HOW TO PUBLISH A RESEARCH PAPER IN A MAJOR BIOMEDICAL JOURNAL

University of Zagreb – School of Medicine, Andrija Štampar School of Public Health and Charité – Universitätsmedizin Berlin, Institute of Public Health

arite – Universitatsmedizin Berlin, Institute of Public Hea

also in affiliation with

the Berlin School of Public Health

Course Directors: Assistant Professor Kristina Fišter (MD, MSc, DSc) Professor Tobias Kurth (MD, ScD)



What to expect in the next three days

Lecturers

Kristina Fišter (MD, MSc, DSc), Assistant Professor, Andrija Štampar School of Public Health

Tobias Kurth (MD, ScD), Professor, Director of the Institute of Public Health at the Charité

Pero Hrabač (MD), Assistant, PhD Candidate **Marco Piccininni**, MSc Statistician, PhD Candidate

Danko Relić (MD), Assistant, PhD Candidate **Jessica Rohmann**, MSc Epidemiologist, PhD Candidate

Day 1: Wednesday 22nd May 2019

0.00-11.30	What editors want (K. Fišter, Lecture)
1.45-13.15	Electronic data capture (K. Fišter, Lecture with demonstration)
4.15-15.45	Searching biomedical literature (D. Relić and P. Hrabač, Practical)
6.00-17.30	Managing citations and references (D. Relić and P. Hrabač, Practical)

Day 2: Thursday 23rd May 2019

10.00-11.30	Common study designs (T. Kurth, Lecture)
11.45-13.15	Introduction to R/R Studio interface (J. Rohmann and M. Piccininni, Practical)
14.15-15.45	Causal inference (T. Kurth, Lecture)
16.00-17.30	Descriptive statistics using R (J. Rohmann and M. Piccininni, Practical)

Day 3: Friday 24th May 2019

10.00-11.30	Analytical tools, epidemiological/statistical methods (T. Kurth, Lecture)
11.45-13.15	Data analysis in R: part 1 (J. Rohmann and M. Piccininni, Practical)
14.15-15.45	Data analysis in R: part 2 (J. Rohmann and M. Piccininni, Practical)
16.00-17.30	How to write: from protocol to research paper (K. Fišter, Lecture)
17.45-18.30	Exam



What editors want

Kristina Fišter (MD, MSc, DSc)

Assistant Professor, Head of the Division for Medical Informatics

University of Zagreb, School of Medicine, Andrija Štampar School of Public Health



Thanks and credit to my editorial mentors

Ana i Matko Marušić @

Croatian Medical Journal (2002-2004)

Fiona Godlee

Trish Groves

John Fletcher, and many others! @

BMJ (2004-2019)

Diane Kelsall

Kirsten Patrick et al @

CMAJ (2017-present)





















"The Big Five"



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

MEETING OF THE EUROPEAN HEART RHYTHM ASSOCIATION

Early or Delayed Cardioversion for AF

N.A.H.A. Pluymaekers and Others

Patients presenting within 36 hours after the onset of atrial fibrillation were randomly assigned to undergo early cardioversion

or to receive rate-control medication followed by delayed cardioversion within 48 hours if there was no conversion to sinus rhythm. The wait-and-see approach was noninferior to early cardioversion for the primary outcome of sinus rhythm at 4 weeks.

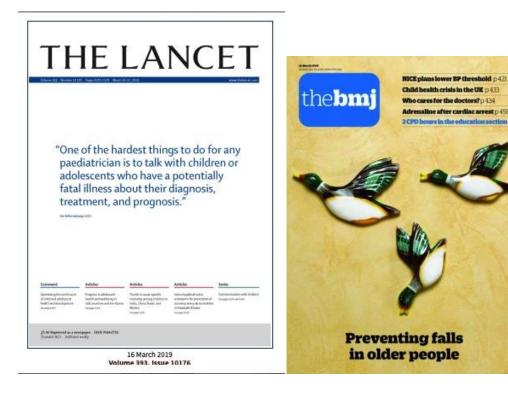
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7 Original Investigation

March 19, 2019

Associations of Dietary Cholesterol or Egg Consumption With Incident Cardiovascular Disease and Mortality

