ($n = 331$), (3) authors of Cochrane systematic reviews ($n = 452$), and (4) a general population of researchers. Details of the search strategy by which we obtained e-mail addresses of potential respondents are available in Appendix B at www.jclinepi.com. Of 1,299 collected addresses, 35 bounced back and 45 were set to automatically reject e-mails from the SurveyMonkey platform. General population of researchers had access to the survey at the Web site of the OPEN project (www.open-project.eu).

2.3. Content analysis of survey responses

Each survey included seven open-ended questions where respondents could leave comments and elaborate their answers to the other survey questions. Both authors read all responses independently and grouped them according to the type of suggestion or opinion on publication bias. All discrepancies were discussed and agreed on for final interpretation.

2.4. Focus group

We also organized a focus group during EQUATOR Scientific Symposium 2012, "ACT now: Accuracy, Completeness, and Transparency in health research reporting", held in Freiburg, Germany, 11–12 October 2012 (information on the meeting is available at http://www.equator-network.org/courses-events/equator-scientific-symposium-2012/). At the start of the focus group, participants were given a short anonymous questionnaire, which included a definition of publication bias and questions on sociodemographic factors and publication experience. After a brief introduction, the participants were asked "What could be the reasons for failing to publish results of completed trials?" After no new information could be gained, the interviewers moved to the question "What are the ways to identify, diagnose and prevent publication bias?", and finally to "What do you think about public access to trials, research information, Masters and PhD theses and ethical board reviews?" All respondents' answers were audio recorded and transcribed verbatim. The content analysis followed the same procedure as that of the online survey.

3. Results

3.1. Online survey

The response rate, up to the end of December 2012 when the survey was closed, was 8% (33 of 441) from researchers who had published in high-impact journals, 7% (21 of 310) from authors in national general medical journal, and 14% (64 of 468) for Cochrane reviewers. We also received 64 responses via the OPEN Web site. The main characteristics of the respondents are presented in Table 1. The respondents had experience in conducting clinical trials, which were mostly investigator driven and mostly either publicly funded or not funded (Appendix C at www.jclinepi.com). More than a third (36%) had

Table 1. Characteristics of survey respondents[a]

	Respondents (*n*, column %)				
Characteristics	**Cochrane reviewers (*n* = 64)**	**Authors in national journals (*n* = 21)**	**Authors in high-impact journals (*n* = 33)**	**Respondents of open web survey (*n* = 64)**	**Total (*n*, row %) (*n* = 182)**
Age (yr)					
18–30	2 (3)	0	0	4 (6)	6 (3)
31–40	17 (27)	8 (38)	4 (12)	9 (14)	38 (21)
41–50	21 (33)	5 (24)	12 (36)	21 (33)	59 (32)
51–65	21 (33)	8 (38)	11 (33)	25 (39)	65 (36)
>65	3 (5)	0	6 (18)	5 (8)	14 (8)
Gender					
Male	34 (53)	15 (71)	21 (64)	38 (59)	108 (59)
Female	30 (47)	6 (29)	12 (36)	26 (41)	74 (41)
Employment					
University or college	31 (48)	7 (33)	16 (48)	22 (34)	76 (42)
Hospital or medical school	20 (31)	13 (62)	7 (21)	29 (45)	69 (38)
Research institution	8 (13)	0	6 (18)	6 (9)	20 (11)
Government	1 (2)	1 (5)	2 (6)	0	4 (2)
Commercial and/or corporate	1 (2)	0	1 (3)	2 (3)	4 (2)
Other[b]	3 (5)	0	1 (3)	1 (2)	5 (3)
Job description					
Senior researcher	31 (48)	8 (38)	26 (79)	30 (47)	95 (52)
Researcher	23 (36)	12 (57)	4 (12)	17 (26)	56 (31)
Doctoral/Research fellow	5 (8)	0	1 (3)	6 (9)	12 (7)
Postdoctoral fellow and/or resident	2 (3)	1 (5)	2 (6)	3 (5)	8 (4)
Consultant	3 (5)	0	0	0	3 (2)
Ethics committee member	0	0	0	2 (3)	2 (1)
Nurse	0	0	0	1 (2)	1 (1)
Drug company employee	0	0	0	1 (2)	1 (1)
Area of research and publishing[c]					
Clinical research	52 (81)	18 (86)	27 (82)	48 (75)	145 (80)
Public health	15 (23)	2 (10)	5 (15)	14 (22)	36 (20)
Basic biomedical research	4 (6)	5 (24)	2 (6)	3 (5)	14 (8)
Other[d]	11 (17)	0	2 (6)	6 (9)	19 (10)

