

EMWA

European  
Medical Writers  
Association

# The *Write Stuff*

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## The comma

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## Journal insights

The **Write Stuff** is the official publication of the European Medical Writers Association. It is issued 4 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims, but opinions expressed in individual articles are those of the authors and are not necessarily those held by EMWA as an association. Articles or ideas should be submitted to the Editor-in-Chief (see below) or another member of the Editorial Board.

## Subscriptions

Subscriptions are included in EMWA membership fees. By writing to info@emwa.org non-members can subscribe at an annual rate of:

- €35 within Europe
- €50 outside Europe

## Instructions for contributors

- The **Write Stuff** typically publishes articles of 800–2800 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by email as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

## Timelines

| Month distributed | Deadline for receipt of articles | Deadline for receipt of adverts |
|-------------------|----------------------------------|---------------------------------|
| March             | 1 <sup>st</sup> January          | 15 <sup>th</sup> February       |
| June              | 1 <sup>st</sup> April            | 15 <sup>th</sup> May            |
| September         | 1 <sup>st</sup> July             | 15 <sup>th</sup> August         |
| December          | 1 <sup>st</sup> October          | 15 <sup>th</sup> November       |

## Advertising rates (in euros, €)

| Corporate   | Private / Freelance members only |
|-------------|----------------------------------|
| • Full page | €1000                            |
| • Half page | €500                             |
| • Full page | €200                             |
| • Half page | €100                             |

## Behind the press

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|---------------------|--|
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## Cover picture

The cover picture is a cartoon drawn by Michael Dawes. The cartoon also appears on page 61 with a caption. The cartoon on page 45 was also drawn by Michael Dawes.





## **EMWA 9<sup>th</sup> Autumn Meeting**

**1-3 November 2007, Basel**



### **You are invited to the 9<sup>th</sup> Autumn EMWA meeting to be held in Basel, Switzerland from 1 to 3 November 2007 at the Ramada Plaza Basel.**

The Autumn conference will again provide members with further opportunity to continue with their training in the EMWA professional development programme. The workshop programme will cover a wide range of medical writing subjects, including advanced workshops for experienced writers looking to keep their knowledge up-to-date or refresh their skills. Further details and regular updates will soon be available on the website at [www.emwa.org](http://www.emwa.org).

Basel is perfectly situated for an Autumn conference. Centrally located on the border of Switzerland, Germany and France, it is easily accessible from all corners of the EU.

The city has the oldest university of the Swiss Confederation (from 1460), one of the best-preserved old towns in Europe and more than 30 museums.

Basel is also a seat of the pharmaceutical industry in Europe and we are hoping to have a speaker from the European Center of Pharmaceutical Medicine, which is located in Basel.

So make room in your calendar now and join us in Basel for a day of expanding your medical writing horizons.

**Julia Forjanic Klapproth**  
*EMWA President*



From the editor's desk:

## The comma

By Elise Langdon-Neuner

Don't be taken in by the theme of this issue. It's not dull and it's not innocuous. The comma has a history and it is still making history.

The comma's ancient origins go back to the Greeks when in the third century BC the head librarian of the library of Alexandria, one Aristophanes of Byzantium, devised a system of dots (distinctiones) placed at the bottom, middle or top of the line to signify how much breath you needed to take to read a fragment of text out loud [1]. The komma, as it was called, was not one of these dots but the term for the shortest passage denoted by a dot placed mid-level ( · ). Some thousands of years later in the 16<sup>th</sup> century the virgule suspensiva (/), which had emerged in the 13<sup>th</sup> century and represented a pause in text, took a curve and tumbled down to the bottom of the line to become our punctuation mark, the comma.

It's been there and causing trouble ever since. In her book *Medical English Usage and Abusage*, Edith Schwager gives an example of how we can trip up on a comma. She paraphrased a citation from the American journalist Theodore M. Bernstein: "In 1873 the Congress enacted a tariff bill intending to exempt certain products from payment of duty, including 'all foreign fruit-plants' that is, *plants* imported for the purposes of experimentation, propagation, or transplantation. The clerk who copied the bill mistakenly used a comma [fruit, plants] instead of a hyphen. Until a new version of the act could be printed, *all* foreign fruit and plants were lawfully admitted to U.S. ports duty-free". The resulting loss of revenues to the USA was more than \$2 million.

