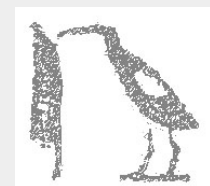


Publication planning and guidelines

Elizabeth Wager PhD

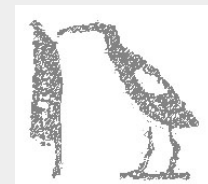
Sideview

liz@sideview.demon.co.uk



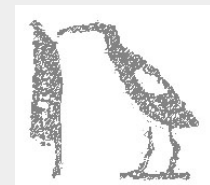
Publication planning

- Publishing other people's data
(keeping everybody happy)
- Understanding medical journals
- Keeping journal editors happy
- Perceptions of medical writers



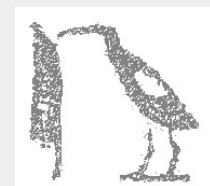
For your most recent publication:

- How did you choose the target journal(s)?
- Did you get accepted by your first choice journal?
- How did you decide who the authors would be?
- How did you decide the order of authors?
- Were there any disagreements?



Now imagine you are a publication planner ...

- How do you keep everybody happy?



Publications involve lots of different people

Investigators

Opinion leaders

Marketing

Sponsor

Medical

Statisticians

CRO

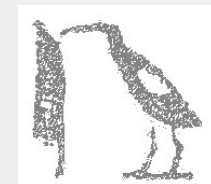
Trial managers

Medical writers

Account managers **Agency**

and companies

Journal editors



People get involved with publications for many reasons

Enhance career

Change practice

Make money

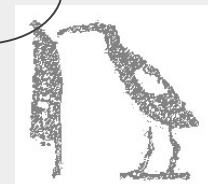
Promote their product

Promote reputation

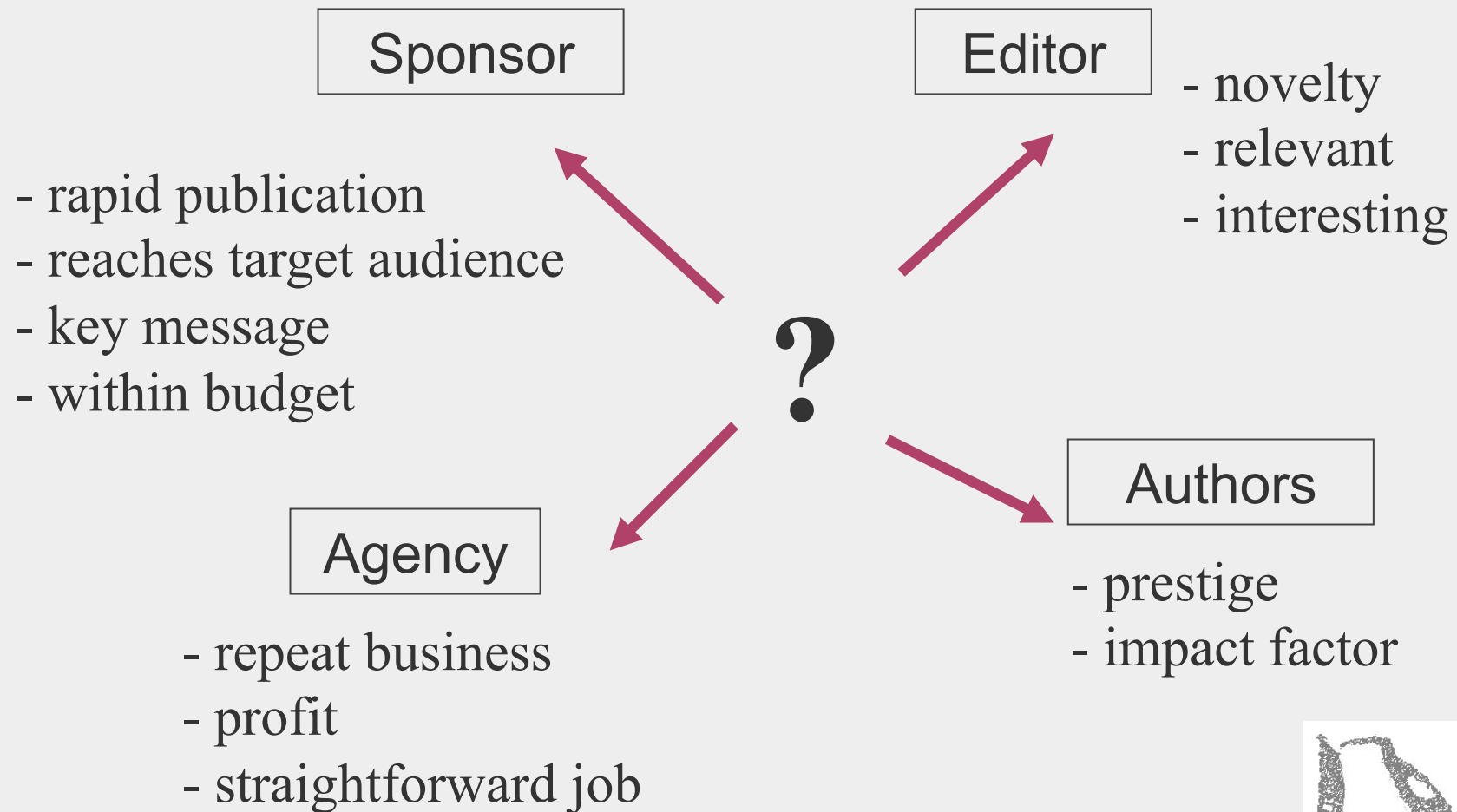
It's their job!

