

# Publication planning: rules and responsibilities for writers

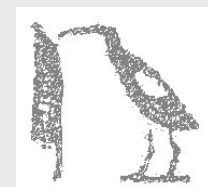
**Liz Wager PhD**

*Sideview*

[liz@sideview.demon.co.uk](mailto:liz@sideview.demon.co.uk)

Chair, *Committee on Publication Ethics*

[www.publicationethics.org](http://www.publicationethics.org)



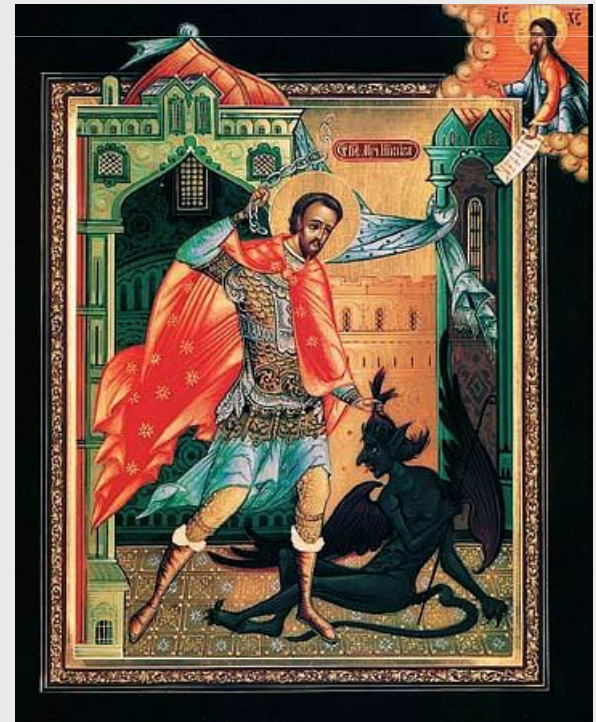
a noble  
profession

So, you want to be a medical writer ....?

ensuring  
research is  
reported  
responsibly

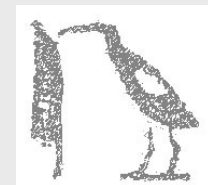


not everybody shares this view of  
medical writers .....



# Revealed: how drug firms 'hoodwink' medical journals

- *The Observer*, 7<sup>th</sup> December, 2003
- "Pharmaceutical giants hire ghostwriters to produce articles – then put doctors names on them"
- "Hundreds of articles in medical journals claiming to be written by academics have been penned by ghost writers in the pay of drug companies, an Observer inquiry reveals ..."



# THE WALL STREET JOURNAL.

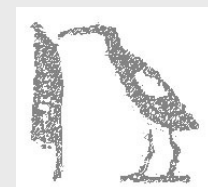
## **Ghost Story: At Medical Journals, Writers Paid by Industry Play Big Role; Articles Appear Under Name Of Academic Researchers, But They Often Get Help; J&J Receives a Positive 'Spin'**

*In recent years, more journal editors have begun demanding that academic authors of studies explain their exact roles and disclose any work by medical writers. The editors say the writers can perform a valuable role so long as it's disclosed to readers.*

*Writers agree -- and the American Medical Writers Association is pressing for greater acknowledgment of its members' work...*

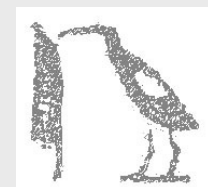
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**By Anna Wilde Mathews, 13 December 2005**



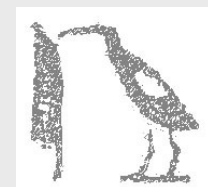
# Exorcising ghosts and unwelcome guests

- *Annals Int Med* 2005;**143**:611-12
- "The author of an article we published in 2003 sent more than a few shivers up the spines of the editors when he admitted to a *New York Times* reporter ... the initial paper was written at Merck and then was sent to me for editing"



# *Annals* editorial contd

- "*Annals* welcomes neither guests nor ghosts"
- "Guest authors and ghostwriters misrepresent authorship and obfuscate potential conflicts of interest"



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# THE LANCET

Volume 359, Number 9313

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**Just how tainted has medicine become?**