Victor W. Zhong, PhD¹; Linda Van Horn, PhD¹; Marilyn C. Cornelis, PhD¹; et al







Contents Annals of Internal Medicine*

357

36.9

1-10

380

Original Research

Predicting Bleeding Risk to Guide Aspirin Use for the Primary Prevention of Cardiovascular Disease. A Cohert Study

V. Saisi, R. Jackson, K. Poppe, B. Wu, M. Harvesod, C. Grey, R. Pylypchuk, S. Mikris, A. Kum, and S. Wells Several prognostic models estimate potential cardiovascular banelita of using applicit for primary prevention. This prognestic model estimates bleading tilk among persons in whom applith may be considered for primary prevention.

Comparative Efficacy of Therapies for Troatment of Depression for Patients Undergoing Maintenance Homodialysis. A Randomized Clinical Trial

R. Mahretz, D. Cakor, M. Umrih, T. Nau, P. Haugerty, S.D. Cohan, L.M. Damber, Y. Diz-Linitar, A. Duboniy, T. Graven, N. Greis, N. Kuter, M. H. Thiwel, D.K. Gainen, N. er Halan, S.D. Wielkord, B.A. Young, P.I. Kirmal, and S.S. Hadspati Nearly 2016 of patients undergoing maintenance hemodialysis have symptoms of depresation, but most do not resolve treatment for this condition. This multicarier, randomized controlled trial auximized whether an angugement hateriew increased hemodialysis patients' Willingtone to be treated for depresation and thes compared the efficacy and safety of

cognitive behavioral therapy versus aartraline treatment. Summary for Patients

A Cost-Effectiveness Analysis of Vactination for Prevention of Herpes Zoster and Robited Complications: Input for National Recommendations L.A. Prosest, R. Harpez, A.M. Rosa, A. Gebrenzatara, A. Guo, I.R. Critego-Sanches, F. Zhou, and K. Dooling

A new herpes coster suburit veccine, recombinant coster vaccine, was approved in 2017 to prevent shingles and complications. This analysis evaluates the cost-effectiveness of that veccine.

Review

Management of Patients With Fever and Neutropenia Through the Arc of Time. A Narrative Review P.A. Fixes The association between fever and neutropenia and the

The autocation between twie and naturopens and miniralk for life-threatening infections in putteria receiving cytotratic chemiotherapy has been known for 50 years. Indeed, infectious complications have been a leading cause of morbidity and mortality in patients with cancer

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But also CMAJ, the Australian Medical Journal, Croatian Medical Journal...

The Vancouver Group! ICMJE

This review chronicles the progress is defining and developing approaches to the management of fewer and neutropenia.

Research and Reporting Methods Graphical Depiction of Longitudinal Study Designs 398 in Health Care Databases

5. Schneewein, J.A. Ramen, J.S. Brown, K.J. Rothman, L. Happe, P. Antel, G. Dal Pan, W. Goettach, W. Murk, and S.V. Wang The authors propose a simple framework of standardized graphical representations that provide clear visualization of longitudinal study designs as well as detail enabling reproduction of low, design parameters.

Ideas and Opinions

Health Care in 2030: Will Artificial Intelligence 407 Replace Physicians?

NR Stat Armed with just the rules of the game, Google's AphaZero mastered cheas after 9 hours of training. The program showed an aveacres new kind of intelligence, creativity, beauty, and perkange even playkiness. What might this tell us about medical practice in the not-eodistant future? Will Google algorithms beat out physicians?

Should a Prison Salt Trial Be Federally Funded?

P.P. Christopher and M.D. Savis Determining whether seatchad said intakin improves key health outcomes would negatime a randomized trial. The authors discass the ethics of whether such a trial should be done with principars.

Editorials

Are We There Yet? Another Milepost in the Journey 411 to Identify Appropriate Candidates for Aspirin Primary Prevention E.P. Whitlock and E.S. Johnson

Salak and colleagues reported are apacitic models to predict risk for major blending events in adults without cardiovascular data are who are not receiving antiplatele therapy. The editorialists clacase the strengths and limitations of these models and why they believe the

antaziona or bees moose ano any may beeve the models offer a major step toward more evidence-based, individualized decision making about aspirin use to prevent cardiovazoilar disease (and perhaps colorectal cancer).