Attend meetings

Share ideas



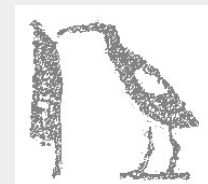
Find out what everybody wants



Even if you don't plan a career in publication planning

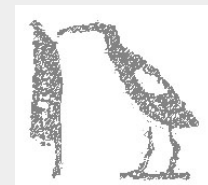
...

- Medical writers often get caught up in policy issues / disputes
- Need to understand people's motivation
- Need to understand what the customer wants
- Need to understand what journals want

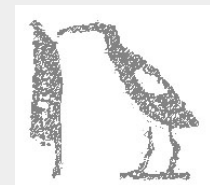


As well as writing skills you need:

- Understanding of journal rules
- Powers of persuasion
- People skills
(dealing with big ego's, people who are much more senior than you)
- Project management skills (*polite nagging!*)

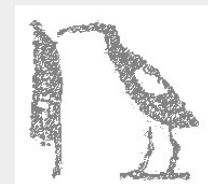


What do editors want?

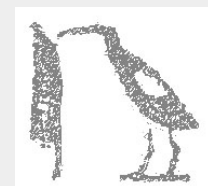


Editors want papers that are:

- 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

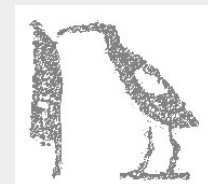


A typical editor?

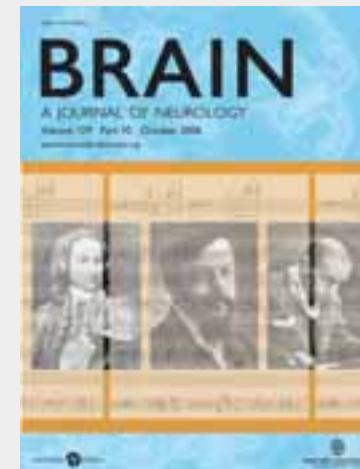


Journals and editors are not
all the same...