BMJ Nov 2000

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**Firm tried to block report on failure of AIDS vaccine**

Scott Gottlieb *New York*

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**Revealed: how drug firms 'hoodwink' medical journals**

Pharmaceutical giants hire ghostwriters to produce articles - then put doctors' names on them

Antony Barnett, public affairs editor  
Sunday December 7, 2003  
The Observer

Science 2004

# NEWS

ANTIDEPRESSANTS AND CHILDREN

**Buried Data Can Be Hazardous To a Company's Health**

reviews

BMJ Jan '03

Spin doctors soft pedal data on antihypertensives

BMJ Jan '02

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**Journal "should have revealed scientist's connection to company"**

Charles Marwick *Washington*

Yet more headlines about ghostwriting ...

## THE WALL STREET JOURNAL.

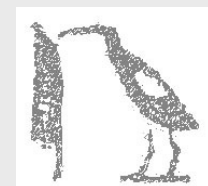
*May 20, 2008*

- In Latest Vioxx Settlement, Merck Swears Off Ghostwriting

## The New York Times

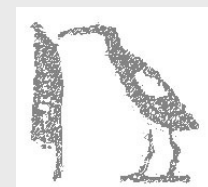
*Dec 12, 2008*

- Drug Maker Said to Pay Ghostwriters for Journal Articles



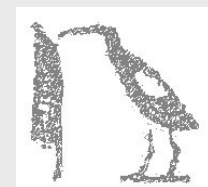
# *BMJ*, May 2011

- *BMJ* 2011;342:d2925
- **Only full access to trial data will show signs of ghostwriting**
- “Problems associated with the ghost authorship of biomedical research studies range from ‘deeply disconcerting to shattering’”
- “Problems with manipulated and misleading reporting of results are extremely difficult to tackle”

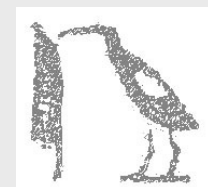


# WAME policy statement

- Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself
- **WAME considers ghost authorship dishonest and unacceptable**



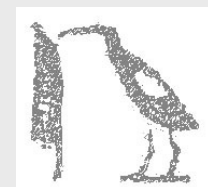
Are medical writers the same as  
ghost writers?



# Not necessarily ...

## WAME goes on to say

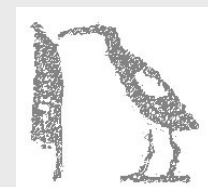
- To prevent some instances of ghost authorship, editors should make clear in their journal's information for authors that **medical writers can be legitimate contributors** and that their roles and affiliations should be described in the manuscript.



You cannot be a 'ghost' if your contribution is acknowledged !



- **What Should Be Done To Tackle Ghostwriting in the Medical Literature?**
- PLoS Medicine Feb 09; 6(2): e1000023.  
doi:10.1371/journal.pmed.1000023



# Anti-ghostwriting checklist

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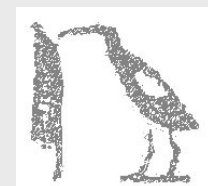
## Question

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- 1 (a) Did the medical writer meet the three criteria for authorship, as specified by the ICMJE ?  
(b) If not, has the writer been identified in the acknowledgments or as directed by the journal?
- 2 Has the source of funding for the medical writer's services been identified in the acknowledgments or as directed by the journal?
- 3 Did the author(s) make the final decision on the main points to be communicated in the manuscript, particularly in the conclusion?
- 4 Did the author(s) make the final decision on the primary and secondary outcomes and relevant data to be reported in the manuscript?
- 5 If requested by the journal, can the medical writer provide evidence that the manuscript was prepared in accordance with international guidelines for ethical medical writing (e.g., Uniform Requirements for Manuscripts Submitted to Biomedical Journals [10]; Good Publication Practice for Pharmaceutical Companies [9]; Position Statements from the European or American Medical Writers Associations or the International Society for Medical Publication Professionals [21])?