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The Vancouver Group

- The International Committee of Medical Journal Editors (ICMJE)
- Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations, "The Uniform Requirements")
 - best practice and ethical standards in the conduct and reporting of research and other material published in medical journals
 - http://www.icmje.org/recommendations/





Types of articles in medical journals

- Original research
- Systematic reviews with or without meta-analyses
- Practice guidelines
- Clinical (narrative) reviews
- Case reports
- Research methods and reporting
- Various opinion articles (editorials, analyses)



Original research

- DATA!
- Research question / clinical question
- Study design (methods)
- Results (statistical analyses)
- Conclusion answer to the research/clinical question



Why conduct and publish research?

Say something important Share your work Change practice Promote thought or debate Educate Get into high impact journal Advance your career Keep your job Make money Entertain/divert/amuse





How to publish in a high impact journal

- use literature to focus the research question and ensure it is important, new, & relevant internationally
- enlist co-authors, statistician, supervisor
- design the study, develop the methods, check ethics
- write the proposal, get funding and ethics approval
- conduct the study well

- use clear, simple language to fully report the study
- follow rules on publication ethics
- choose the right journal
- communicate effectively with editors



Research ethics



Rules for ethical research with humans

Guideline for Good Clinical Practice (1996) from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Bionet recommendations on ethical governance of Sino-European biological and biomedical research (2010)





Since the update in 2008, it states that

every clinical trial must be **registered** in a publicly accessible database before recruitment of the first subject to prevent cherry picking!

each potential subject must be adequately informed of the aims, methods, sources of funding, any possible **conflicts of interest**, **institutional affiliations** of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study



Ethical issues – the wider aspects

- what information will you give participants before seeking their consent?
- how much will the study deviate from current normal (accepted, local) clinical practice?
- what full burden will be imposed on participants?
- what risks will participants/others be exposed to?
- what benefit might participants or others receive?
- how might society/future patients benefit in time?
- might publication reveal patients' identities?



How to publish in a high impact journal

- use literature to focus the research question and ensure it is important, new, & relevant internationally
- enlist co-authors, statistician, supervisor
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The research question



Editors want to publish papers that are

- novel
- important
- relevant (to the journal's readership)
- true

the research question!



What is a research question?

The researcher asks a specific question and tests a specific hypothesis

The question may also be called an objective or aim

Calling it a question helps to focus the hypothesis and helps to find an answer



What makes a poor research question?

A question that matters to nobody, even you

- Hoping one arises from routine clinical data or records
- problems with bias and confounding
- Gathering data and hoping a question will emerge: this is like a fishing expedition





Good research questions

- focussed, and well grounded in previous research
 - e.g. What impact has China's New Rural Cooperative Medical Scheme had on village health clinics?
 - or, How effective is the Shenzhen antenatal syphilis screening programme at identifying infants at high risk?
 - both were published in the BMJ

- take a look at the journals you would like to publish in!
- editorial policies are often explained in editorials



SOUNDING BOARD PICKING A RESEARCH PROBLEM The Critical Decision

THERE is probably no question that plagues investigators, especially young investigators, more than how to pick a research project. This decision is not one that must be faced only once in a lifetime; rather, it must be continually revisited. Although it is easy to assume that success in research is just the difference between good and bad luck (and indeed there is a certain amount of luck in research), most highly regarded investigators will have many successful research experiences during their careers.

For the new investigator and junior faculty member just starting his or her career, the decision about a research project is further complicated by many other questions. How should one weigh high-risk, highinterest projects against lower-risk projects of lower interest? How similar or different should the project be from work done during one's postdoctoral fellowship? Can one remain in the same institution as one's postdoctoral mentor and still make an impact, and if so, how is this best achieved? How many different projects should an investigator attempt to be involved in or undertake? How important is complete independence? When is collaboration good, and with whom? Should the M.D. investigator do anything differently from the Ph.D. investigator in picking a research project? What do you do when you are faced with some aspect of a project for which you are not technically prepared? How should one balance projects funded by the National Institutes of Health (NIH) against projects without such funding? In contrast to the rich scientific base that underlies the research itself, little has been written to help the investigator facing these challenges.1-6 Clearly the answers to these questions depend on the exact circumstances, background, expertise, and desires of the individual investigator, but every investigator should have a

strategy for picking a research problem that optimizes the chances of success.