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

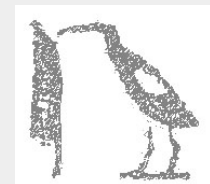


Types of publication



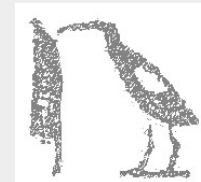
Different economic models

- 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



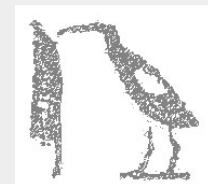
Examples of different funding models

Subscription only / pay-per-view	Most specialty journals <i>Nature</i> (research articles)
Open access	<i>PLoS, BioMed Central, eLife, BMJ</i> (research articles)
Hybrid (research articles available after delay)	<i>JAMA, Lancet, Blood</i>
Hybrid (authors can pay extra for open access)	Wiley-Blackwell, OUP & Springer journals



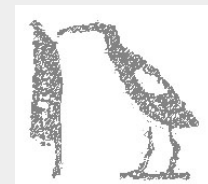
Different media

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



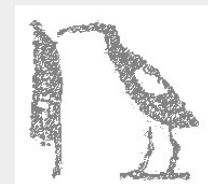
Different types of organization

- 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



Different peer review systems

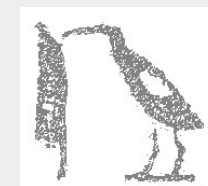
Type	Speed of decision	Feedback
In-house	Rapid (if rejected at this stage) (days or weeks)	Reason for rejection
External review	Slow (weeks or months)	Detailed review
Additional review	Even slower	Detailed, multiple reviews

From: Wager, Godlee & Jefferson,
How to Survive Peer Review



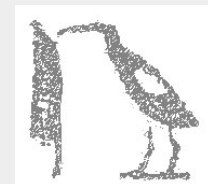
Publication timelines

Journal type	Example	Decision (months)	Publish (months)
Weekly general	<i>Lancet, BMJ</i>	1-3	3-6
Weekly specialist	<i>Circulation</i>	2	6
Monthly	<i>Heart</i>	2	6-7
Quarterly / slow	<i>Jnl Vasc Access</i> <i>Jnl Int Cardiol</i>	3-6	12
Rapid	<i>CMRO,</i> <i>BioMedCentral</i>	< 1	1-3



Rejection rates

Readership	Journal	Rejection rate
General	<i>Lancet, NEJM</i>	>90%
Specialist	<i>Circulation, Heart</i>	85% 75%
Sub-specialty	<i>Jnl of Interventional Cardiology</i>	50-60%
Super-specialist	<i>Jnl of Vascular Access</i>	c50%
Bias to publish	<i>CMRO, PLoS One</i>	10-30%



Different ‘philosophies’

- *Lancet* “prioritises reports of original research that are likely to change clinical practice”
- *BMJ Open* “all research study types – including small or potentially low-impact studies”