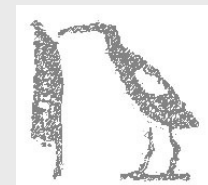
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This checklist is available as an MS Word document in Table S1.  
[doi:10.1371/journal.pmed.1000023.t001](https://doi.org/10.1371/journal.pmed.1000023.t001)



# What else do journal editors object to?

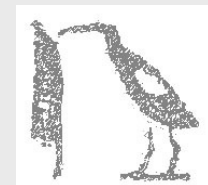
- Suppression of unfavourable data
- Undisclosed conflicts of interest
- Redundant publication (salami slicing)
- Selective reporting (cherry-picking endpoints)



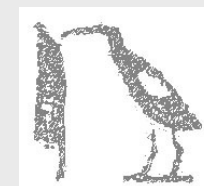
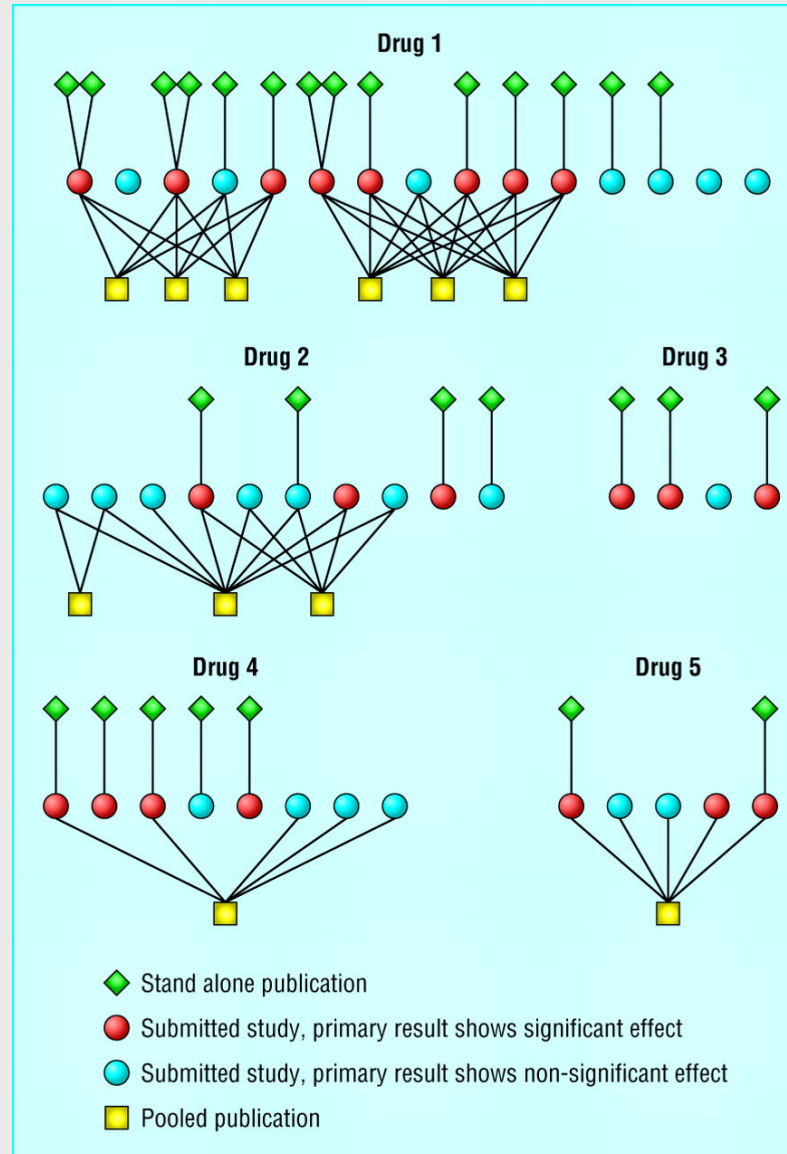
# Melander *et al.* 2003

Evidence b(i)ased medicine – selective reporting from studies sponsored by pharmaceutical industry:  
review of studies  
in new drug applications

*BMJ* 2003;**326**:1171-3



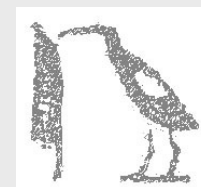
## Publication pattern for studies of the five selective serotonin reuptake inhibitors approved in Sweden between 1989 and 1994 for treating major depression