The first step in picking a research project is to understand what makes research "good." Indeed, considering the extremely competitive nature of research funding and the rigorous review process used by top academic institutions for promotion, this question should be more accurately phrased, "What makes a research project outstanding?" Certainly, there are fundamental characteristics that everyone would agree are important. The study should be well performed and use appropriate and up-to-date forms of technology. The data should be carefully analyzed and accurately reported. For studies involving animals and humans, ethical considerations must be dealt with appropriately. But is this enough? Are these the variables that make us feel that the work of one investigator is superior to the work of another? Usually not.

In my opinion, there are several features that make a research project "outstanding." First, it must ask important questions. If the question is not important, then it is likely that no matter how carefully the study is performed, how accurately the results are tabulated, or how well the work is reported, this will not be viewed as an outstanding piece of work. Second, if possible, the project should have the potential to yield a "seminal" observation - one that creates truly new knowledge, leads to new ways of thinking, and lays the foundation for further research in the field. We often recognize a seminal observation as the first major publication in an area, which sets the stage for subsequent work and will be followed by many reports from the same and other laboratories extending and developing the point and expanding it to related areas. If these first two criteria are met, the remaining criteria for good research are usually easily fulfilled. Thus, the results of the project will be publishable in respected journals, recognized and cited by peers, presentable at high-quality meetings in the field, and of course, fundable on competitive grant review.

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Khan CR. N Engl J Med 1994;330:1530-33



Priority Setting Partnerships

Search	Q
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Academic and research forums

Discussions of visibly published articles

JLA Guidebook About the JLA The PSPs Home Top 10s Making a difference **Current surveys News and Publications** translate page V

You are in: Home

The James Lind Alliance

The James Lind Alliance (JLA) is a non-profit making initiative established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise the Top 10 unanswered questions or evidence uncertainties that they agree are the most important.

The aim of this is to make sure that health research funders are aware of the issues that matter most



Minimising bias and confounding

Chance - measurements are nearly always subject to random variation. Minimise error by ensuring adequate sample size and using statistical analysis of the play of chance

Bias - caused by systematic variation/error in selecting patients, measuring outcomes, analysing data etc.

Confounding - factors that affect the interpretation of outcomes and should be measured too eg people who carry matches are more likely to develop lung cancer, but smoking is the confounding factor



Which study design will answer your question?



PICO question (or PECO – for exposure)

Patients

- disease or condition
- stage, severity
- demographic characteristics (age, gender, etc.)

Intervention

- type of intervention or exposure experiment or observation?
- dose, duration, timing, route, etc.

Comparison

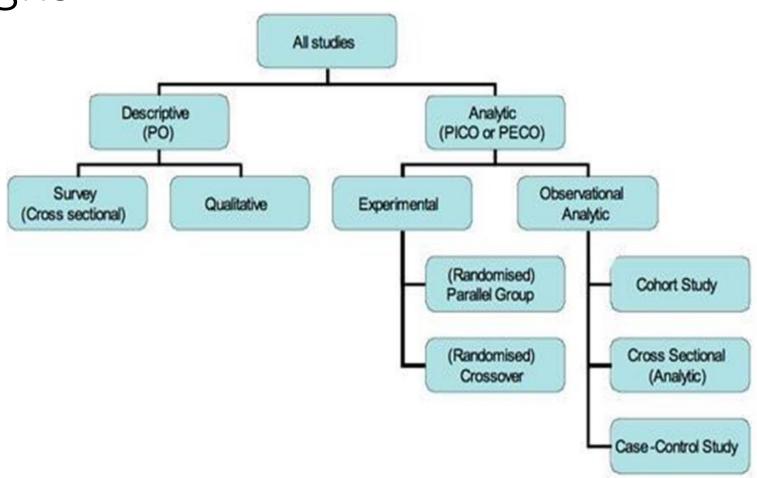
- treatment or risk
- placebo or other active treatment

Outcome

- frequency, risk, benefit, harm
- dichotomous or continuous
- type: mortality, morbidity, quality of life, etc.