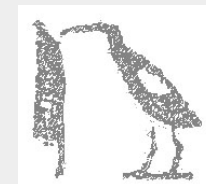
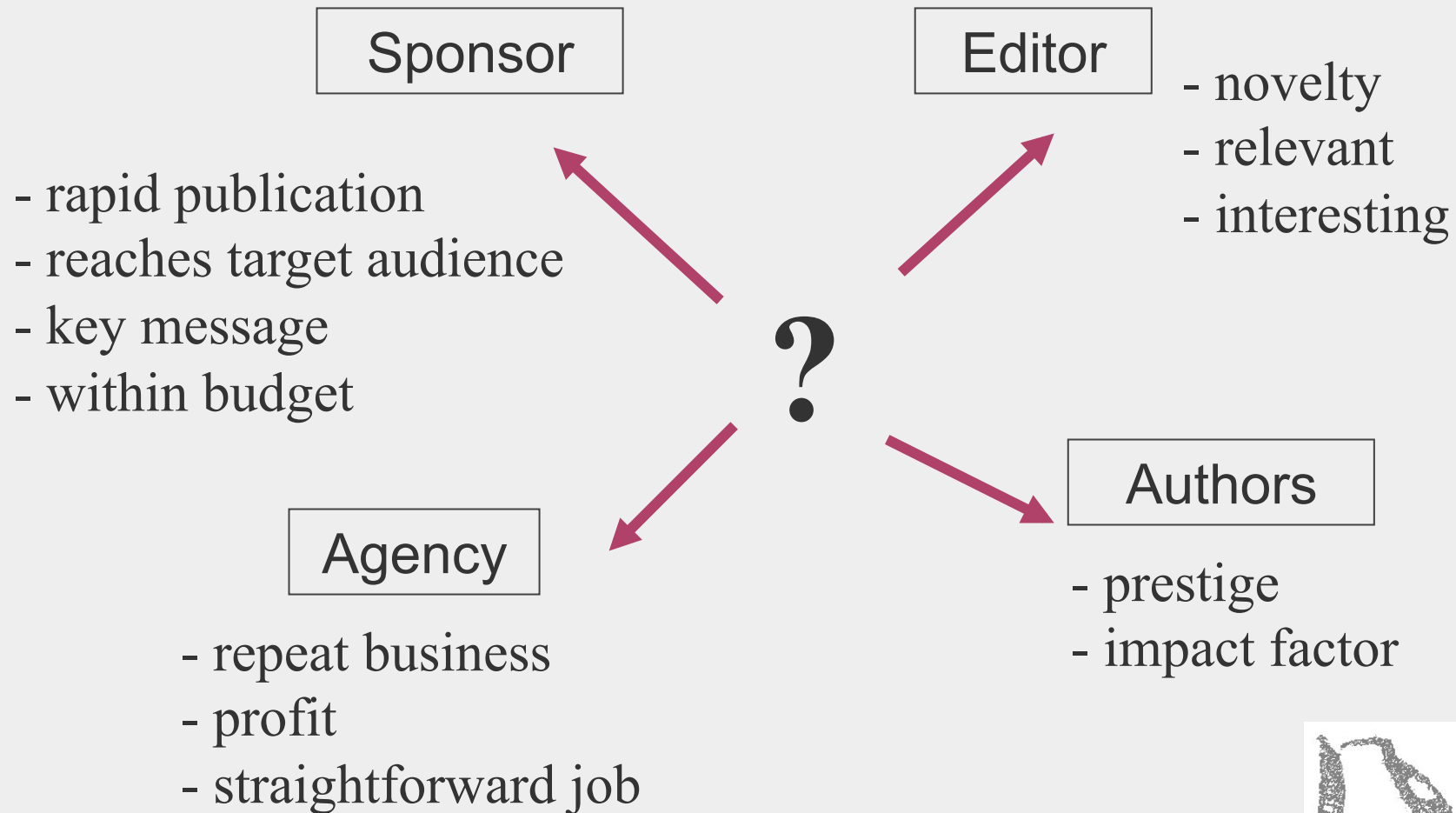


New philosophy

- *“Our editorial view is that readers can decide for themselves whether or not an article has value or relevance to them, and this is the way that the internet has transformed publication of all kinds. Print publication, because of space limitations, forces decisions on editors based on their judgement of what’s of interest to readers. Online publication allows readers to decide what’s of interest to them.”*
- Kamran Abbasi, *JRSM Short Reports*

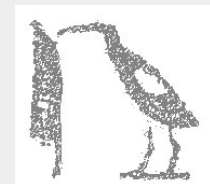


Keeping everybody happy



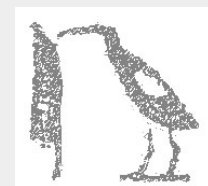
Keeping everybody happy

and following the guidelines ...



When you published your research

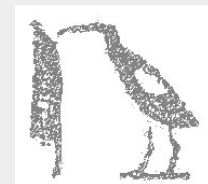
- Did you consult any reporting guidelines?
- Did the journal require you to follow any particular guidelines?
- Are you aware of any other guidelines on publications?



Guidelines to be aware of:

- ICMJE Uniform Requirements
- Good Publication Practice (GPP2)
- EMWA g/l for medical writers
- PhRMA principles / EFPIA
- ICMJE, WAME, CSE statements
- Declaration of Helsinki
- ISMPP position statement
- FDAAA (US law) re results disclosure

mainly process:
how / what /
when



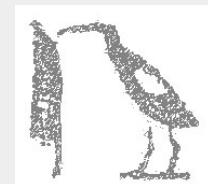
revised in
2013!