# Melander *et al.* 2003

*'The pooled analyses of published data generally gave larger differences in response rate than did the estimates from all submitted studies....*

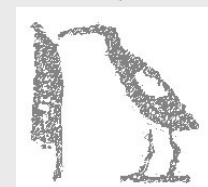
*The overestimates are due to selective reporting'*



# Guidelines to be aware of:

- ICMJE Uniform Requirements
- Good Publication Practice
- EMWA g/l for medical writers
- PhRMA principles
- ICMJE, WAME, CSE statements
- Declaration of Helsinki
- ISMPP position statement
- FDAAA (US law) re results disclosure

mainly process:  
how / what /  
when



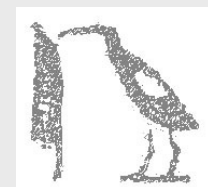
# ICMJE (Vancouver Group)

## Uniform requirements & statements

Covers a wide range of topics:

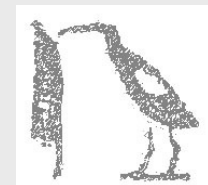
- authorship
- overlapping publications
- prior publication
- conflicts of interest
- dealing with the press
- trial registration

[www.icmje.org](http://www.icmje.org)



# ICMJE authorship criteria

- All persons designated as authors should qualify for authorship, and all those who qualify should be listed
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content



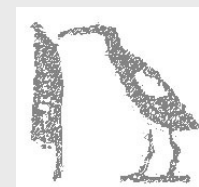
# ICMJE continued

Authorship credit should be based on:

- 1) substantial contributions to conception and design, or 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.

*Conditions 1, 2, and 3 must all be met.*

- Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship

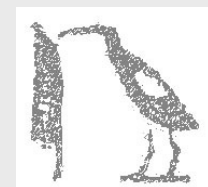


Good publication practice for  
communicating company sponsored  
medical research:  
the GPP2 guidelines

*BMJ* 2009;**339**:b4330

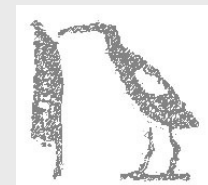
doi 10.1136/bmj.b4330

[www.gpp-guidelines.org](http://www.gpp-guidelines.org)



# GPP2

- Relation between sponsor and investigator
- Role of professional writers
- Acknowledgement
- Publication planning
- Documentation



# EMWA guidelines

## European Medical Writers Association

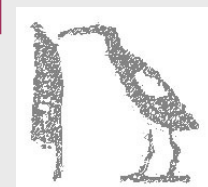
- Follow from AMWA guidelines and GPP
- Aimed at individual writers  
(rather than the companies they work for)
- Cover role of professional writers in developing peer-reviewed publications



*CMRO* 2005;21:317-21

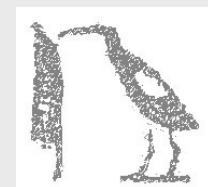
[www.emwa.org](http://www.emwa.org)

Jacobs & Wager



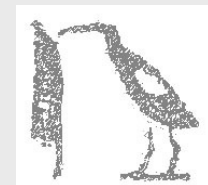
# EMWA guidelines

- In most publications reporting clinical trials, a medical writer who has not been involved in study design, data analysis, or interpretation will **not** qualify to be listed as an author according to the Vancouver criteria.
- However, they may qualify for authorship of review articles, for example if they have conducted an extensive literature search.



# EMWA guidelines

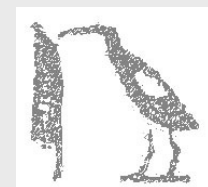
- Writers should request that sponsors involve authors at an early stage in the publication planning
- Writers should discuss and agree the content of a publication with the named authors before preparing a detailed draft (e.g. approving an outline)



# ISMPP position statement

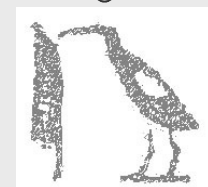
- International Society for Medical Publication Professionals (ISMPP)
- Position statement: the role of the professional medical writer
- Supports contributorship system