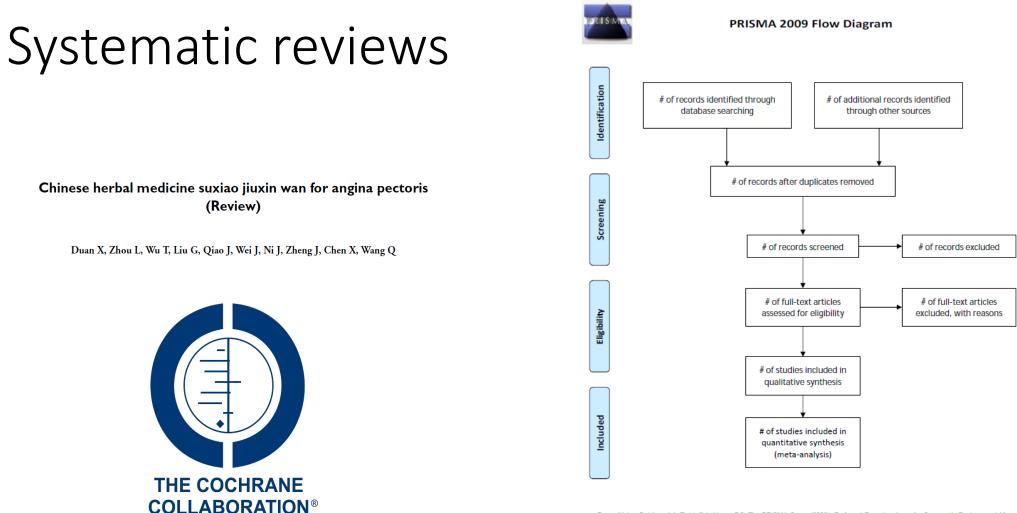


Study designs



Centre for Evidence Based Medicine, Oxford, UK www.cebm.net





From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting /tems for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 8(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.



Agree authorship before starting the study!



Authorship and contributorship

These denote credit and accountability

But many authors on papers have done little

People's names are left off papers

Authors do not know the authorship criteria

Contributorship is also used by some journals



Authorship: ICMJE criteria

Authorship credit should be based on:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All these conditions must be met.

Participation solely in the acquisition of funding or the collection of data

does not justify authorship [no guest authors].

All authors included on a paper must fulfil the criteria [no ghost authors].

No one who fulfils the criteria should be excluded.



Non-authorship contributions

Contributors who meet **fewer than all 4 of the above criteria** for authorship should not be listed as authors, but they should be acknowledged.

- Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are
 - acquisition of funding
 - general supervision of a research group or general administrative support
 - writing assistance, technical editing, language editing, and proofreading



Role of medical writers

European Medical Writers Association policy:

- medical writers have a legitimate role in assisting named authors in developing manuscripts for peer-reviewed journals and presentations
- such contributions and funding information should be openly acknowledged
- not 'ghostwriter', which wrongly implies something secretive
- experts in scientific communication, data presentation, journal and congress requirements of journals, and publication ethics
- may therefore raise the standard of publications and accelerate the process



How to choose a journal and survive peer review



How to choose a journal

- journal scope, reach, & readers
- indexed, peer reviewed
- Impact Factor *
- Open access or not?
- and...
 - rejection rate
 - time to decision; time to publication
 - article length restrictions (word limit)
 - charges: OA publication fees, pages, colour...

* Impact factor is used as a measure of the academic usefulness of a journal

IF = recorded number of citations in a year (eg 2018 to scholarly i.e. "citable" articles in the journal in preceding two years (eg 2017 and 2016)

2017 Impact Factors NEJM 79.258 The Lancet 53.254 JAMA 47.661 BMJ 23.295 Annals 19.384 ... CMAJ 6.8 ... CMJ 1.422



Five key questions when choosing a journal

Whom do I want to reach (target audience)?

How do I intend to reach the desired audience?

How will readers access my article? *

What type of journal will best meet my needs?

How soon do I want or need to publish the data?

* Can I afford the publication fee at an open access journal?