[a] Survey respondents came from 41 countries: Albania, Australia, Austria, Belgium, Brazil, Canada, Croatia, Denmark, Egypt, Equatorial Guinea, Finland, France, Germany, Guinea, Greece, India, Ireland, Italy, Kenya, Lithuania, Macedonia, Malta, Mexico, Netherlands, New Zealand, Nigeria, Pakistan, Portugal, Romania, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States. There were no statistically significant differences among groups in any characteristic (*P*-value range: 0.072–0.467; χ^2 test). Four respondents (6%) to the survey on the OPEN project Web site did not provide demographic data, so that the percentages for that group and for the total sample do not add to 100% but to 98%.

[b] Includes Cochrane Collaboration, Health Technology Assessment Agency, National Institute for Public Health, European Technical Agency.

[c] Survey respondents could check more than one answer; all percentages are to the total number of respondents in the group.

[d] Includes research methodology, evidence synthesis, implementation research, observational research, safety and health, biostatistics, ethics, health services research, health technology assessment.

unpublished clinical trial(s), and 30% had participated in trial(s) with selective reporting of outcomes or analyses (Appendix C at www.jclinepi.com). Respondents listed lack of time as their main reason (44%) for not publishing clinical trial results, followed by methodological problems, such as sample size or study quality (38%), and perceived unimportance of the results (25%; Appendix C at www.jclinepi.com).

Publication bias had been encountered by 66% of the respondents while working on a Cochrane review and by 44% when reviewing articles for journals. Only 4% thought publication bias did not constitute a problem (Appendix C at www.jclinepi.com).

The respondents expressed doubts that the current practice of trial registration and posting of trial results in public databases would decrease publication bias (Table 2). Most of the respondents were in favor of transparency of research from access to the full protocol (57%) to existence of a trial (73%), but only 25% favored access to individual patient data (Table 3).

3.2. Content analysis of respondents' comments

Respondents could leave comments for seven questions. As answers to individual questions often addressed issues raised in other questions and we found no differences in responses between those with and without experience of conducting clinical trials (*P*-value range: 0.139–0.938, χ^2 test), we analyzed all comments together and grouped them according to three themes: reasons for publication bias, importance of publication bias, and ways of reducing publication bias.

Table 2. Opinions of survey respondents on the current practice of registration of trials and means of decreasing publication bias

Opinion	Cochrane reviewers, n (%) (n = 64)	Authors in national journals, n (%) (n = 20)	Authors in high-impact journals, n (%) (n = 32)	Respondents of open web survey, n (%) (n = 49)	Total, n (%) (n = 165)
Opinions on the current practice of registration of trials and posting of their results in a public registry					
These measures will greatly decrease publication bias	29 (45)	8 (40)	15 (47)	18 (37)	70 (42)
These measures are not enough to decrease publication bias	23 (36)	4 (20)	13 (40)	21 (43)	61 (37)
I don't know	12 (19)	8 (40)	4 (13)	10 (20)	34 (21)
Opinions on whether reporting bias can be decreased by making results of trials public in outlets other than journals					
Yes, there should be outlets other than peer-reviewed journals for the results from clinical trials	38 (59)	6 (30)	16 (50)	26 (53)	86 (52)
No, peer-reviewed journals are the best quality check for a publication	18 (28)	9 (45)	13 (41)	16 (33)	56 (34)
No opinion on this issue	8 (13)	5 (25)	3 (9)	7 (14)	23 (14)
Opinions on whether there are other ways to decrease publication bias					
I don't know	29 (45)	15 (75)	17 (53)	26 (53)	87 (53)
Yes	31 (48)	5 (25)	13 (40)	18 (37)	67 (41)
No	4 (6)	0	2 (6)	5 (10)	11 (7)

3.2.1. *Reasons for publication bias*

Respondents expressed strong views that current publication practices, such as trial registration which is “*required by an insufficient number of journals*” and the “*peer review concept in general*,” greatly contribute to publication bias and are the major reasons for its existence. Many stressed journals' willingness is to only “*publish significant, illustrative and* ‘*spectacular*’ *findings*.” This, respondents wrote, in turn makes authors accomplices as they do not want to “*waste their time trying to publish a manuscript that they know will be rejected*.” Respondents acknowledged their reasons for nonpublication: “*Some failure to publish may be deliberate (eg, the results are not as hoped and a decision is made to not publish*). I think more work is left unpublished because researchers collect more data than they a) need and b) can deal with and report.”