ICMJE (Vancouver Group) Recommendations

Covers a wide range of topics:

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

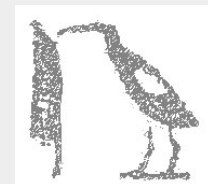
www.icmje.org



ICMJE authorship criteria

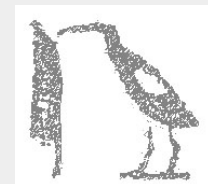
Authorship credit should be based on:

1. substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
2. drafting the work or revising it critically for important intellectual content; and
3. final approval of the version to be published; and
4. agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.



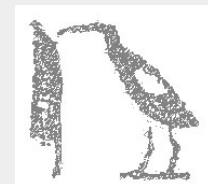
ICMJE continued

- “All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors”
- “All authors should be able to take public responsibility for the work”



ICMJE continued

- “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 include ... writing assistance, technical editing, language editing, and proofreading.”



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

BMJ 2009;**339**:b4330

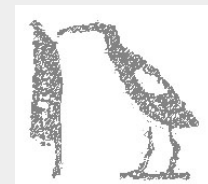
doi 10.1136/bmj.b4330

www.ismpp.org/gpp2



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

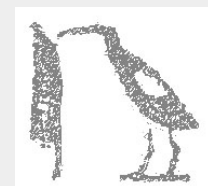
www.emwa.org

Jacobs & Wager



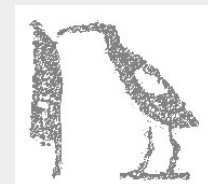
EMWA guidelines

- 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.



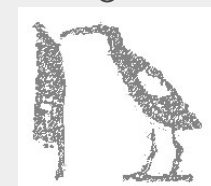
EMWA guidelines

- 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)