Some other journal-related factors

Rejection rate
Indexing (Medline)
Time to acceptance; time to publication
Impact Factor
Word limit
Types of article typically published
Policy on industry sponsored work
Policy on acknowledged medical writing assistance
Charges for pages, publication, colour figures or open access
Fast track peer review or publication

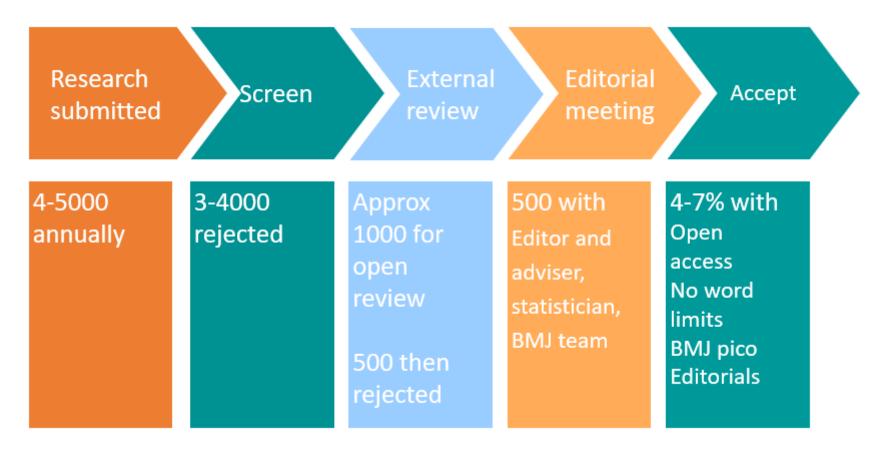


Acceptance rates at major journals

Journal	Research papers	Acceptance rate
NEJM	5000	5%
Lancet		5%
JAMA	4700	4%
BMJ	3000	4%
PLoS Medicine		3%
Circulation		11%
Stroke		16%
JACC		17%
PLoS One		69%



The peer review process (example from the BMJ but other major journals similar)





Appeals

data)

Serious appeals usually welcomed

Criticisms have to be addressed convincingly Up to 20% accepted (BMJ

But only one appeal Make it good



Publication ethics



Misconduct in research and publication

Fabrication: making up data or results and recording

or reporting them (through publication or presentation)

Falsification: manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record

Plagiarism: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit



Publication ethics

- avoid misconduct
- protect patients' identities
- report informed consent and wider ethics issues
- declare competing interests

Stating approval by an ethics committee or institutional review board may not suffice



Competing interest

A person has a competing interest when he or she has an attribute that is invisible to the reader or editor but which may affect his or her judgment

Always declare a competing interest, particularly one that would embarrass you if it came out afterwards



Detecting plagiarism

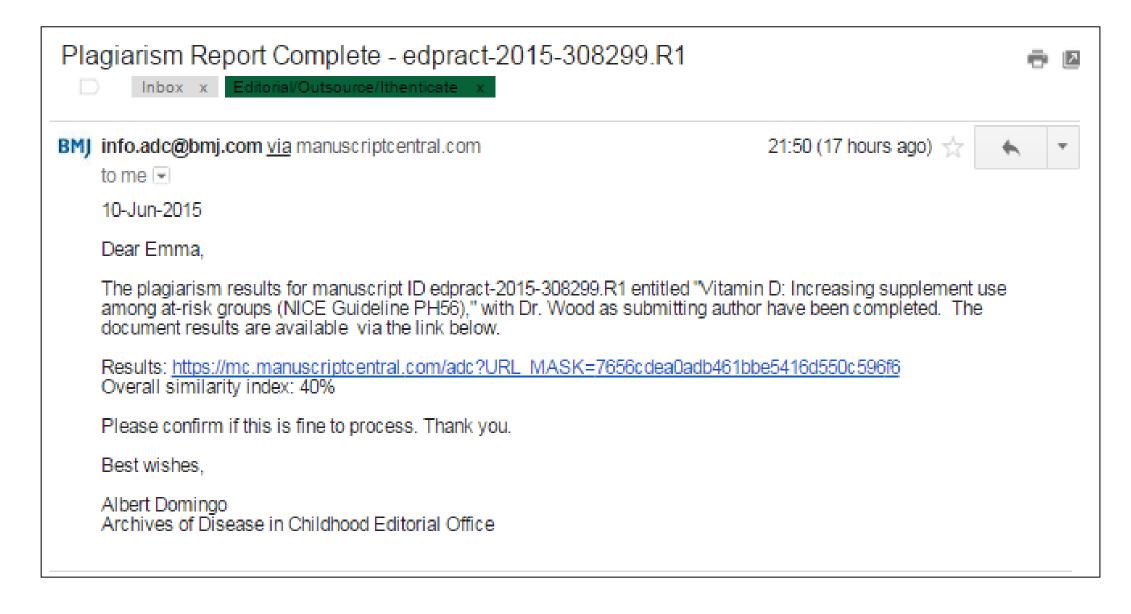
- most journals use some kind of software now
- iThenticate
 - In addition to the internet, manuscript are compared to more than 40 million published research articles from 590+ global scientific, technical and medical publishers (gets behind access controls free tools don't do this)
 - iThenticate's comparison database includes more than one million abstracts and citations from PubMed, and more than 20,000 research titles from EBSCOhost and the Gale InfoTrac OneFile. iThenticate also maintains its own web crawler, indexing over 10 million web pages daily and totalling over 50 billion web pages.