Norris *et al.* *CMRO* 2007:**23**:1837-40

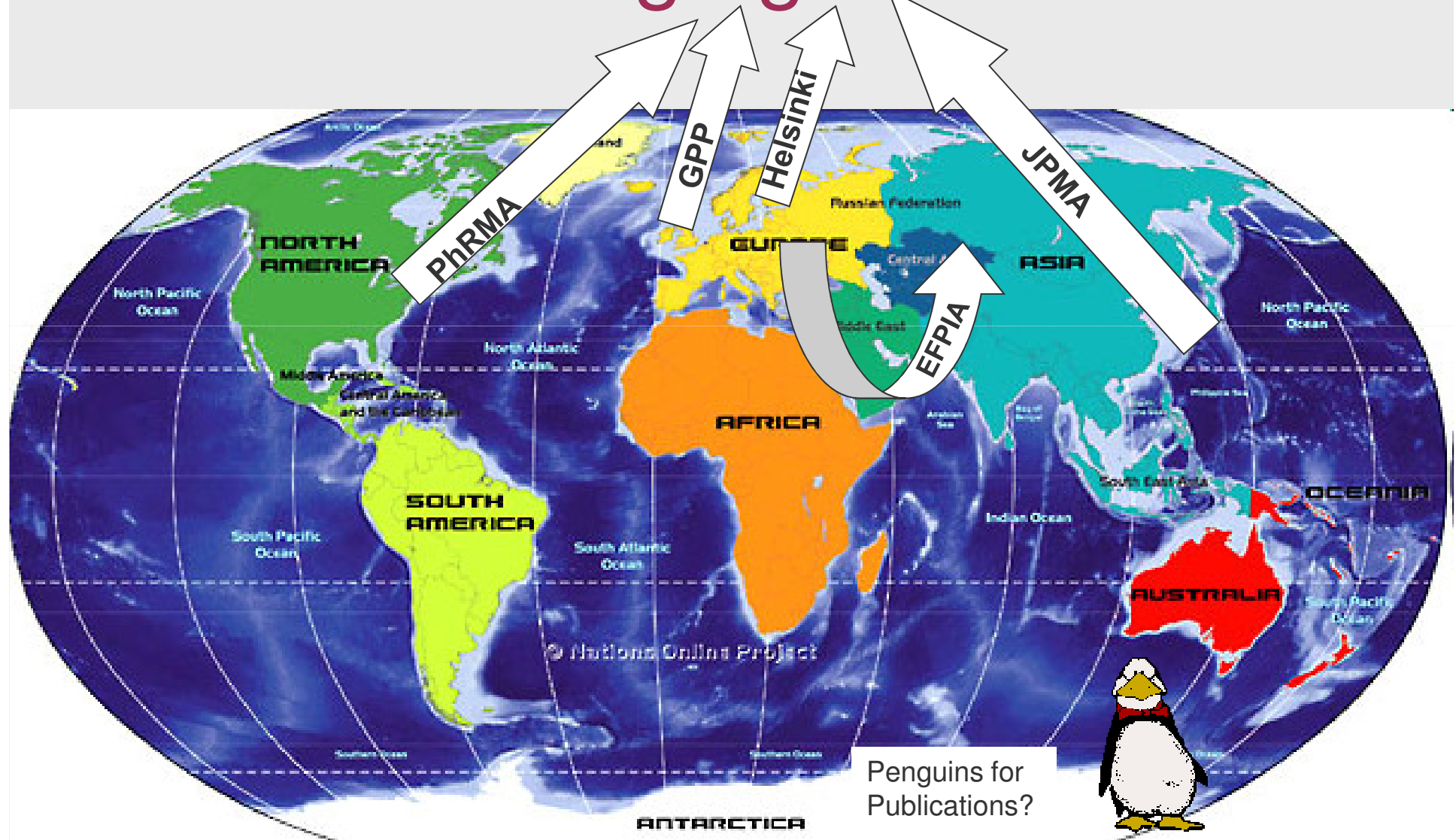


# More guidelines!

- CONSORT
- PRISMA (QUOROM)
- STROBE
- STAR-D



# Enough guidelines?



# If you only look at two sites:

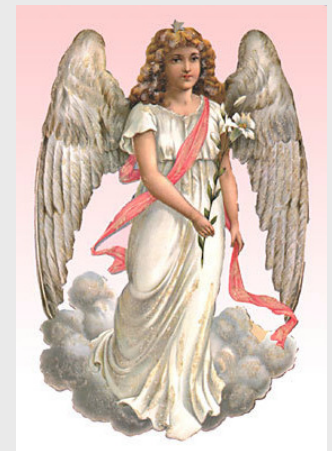
- [www.icmje.org](http://www.icmje.org)
- [www.equator-network.org](http://www.equator-network.org)





# Key messages

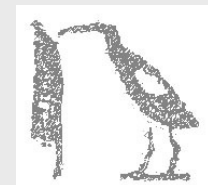
- Medical writers are not necessarily ghost writers or ghost authors
- The role of writers (and their funding) should be acknowledged
- There are lots of guidelines to follow!



# It's not enough to know the rules

Medical writers often have to:

- liaise between authors and sponsors
- liaise with journals