Finally, respondents mentioned that the interplay of individual and systemic publication practices keeps the bias flowing.

3.2.2. *Importance of publication bias*

Many respondents wrote that nonpublication represents a serious problem for health care, that it is “*unethical*” and should be considered a form of “*scientific misconduct*” as it “*fails to honour the commitment of participants to contribute to generalizable knowledge*” and the obligation it holds toward “*junior researchers*” and “*funders*.”

There was a single strongly dissenting response from an author from a European journal who thought that bias is not important and meta-analyses were inherently wrong (Appendix D at www.jclinepi.com).

3.2.3. *Ways of reducing publication bias*

Many respondents made general suggestions for reducing publication bias, such as “*more careful data collection and more sympathetic funding*,” “*adequate training of researchers*,” “*an increase in the awareness of the scientific community*,” “*pressure from funding agencies*,” “*breaking the association between significant results and impact factor*.” However, many also suggested more specific actions, especially concerning publication practices and their transparency, improvements to trial registries, search engines and databases, enhancement of the role of institutional review boards, positive encouragement of scientists, and the need for policy changes (Table 4).

3.2.3.1. *Improving publication practices and their transparency*.

Most of the respondents' comments were directed toward current publication practices. Several suggested that results of clinical trials should be kept in databases independent of journals and that “*the results should be commented in journals by experts without conflicts of interest*.”

The belief in transparency as a cure for publication bias can be summarized in the comment made by one of the respondents: “*Publication is less important than access*.” It was, however, recognized that transparency itself would not be enough and that *researchers* “*will need to be vigilant regarding other ways to manipulate study findings*.”

The peer-review process was heavily criticized. One respondent wrote “*there are too many journals engaging in* ‘*peer reviewed publication*’ *that falls far short of achieving this appellation*”, whereas another wrote “*peer review is a ridiculous requirement except as a post-publication review process*.”

3.2.3.2. *Improving trial registries, data depositories, and search engines*.

Respondents called for a greater functionality of already existing trial registers and bibliographical databases. They mentioned that the existing practice of registering trials and posting results in a public registry is “*not detailed enough*” and that it enables authors to “*manipulate results*.” One respondent also mentioned that the process of posting results in ClinicalTrials.gov “*is*

Table 3. Opinions of survey respondents on publication bias and aspects of trials that should be publicly available

Opinion	Cochrane reviewers, n (%) ($n = 64$)	Authors in national journals, n (%) ($n = 20$)	Authors in high-impact journals, n (%) ($n = 32$)	Respondents of open web survey, n (%) ($n = 49$)	Total, n (%) ($n = 165$)
Opinions on whether studies ought to be published regardless of their outcomes[a]					
Both intervention and observational clinical studies (cross-sectional, cohort, and case–control studies) should be published	59 (45)	15 (75)	28 (88)	39 (80)	141 (85)
Authors should decide whether they want to publish their results	0 (0)	8 (40)	4 (13)	8 (16)	20 (12)
Only intervention studies such as randomized clinical trials should be published	5 (8)	0 (0)	3 (9)	6 (12)	14 (8)
Sponsors of the study should decide whether they want to publish their results	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Opinions on which aspects of clinical trials should be publicly available[a]					
Existence of a trial	56 (88)	9 (45)	31 (97)	37 (76)	133 (81)
Results of primary outcomes in a scientific (peer-reviewed) publication	52 (81)	14 (70)	30 (94)	36 (73)	132 (80)
Summary of results	50 (78)	13 (65)	26 (81)	41 (84)	130 (79)
Summary of trial protocol	46 (71)	14 (70)	30 (94)	31 (63)	121 (73)
Results of other outcomes in a scientific (peer-reviewed) publication	45 (70)	13 (65)	27 (84)	28 (57)	113 (68)
Access to full protocol	51 (80)	8 (40)	18 (56)	26 (53)	103 (63)
Access to individual patient data	26 (41)	3 (15)	7 (22)	9 (18)	45 (27)
None	0 (0)	1 (5)	0 (0)	0 (0)	1 (1)

[a] Survey respondents could check more than one option; all percentages are to the total number of respondents.

horribly user-unfriendly." Some also suggested that registries be searchable through PubMed and other search engines and called for "*annual updates of all registered trials*." One respondent also suggested giving all data sets their own unique IDs, which would be quoted with each submission of an analysis from that data set.

