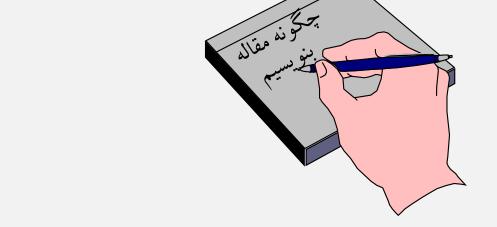




### چگونه مقاله بنویسیم؟

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# Fundamentals of good medical writing

### The scope of medical writing

Internal reports

Regulatory reports

Conference presentations

- abstract
- oral presentation
- poster

#### Journal articles

- original research paper
- review article
- case report
- letter to editor

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#### Start with good science

Communalism - common ownership of scientific discoveries

Universalism - evaluation using universal, unbiased criteria

Disinterestedness - scientists should act selflessly

Organised scepticism - ideas tested and subjected to rigorous, structured scrutiny by peers

US sociologist Robert Merton b1910

#### Plan effectively

For original research: have a clear research question seek statistical advice use the right study design act ethically keep an open mind and minimise bias agree who will be principal investigator agree who will be authors and contributors agree to publish even negative results

#### **Behave ethically**

Research ethics – declaration of Helsinki, ICH

#### **Publication ethics**

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avoid misconduct protect patients' identities report clearly:
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informed consent
any deviation from usual practice
full burden imposed on participants
total risks posed to participants or others
benefits to participants, patients, society

It's not always enough to state that the study was approved by an ethics committee or IRB

#### Protect patients' confidentiality

Beware identifiers:

age, sex, location

clinical details, test results

unusual personal story or context

photo (even if of a body part or clinical image)



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There are now many evidence based clinical guidelines and good systematic reviews, some of which may relate directly to your article. We would like you, therefore, to provide suitable evidence for key statements - the Cochrane Library or a medical librarian should be able to help you.

#### Guidelines

Try to indicate probabilities and levels of evidence:

- Frequency information: when giving a differential diagnosis for a particular presentation please provide population estimates of the frequency of each separate diagnosis
- rates (or sensitivities and specificities) and, if possible, the causes of false positives and false negatives Prognosis: information on prognosis or natural history is often missing

Diagnostic tests: please give their false positive and false negative

- from medical articles but is vital for rational decision making. Wherever possible, give information about remission, progression and risks of disease
- **Treatments:** please mention the level of evidence on which main treatment recommendations are made. This can be kept relatively simple, using three levels:
  - No clear evidence: opinions based on clinical experience, anecdotal case studies, or descriptive articles; conflicting evidence from studies or poorly designed studies, even if randomised controlled trials
  - Suggestive evidence: evidence from cohort, case control, beforeand-after studies; evidence from non-randomised experimental studies
  - Firm evidence: evidence from at least one properly designed randomised, controlled trial with adequate sample selection, sample size, and appropriate controls; with double or single blinding; and with clear outcome(s)

Please try to quantify the benefit of treatment, giving the relative risk reduction

### **Clear writing**

Keep it simple: use short, familiar words

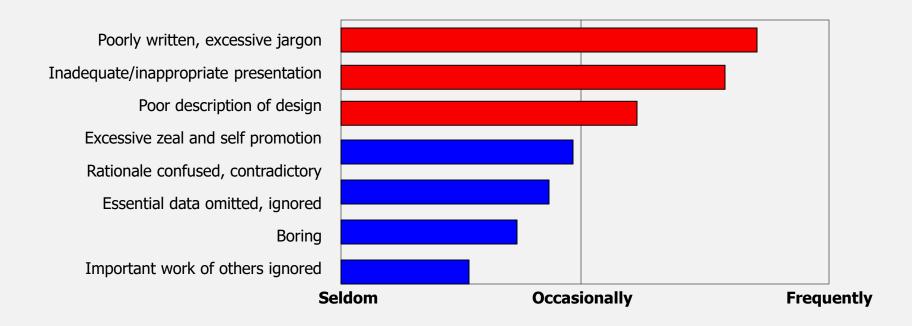
Avoid jargon and acronyms

Be specific

Be concrete, not abstract

Say what you mean and mean what you say

# How frequently do editors encounter manuscript problems?



Byrne DW, Publishing Medical Research Papers, Williams and Wilkins, 1998

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### Who did what and why?

authors

contributors

competing interests

publication ethics

## **Authorship Avoid guest- and ghost-writers**

Authorship credit is based only on **<u>substantial</u>** contribution to:

- conception and design, <u>or</u> data analysis and interpretation
- drafting the article <u>or</u> revising it critically for important intellectual content
- <u>and</u> final approval of the version to be published

All these conditions must be met Solely acquiring funding or collecting data does not justify authorship All authors included on a paper must fulfil the criteria No one who fulfils the criteria should be excluded

#### Contributorship

contributors who took part in planning, conducting, and reporting the work, including professional medical writers

guarantors (one or more) who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish

researchers must decide among themselves the precise nature of each contribution

#### Who did what?

Helen C Eborall, post-doctoral research fellow1, Simon J Griffin, programme leader2, A Toby Prevost, medical statistician1, Ann-Louise Kinmonth, professor of general practice1, David P French, reader in health behaviour interventions3, Stephen Sutton, professor of Behavioural science1

Contributors: SS, DPF, ATP, A-LK, and SJG conceived and designed the original protocol. All authors were involved in amending the protocol. HCE coordinated the study throughout. Data entry was carried out by Wyman Dillon Ltd, Lewis Moore, and HCE. HCE cleaned the data and ran preliminary analysis with input from Tom Fanshawe. ATP analysed the data. ADDITION trial data were supplied by Lincoln Sargeant and Kate Williams. HCE wrote the first draft of the manuscript with ATP and SS. All authors contributed to subsequent and final drafts. HCE is guarantor of the paper.