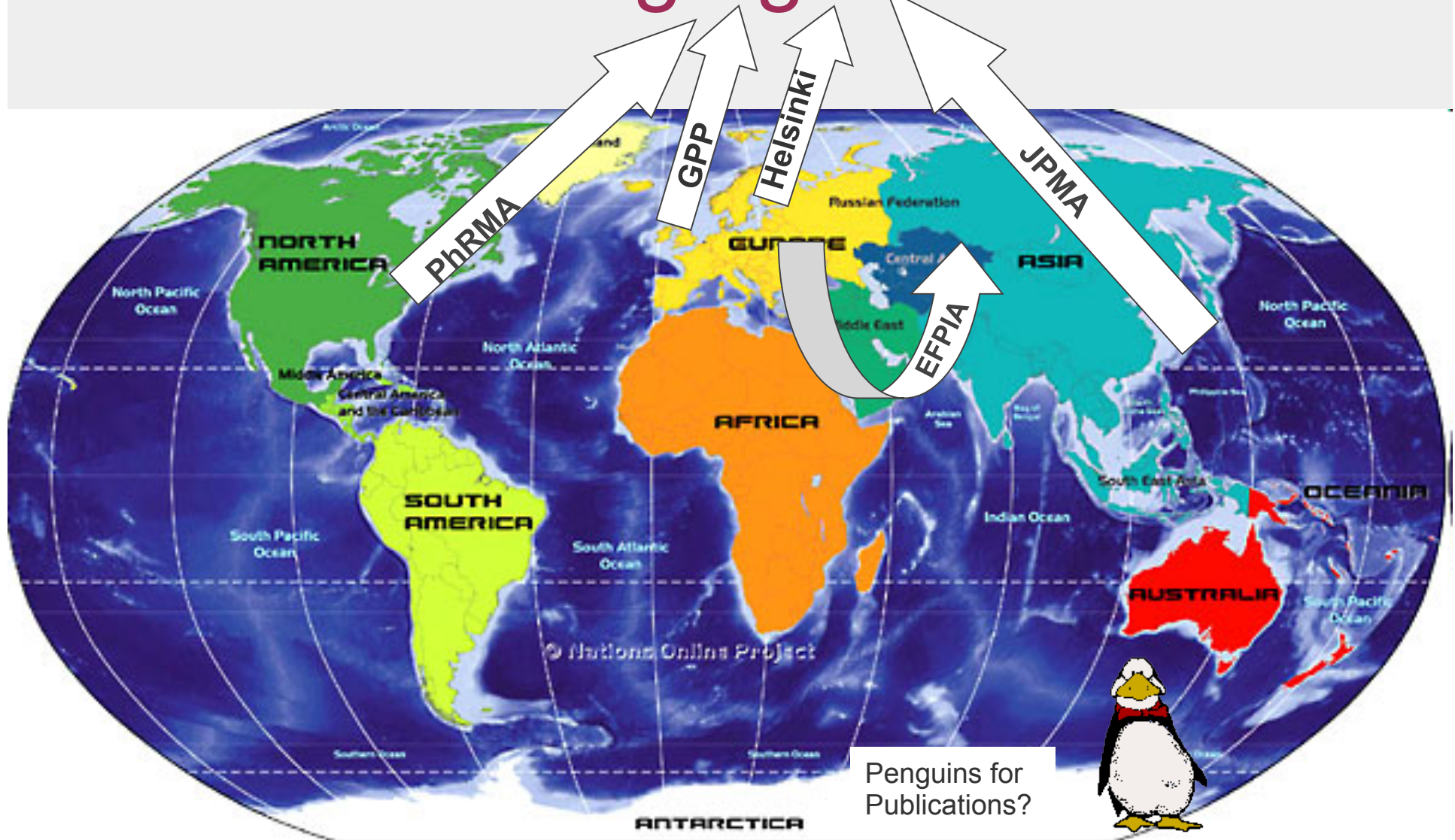


More guidelines!

- CONSORT
 - PRISMA (QUOROM)
 - STROBE
 - STAR-D
- All available at:
www.equator-network.org

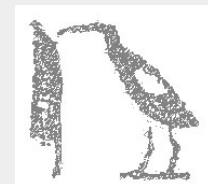


Enough guidelines?



Key points

- Medical writers need to be aware of guidelines on
 - Content (eg CONSORT)
 - Process (eg GPP2)
- And on specific journal requirements



If you only look at two sites:

- www.icmje.org
- www.equator-network.org



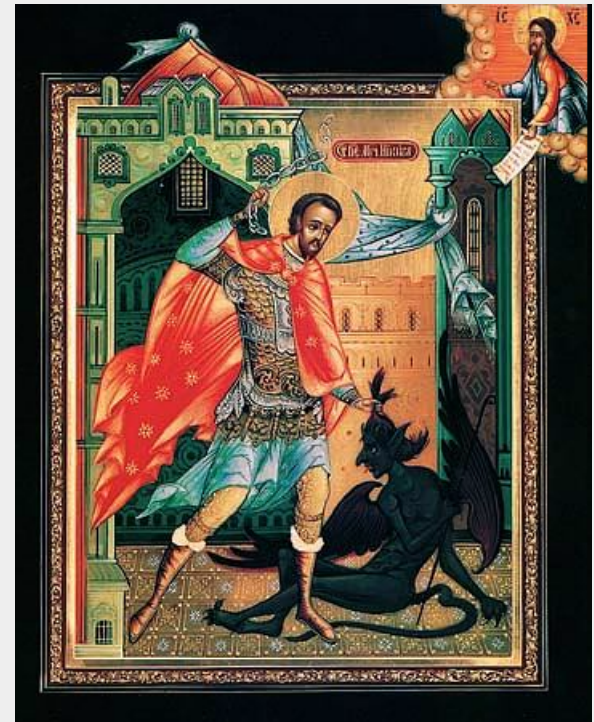
a noble
profession

So, you want to be a medical writer?

ensuring
research is
reported
responsibly

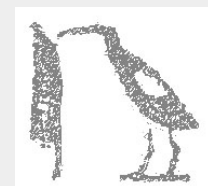


not everybody shares this view of
medical writers



How drug companies' PR tactics skew the presentation of medical research

- *The Guardian*, 20th May, 2011
- “army of hidden scribes paid by the drug companies to influence doctors”
- “publication planners ... work hand-in-glove with drug companies to create the first draft”
- “key messages laid out by the drug company are accommodated to the extent that they can be supported by available data”