3.2.3.3. Enhancing the role of funders and institutional review boards. Several respondents suggested that both funders and institutional (ethics) review boards be accountable for the studies they fund or approve and that they should "*satisfy themselves that previous trial results are fully disclosed before releasing further funding*."

Respondents suggested that researchers should "*be encouraged to publish*" through positive incentives, such as monetary rewards and metrics that are based on responsible publication practices, for example, "*rate the authors on a scale for each publication. A sort of author impact factor*." Others suggested that nonpublication be made "*socially unacceptable*" through education and research culture in general.

3.2.3.4. Making publication of trials a legal requirement. The second most common suggestion was to make publication mandatory by law, including enabling "*public access to trial details and results*." One respondent wrote: "Data related to public and patient health should NOT be proprietary information. It should be a criminal offense to hide information." Some expressed the need for additional precautions, such as authorities and health agencies having to "*follow-up and check the final reports of the clinical trials*," with the possibility of creating quality assurance systems or agencies to regularly monitor data analysis and reporting.

3.3. Focus group

Nine researchers took part in the focus group discussion, four men and five women, median age 38 (range: 30–60), eight from academic institutions and one from a public health organization. They had published a median of seven articles (range: 1–30) and six had registered a trial in a public registry. We were particularly interested in their suggestions that went beyond the answers provided in the online survey.

3.3.1. Reasons for publication bias

All participants emphasized bias of journals toward positive results but also reported on specific problems in developing countries, such as natural disasters or wars that may prevent publication. They also stressed that the invisibility of gray literature contributes to the biases in information synthesis. One participant mentioned that many trials only get partial funding or start underfunded, forcing trials to be stopped midway.

3.3.2. Means of reducing publication bias

One of the respondents suggested that better gender and age balance in editorial boards may reduce selective publication practices. A systematic reviewer called for regular updates of contact information of investigators. To increase the visibility of local research, one participant recommended educational and other initiatives that would

Table 4. Survey respondents' suggestions to reduce publication bias

Suggestions
Improve current state of publication practices
• Provide adequate training of researchers and peer reviewers
• Implement mandatory publication of trial protocols with complete analysis plans
• Implement reporting standards, including standards for reporting of conflict of interest
• Increase transparency of peer review and journal decision making practices
• Publish peer review comments alongside trial results
• Secure adequate age and sex representation in editorial and other bodies
• Increase importance and means of postpublication peer review
• Link trial registries, data repositories, publications, and postpublication comments with search engines and bibliographic databases
• Increase ease of use of existing trial and data repositories
• Implement annual updates of all registered trials
• Create additional result repositories
• Enable local and national trial registries accessible to the public
• Enable indexation of local and regional journals in international databases
• Provide funding schemes or secure parts of funding exclusively for publishing purposes
Increase accountability of all parties
• Funders and ethical review boards should monitor and be accountable for studies they approve/fund
• Ethical review boards should approve only those studies previously registered
• Principal investigators should be made accountable for nonpublication of their research
Change current publication practices
• Change the function of journals to one for synthesizing and commenting on trials reported exclusively in trial registries
• Create specific publishing platforms for clinical trials
• Enable accessibility of all documentation submitted to review boards and funders
• Refuse funding or research approval(s) to investigators with nonpublished trials
Make the required changes mandatory by law (including enforcement of sanctions)
Increase public awareness, monitoring, and involvement in publication practices

help smaller journals get indexed in international databases or be covered by search engines. One participant also suggested awareness be raised among health care consumers.

4. Discussion

Our study, which included authors of clinical trials and authors of Cochrane systematic reviews from 41 different countries, demonstrated that researchers are aware of being the main culprits of nonpublishing or selective publishing of results from clinical trials, as suggested by other stakeholders in the field [3,5,13]. However, they felt strongly that blame rested not solely with them but with the system that encourages and supports practices that lead to publication bias—from funders and research institutions to journals and trial registries.