# Publications involve lots of different people

Investigators

Opinion leaders

Marketing

**Sponsor**

Medical

Statisticians

**CRO**

Trial managers

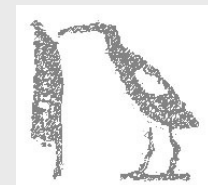
Medical writers

Account managers

**Agency**

and companies

Journal editors

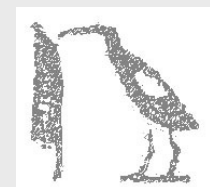


“If there is a 50-50 chance that something can go wrong, then 9 times out of ten it will”

Paul Harvey

“Things go wrong because people build walls instead of bridges”

Anon



# People get involved with publications for many reasons

Enhance career

Change practice

Make money

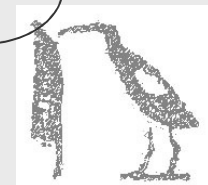
Promote their product

Promote reputation

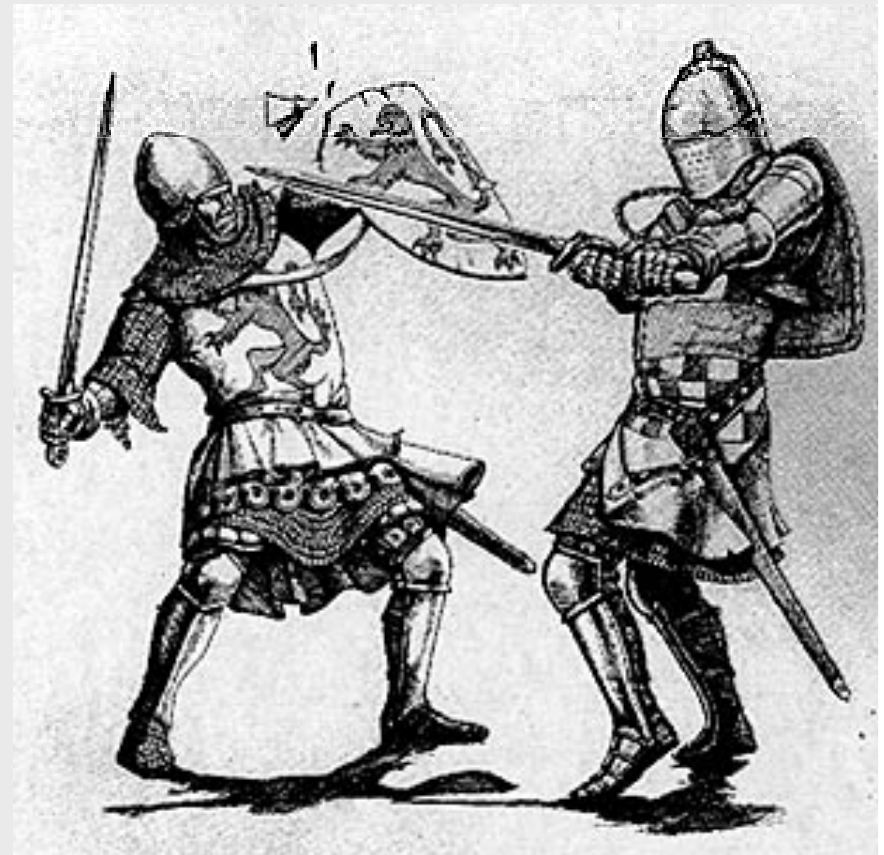
It's their job!