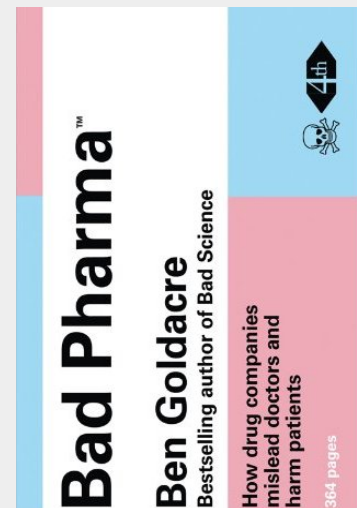




Ben Goldacre: Bad Pharma

- *“academic articles are often covertly written by a commercial writer employed by a pharma company”*
- *“the entire academic literature .. is ghost managed, behind the scenes, to an undeclared agenda”*
- *“commercial medical writers – and the ICMJE – need to fix their ridiculous guidelines, because everybody knows that they still permit ghostwriting to happen”*

Published, 4th Estate, Sept 2012



THE LANCET

Volume 359, Number 9313

Just how tainted has medicine become?

BMJ Nov 2000

Firm tried to block report on failure of AIDS vaccine

Scott Gottlieb *New York*

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

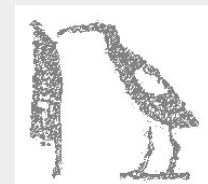
BMJ Jan '02

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

Charles Marwick *Washington*

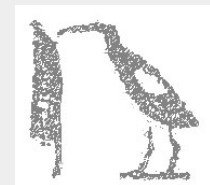
BMJ, May 2011

- *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**

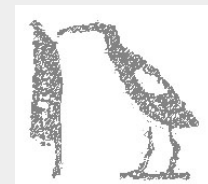


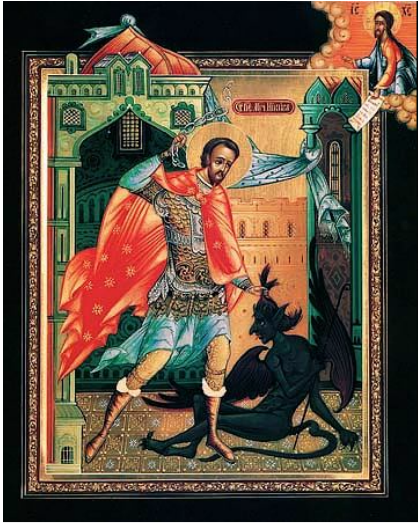
Are medical writers the same as
ghost writers?



Not necessarily ... WAME goes on to say

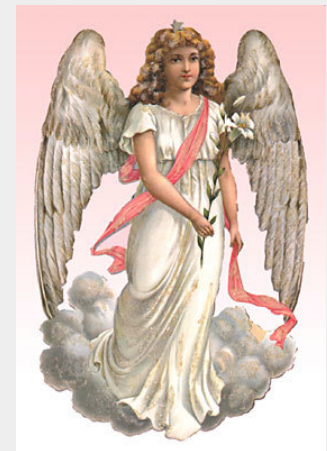
- To prevent some instances of ghost authorship, editors should make clear in their journal's information for authors that **medical writers can be legitimate contributors** and that their roles and affiliations should be described in the manuscript.





Key messages

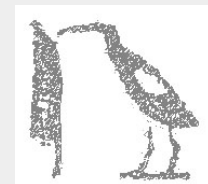
- Medical writers are not necessarily ghost writers or ghost authors
- The role of writers (and their funding) should be acknowledged
- There are lots of guidelines to follow!



It's not enough to know the rules

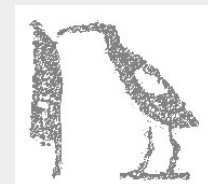
Medical writers often have to:

- liaise between authors and sponsors
- liaise with journals

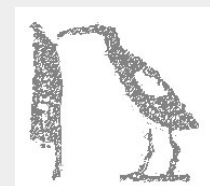


Medical writing

- 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 ...

**\$1000 CASH
REWARD**