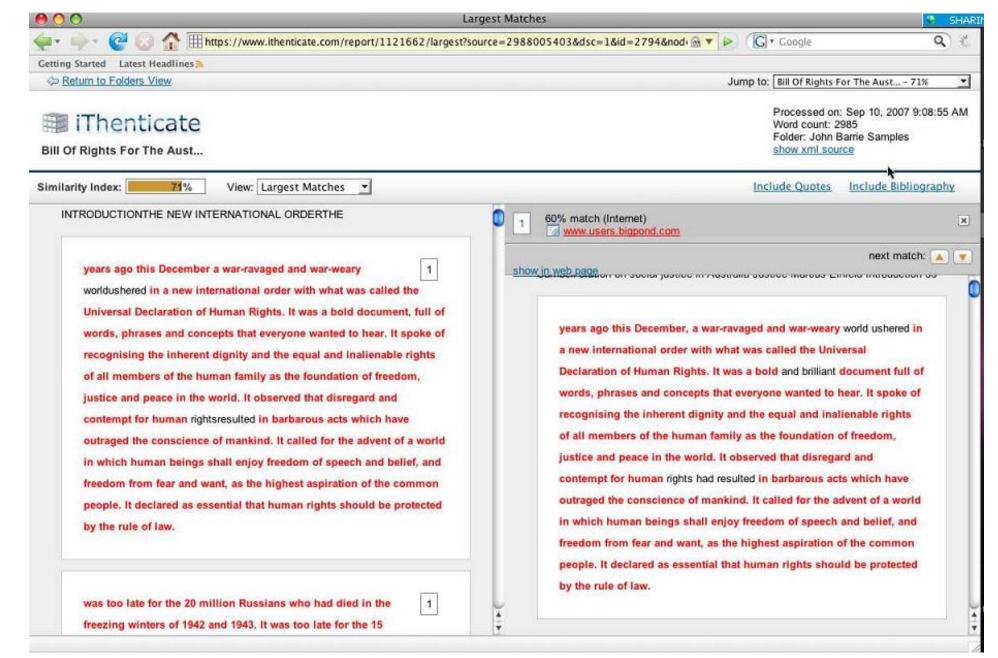
iThenticate @ the BMJ

- all revised papers are automatically sent through iThenticate at submission
- results are given a score (%) on the level of duplication the program has picked up.
- BMJ set the threshold at 25%
- An email is automatically triggered when a paper exceeds this, and is sent to the editorial office













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.	Professional Pl	agiarism Prevention