Attend meetings

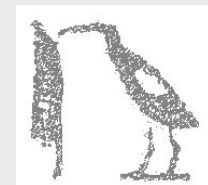
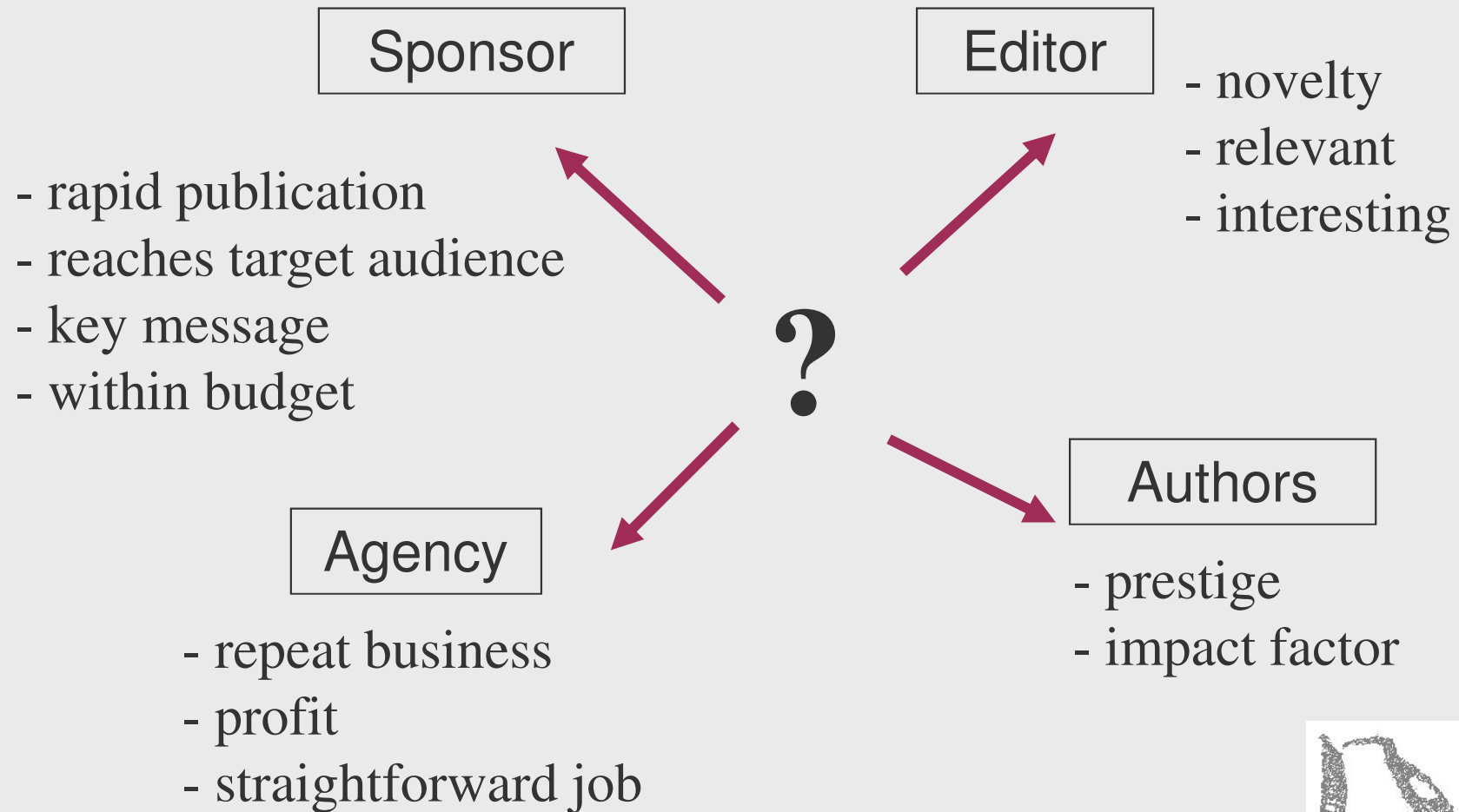
Share ideas



so don't expect them to agree!