In an interview with Wolf Blitzer broadcast on CNN on 24<sup>th</sup> September 2006 President Bush, asked about the war in Iraq, said "I like to tell people when the final history is written on Iraq, it will look like just a comma". This provoked outrage. Many people viewed the statement as a dismissal of the deaths from the war as nothing more than 'just a comma' [2]. A salutary cartoon depicting a military graveyard with row upon row of plain white graves embossed only with a large black comma captured this view [3].

In 'The fatal comma' article in this issue of *TWS* Richard Clark refers to a court case currently being fought in the US which hangs on a comma and could cost the defendant over \$2.13 million. He also gives examples of a comma that reprieved a prisoner from exile to Siberia and an attempt to use the absence of a comma by the barrister representing Sir Roger Casement, the Irish nationalist hero, to save his client from hanging for his part in planning the Dublin Easter Rising of 1916.

The massive success of the Lynne Tullis' book *Eats shoots and leaves* is another reason that the comma and punctuation in general should not be ignored. Messing around with punctuation no longer has the image of a backroom pastime indulged by the greying lady editor with her hair tied back in a bun. You only have to write about these things to bounce out of the backroom and become rich and famous. (There's hope for *TWS* yet.) Books abound with titles like *Lapsing Into a Comma* (by Bill Walsh), *Comma Sutra* (by Laurie Rozakis), *Commas Are Our Friends* (by Joe Devine), and *Comma Sense: A Fun-damental Guide to Punctuation* (by Richard Lederer and John Shore).



So the comma which started life as an indication of where to take a breath has taken our breath away more than once in its long history. The North Americans have a reputation for littering their text with commas. An American writer and editor confided to me that she had no idea where to put commas but would generally insert them where she would take a breath in reading. Bill Walsh admits in his book mentioned above that the 'take a breath' comma is occasionally appropriate when the wording is unwieldy or when a dramatic pause is desired. He gives the following example: "Today, Shelley is on duty in what he calls a 'one-man fighting hole' on another battlefield—a Marine recruiting station in Lexington Park, Md., in St. Mary's County—with a mission to persuade young men and women to enlist, and probably go to war". The comma



## From the editor's desk

after enlist introduces a pause effect. The phrase following it is not a straightforward part of the persuasion; it's a necessary consequence of the other things he's persuading people to do [4].

Usually North American style guides now recommend using fewer commas rather than more. Most writers and editors still do not go as far as Gertrude Stein who thought that we could manage very well without commas. Yet her texts were clear and demonstrated a mastery in the craft of writing seldom encountered in medical writing. Mary Ellen Kerans writes about Stein in this issue of *TWS* and gives examples of her penmanship. Ordinary mortals could take the opportunity to use a full stop rather than 'and' or 'but' where a comma would otherwise be needed (, and). The test for this is whether it is indeed possible to divide the sentence into two sentences.

Ursula Schoenberg discusses the cultural differences between English and German comma usage in her article in this issue of *TWS*. I edit English text written by native speakers of German. There is one rule of English comma usage—and it really is a rule—which is often broken by these authors: a subject should never be separated from its verb by just one comma. An example of this transgression is: "The expression vectors harboring the antibody genes used in this study, were constructed at our facility". The expression vectors are left stranded from their verb 'were constructed'. A second comma is needed after 'genes' to separate off what in their articles in this issue of *TWS* Alistair Reeves calls a commenting clause and Valerie Elliston calls an isolating or bracketing comma. Everything else that needs to be said about commas I will leave to the experts. This issue of *TWS* gives you a series of comprehensive articles by Alistair Reeves, Valerie Elliston, and Richard Clark. But sometimes experts disagree. If you want to test your comma prowess after reading these articles try the BCC's quiz and their game with the scenario "You've got a new job, so you're going to need to know your commas for those lists and reports" (both at <http://www.bbc.co.uk/skills/words/grammar/punctuation/commas/>). The game might help you when making notorious dedications of this nature: "To my parents Ayn Rand and God". This is an apocryphal book dedication which should have been written "To my parents, Ayn Rand, and God." to avoid the impression that the person's parents were Ayn Rand and God. The example is used to support the argument for using a serial comma [5].