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40%

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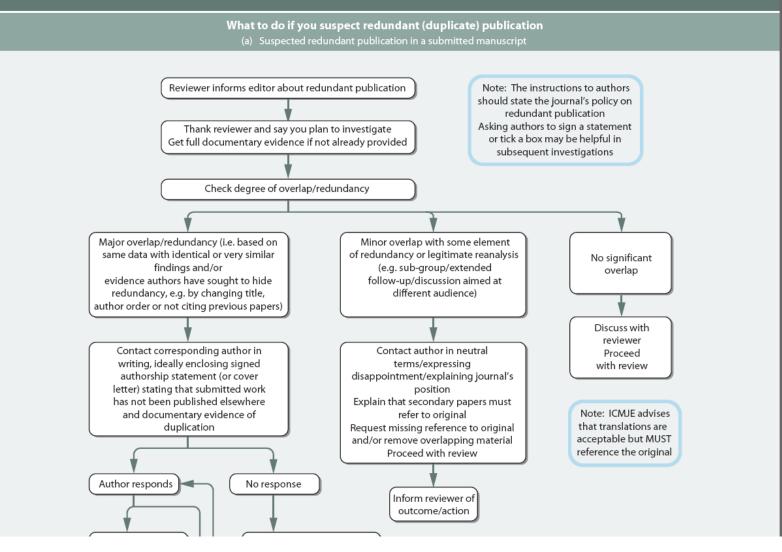
Mode: Content Tracking	Include Quotes Include Bibliography Exclude small sources
National Institute for Clinical Excellence (NICE) published a guideline entitled	381 words / 17% - Internet from 08-May-2015 12:00AM www.nice.org.uk [-]]
Vitamin D: Increasing supplement use among at-risk groups	This is source #1 in the Similarity report. This source is partially hidden by one or more sources in the Similarity report.
(PH56).[6] The aim of this guideline is to increase Vitamin D supplement use to prevent Vitamin D deficiency. The guideline focuses on	 381 words / 17% - Internet from 20-May-2015 12:00AM www.nice.org.uk
the following at risk groups: ? Infants and children aged under 5 ? Pregnant and breastfeeding women, particularly teenagers and young women ? People over 65 ?	359 words / 16% - Internet from 19-May-2014 12:00AM www.nice.org.uk ™ This is source #2 in the Similarity report. This source is partially hidden by one or more sources in the Similarity report.
People who have low or no exposure to the sun, for example those who cover their skin for cultural reasons, who are housebound or confined indoors for long periods ? People with darker skin, for example, people of African, African-Caribbean or South Asian family origin.	○ 359 words / 16% - Internet from 15-Jan-2015 12:00AM <u>www.nice.org.uk</u> This source is completely hidden by one or more sources in the Similarity report.
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guidelines for	Internet from 11-Feb-2014 12:00AM www.feedingforlifefoundation.co.uk This is source #14 in the Similarity report.
ecommended daily intakes of vitamin D and it is advised that people should follow the NICE	This source is partially hidden by one or more sources in the Similarity report.

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$\left| \mathbf{C} \right| \mathbf{O} \left| \mathbf{P} \right| \mathbf{E} \right|$ committee on publication ethics

WWW.PUBLICATIONETHICS.ORG

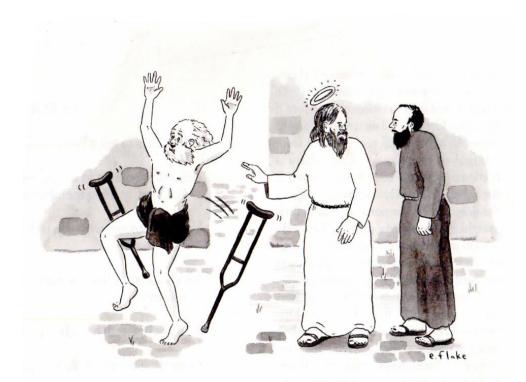




To sum up – what editors want

Importance **Originality** (novelty) Relevance to the readership Truth and transparency Real potential to improve decision making Clear writing that people want to read Excitement/ "wow" factor

(without going overboard)



"Yeah, but good luck getting it peer-reviewed."



Useful resources



3rd EDITION

Users' Guides to the Medical Literature

A MANUAL FOR EVIDENCE-BASED CLINICAL PRACTICE

Gordon Guyatt, MD Drummond Rennie, MD Maureen O. Meade, MD Deborah J. Cook, MD



JAMA evidence





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ICMJE Recommendations ("The Uniform

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ICMJE Recommendations ("The Uniform Requirements")

Where can I find the URMs?

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The ICMJE has revised the Uniform Requirements for Manuscripts (URMs). To better reflect its current content and purpose the document has been renamed, Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations). The ICMJE Recommendations may be found here.