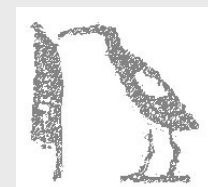


# Find out what everybody wants

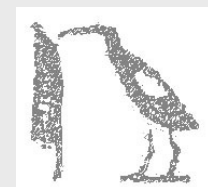


# Editors want papers that are:

- Novel
- Relevant to their readers
- Comprehensible to their readers
- Interesting / controversial / topical
- Suited to the journal's style / format
- Citable (for impact factors)
- Relevant to advertisers
- Interesting to lay media

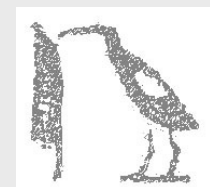


# A typical editor?

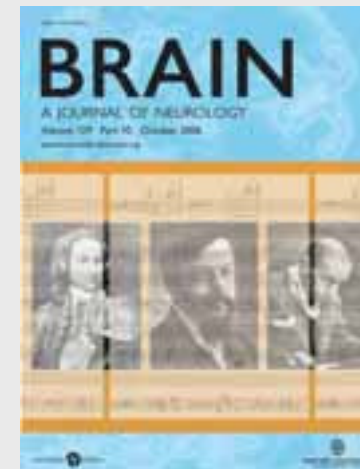


Journals and editors are not  
all the same...

medical writers need to know  
how to identify and handle the  
different varieties

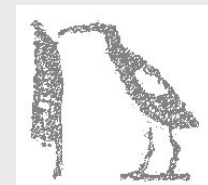


# Types of publication



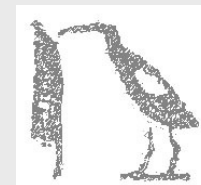
# Different economic models

- Subscription based (traditional)
- Open access (author pays)
- Hybrid (some open access, some premium content)
- Hybrid (authors can select open access and pay extra for it)
- Pay-per-view



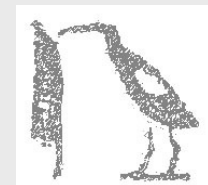
# Examples of different funding models

Subscription only / pay-per-view	<i>Jnl Gen Int Medicine, Nature</i>
Open access	<i>PLoS, BioMed Central</i>
Hybrid (research articles available after delay)	<i>JAMA, Lancet, Blood</i>
Hybrid (authors can pay extra for open access)	Some Blackwell & OUP journals



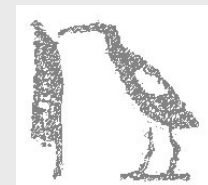
# Different media

- Print only
- Print & website (identical)
- Print & extra content on website
- Electronic only



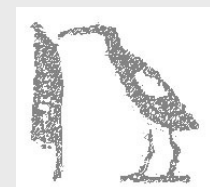
# Different types of organization

- Commercial publishers
  - multi-national (BIG!)
  - independent (small!)
- Academic societies
- Commercial publishers on behalf of academic societies



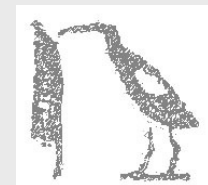
# Different levels of funding / staff

- Full-time editors
- Major journals with large in-house staff
- Academic (part-time) editors
- Volunteer (unpaid) editors

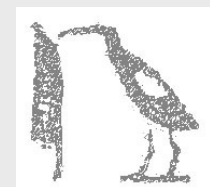


# Medical writing

- Involves more than just putting the words on the paper
- Often involves negotiation / liaison
- May raise ethical issues
- Often exists at the borderline between science and commerce



but that's what makes it  
so interesting!



# WANTED

excellent communicator,  
scientist, statistician,  
graphic artist, diplomat,  
negotiator, nitpicker,  
proof reader, creative,  
ethics advisor ...

**\$10000 CASH  
REWARD**