#### **Competing interests**

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

#### **Misconduct**

**Fabrication:** making up data or results and recording or reporting them

**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

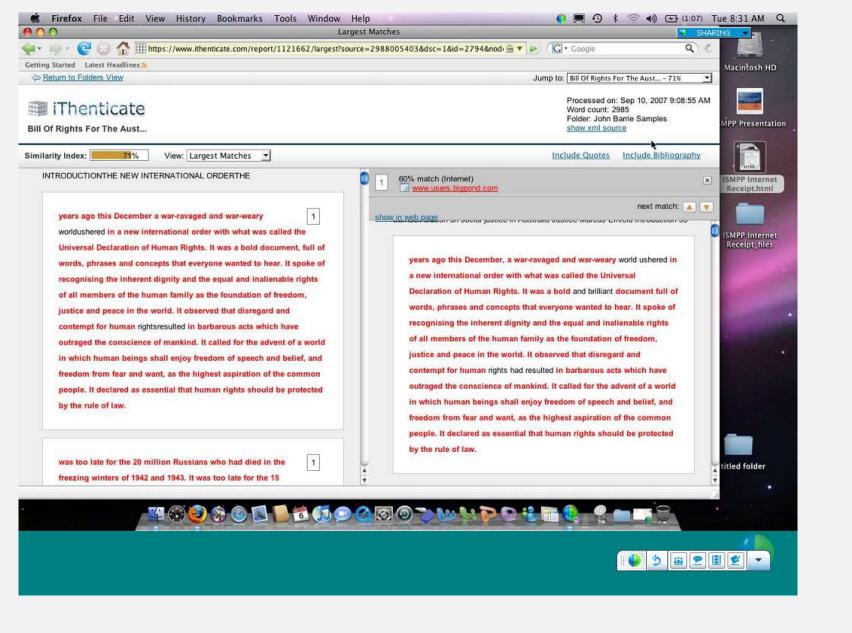
**Plagiarism:** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit

#### CrossCheck

web tool searches for overlapping content:
 prepublication
 postpublication

specialist search engine (iThenticate) uses "text fingerprinting" and "string matching"

gets behind access controls (unlike free tools) to search >9 billion articles in CrossRef database



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### **Assessing the audience**

Regulators

**Markets** 

Conferences

**Journals** 

Clinicians

## How to please editors and peer reviewers

make sure the message is clear in the paper and abstract, not just in the cover letter

#### also send:

extra materials eg CONSORT checklist details of any closely related papers previous peer review reports

communicate clearly and promptly

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#### The message

For original research:

Introduction: why ask this research question?

Methods: what did I do?

**R**esults: what did I find?

and

**D**iscussion: what might it mean?

# What makes a good research question?

FINER criteria

**F**easible (answerable with a robust method)

**I**nteresting

Novel

**E**thical

Relevant

# What makes a poor research question?

a question you don't care about, nor does anyone else

looking at routine clinical data and trying to think of a question

- the records will be biased and confounded
- they may lack the information you need to answer your question reliably, because they were collected for another reason

a fishing expedition/data dredging – gathering lots of information and hoping a question will emerge

 statistical analysis of many outcomes post-hoc may yield false positives (type I errors) or false negatives owing to lack of power (type II errors)

### Spin: the dishonest drug trial

Not transparent (sponsors' roles, competing interests) Compares intervention with one known to be inferior with ineffective dose of competitor intervention with so much of competitor intervention that ADRs likely Uses multiple endpoints and reports selectively Reports results only from favourable centres Reports only favourable subgroup analyses Presents only most impressive results — eg reduction in relative rather than absolute risk

### **Spin – it's not only in trials...**

2006 BMJ paper found that industry supported systematic reviews were of lower quality than Cochrane reviews of the same drugs, were less transparently reported, had fewer reservations about methodological limitations, and always recommended the sponsor's drug without reservations

2007 BMJ paper found that sponsored meta-analyses on antihypertensive drugs were not associated with favourable results but had overgenerous conclusions

#### **Industry-commissioned reviews**

### primary research articles create influence

peer review approves the science

journal brand endorses the message

better than drug reps

### secondary articles spread influence

more likely to be read than research

especially if KOL authors

can alter policy

#### The honest review article

describe sources of information and methods of selection

ideally, cite Cochrane and other systematic reviews

clarify type and strength of evidence for key statements
"A large well conducted randomised conducted trial finds..."

"The findings of a small case series suggest..."

declare provenance, funding, and competing interests

#### How can journals help?

BMJ asks authors submitting or offering unsolicited reviews and editorials on potentially commercial topics three questions

And every published article declares competing interests and provenance

- has anyone prompted or paid you to write this article?
- would/did a professional writer contribute to the article? to what extent?
- would the BMJ article be original, or would it be similar to articles submitted or published elsewhere?