The prevalence of publication bias reported in our study (30–66%) is in line with the findings of a recent systematic review on trial publication bias (publication rates of 21–93% of completed trials, and rates of 40–62% for selective reporting) [14]. Similarly, the respondents often mentioned reasons for publication bias that have been reported before, including the lack of time or funding, preference for results with statistically positive findings, weak trial methodology, and contractual obligation with the sponsors [9–11,13,15–17].

The primary limitations of our study are its low response rate, which is common in Internet surveys of health professionals [18]. We also had an unequal representation of industry-funded trialists. However, the aim of our study was not to replicate previous surveys of the prevalence of publication bias but to involve researchers in a discussion about publication bias. Furthermore, the results of the qualitative analysis of the survey responses were confirmed in a separate, methodologically rigorous focus group discussion. The respondents were probably more aware of and interested in the problem of publication bias than the nonresponders. But even in such a group of experts, the prevalence of reported nonpublication was similar to that in several studies performed since the 1980s [14]. The respondents in our study came from 41 countries, providing a global perspective on the problem of publication bias, whereas other studies which qualitatively explored the views of editors on publication bias [13], experienced genetic scientists [19], or trialists on outcome reporting bias [17] included respondents from developed countries, such as the United States and the European Union countries.

The fact that most respondents felt that nonpublication was unlikely to be prevented solely by mandatory trial registration (currently required by only 16–33% of journals [13]) or mandatory registration of trial results [20] could have contributed to the multiple approaches they suggested for reducing publication bias, especially their request for a top–down approach. Respondents were clearly dissatisfied with the current voluntary initiatives to increase transparency of clinical trials' existence and results [1,21]. For example, despite the general approval of mandatory trial registration, the uptake of this policy by journals from many medical disciplines remains poor [22]. Registered trials are predominantly small and single centered, with significant heterogeneity in methodological approaches, such as blinding, randomization, and the use of a data-monitoring committee [23]. With rare exceptions [24], institutional (ethics) review boards still generally do not require trial registration and results posting [20]. Finally, progress in the transparency of clinical trials has not yet reached developing countries, where trial registration is still uncommon [25] and researchers face numerous barriers to trials' regulations [26]. Our respondents thus felt that publication bias could be minimized only when multiple existing practices are changed at the same time, transparency of the whole process is achieved, innovative approaches to finding and sharing data are implemented, and public and researchers' awareness of the importance of publication bias is increased. This multifaceted approach has also been recently advocated by prominent scientists and journal's editors discussing waste in health research [27]. Perhaps the most radical proposition was to drastically change the current publication practices, for as one respondent wrote "*Publication is less important than access.*" Respondents called for moving away from the current publishing system in which journals are the main outlets for results dissemination to other platforms, such as national or international registries. This proposition is similar to existing practices in other disciplines. In physics, researchers use a preprint publishing platform, the "arXiv" database, to exchange and test their research before they submit it to journals [28]. Some researchers never publish their work in a journal even when the research has proved to be very influential [29]. It may seem impossible that medical researchers would ever want to send their work to such user-driven services because of the fear that medical journals would not wish to publish such "previously published" results. The International Committee of Medical Journal Editors had to accommodate the legal regulation of mandatory results posting in the United States by changing its definition of what constitutes prior publication: they still do not consider abstracts that have a table and less than 500 words as a barrier to publication, but they restrict this waiver only for results posted in the same clinical trial registry as the initial registration [30]. In other competitive biomedical fields, such as genetics, some researchers have started posting their articles in arXiv [31]. They say that they are not concerned about priority claims as they have learned that research communities count arXiv publication as the first publication and journal reviewers use arXiv to check correct attributions [31]. With reassurances from journal editors that mandatory registration of trial results will not prevent further publishing of the results in other media, the development of trial dissemination services may be realistic.

Any future action aiming to increase the transparency of clinical research such as the *AllTrials* campaign, which calls for all trials to be registered and all results to be reported, for example, by posting clinical trial reports [3], should give serious consideration to the views of authors and researchers as crucial stakeholders in clinical research and its dissemination. Above all, any policy change should, in the words of one of the respondents, "evaluate the effects of these measures to see whether reporting bias will be decreased effectively."

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Appendix

Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jclinepi.2014.06.002.

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