If you know all about commas and never err in their usage do not despair because there is plenty more to read about in this issue of *TWS*. One article on clinical trial disclosure is particularly topical. Special thanks to Kathy Thomas and Claudia Tesch for all their efforts which have made it possible to include the article in this issue of *TWS*. At the last minute before the issue was due to be sent to the printers the International Committee of Medical Journal Editors made a statement about clinical trial registration. The authors have worked hard to include a commentary on the statement in their article. An accompanying box draws attention to the meta-analysis by Steven Nissen and Kathy

Wolsk published in the *New England Journal of Medicine* which has evoked a heated debate about the safety of rosiglitazone. Data from GlaxoSmithKline's study results database were used for the meta-analysis by these independent scientists. The report has led to hectic activities by GlaxoSmithKline and the US Federal Drug Agency and shareholders are suing the company for not adequately disclosing studies it had conducted into rosiglitazone.

### Elise Langdon-Neuner

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#### References:

1. [http://en.wikipedia.org/wiki/Comma\\_\(punctuation\)](http://en.wikipedia.org/wiki/Comma_(punctuation))
2. <http://www.washingtonpost.com/wp-dyn/content/article/2006/10/04/AR2006100401707.html>
3. [www.anntelnaes.com/images/092606BushCommas.gif](http://www.anntelnaes.com/images/092606BushCommas.gif)
4. <http://theslot.blogspot.com/2005/03/i-rant-and-rave.html>
5. [http://en.wikipedia.org/wiki/Serial\\_comma](http://en.wikipedia.org/wiki/Serial_comma)

## What's news at EMWA?

*The EMWA Spring Conference, Vienna 2007*

## Why I enjoy EMWA Spring conferences

by Margaret Bray



I always enjoy EMWA Spring conferences and this year's conference in Vienna was no exception. This was my 7th Spring conference, and in my view the best venue we've had for a conference in my time as an EMWA member, and one of the best in terms of workshops, social programme and the special focus on medical communications. I've never travelled to Vienna before, and I found it such a welcoming place. The sun was shining, the atmosphere in the hotel/conference centre was great and within 5 minutes you were within the majestic environs of the city. Indeed, a highlight of the week was the tour of some of the galleries of the Kunsthistorisches Museum, prior to our banquet under the museum's dome. Built to house the Hapsburg monarchs' art treasures, we were given a tour of the museum's collections of paintings by the great renaissance painters such as Arcimboldo, Rubens, Titian, Velazquez, Carravagio and Bruegel, and given a fascinating insight into the history and techniques behind the paintings.

I participated in three main workshops. Periodic Safety Update Reports led by Alison Rapley was for credit on the Advanced Programme. I have written a number of PSURs, but have received little training and it was good to hear what Alison had to say. It was also good to attend this workshop to bring myself up-to-date with new guidelines,

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>>> **What's news at EMWA?**

something I would not necessarily have found out myself. So thank you Alison! One of the interesting and important aspects of PSURs is the different safety terminology used in these reports compared to, for example, clinical study reports. It's very useful to be familiar with PSUR terminology especially when it comes to understanding drug labelling etc. So, I recommend any writer involved in drug development to attend this workshop.

Medical Writing and Observational Studies led by Thomas Wagner was also part of the Advanced Programme. I've never written an observational study, although I have come across them from time to time in the course of my work. It was good to learn to recognise the difference between observational studies and the standard 'drug interventional study'. I also participated in one workshop from the Foundation Programme, Helen Baldwin's From Clinical Study Report to Manuscript. In the course of my work I'm often requested to write a manuscript from a study report, and it was good to get some fresh ideas from Helen.

However, workshops aren't everything at a conference, and for me the most important aspect is to spend 5 days in the company of other writers talking and networking, meeting old colleagues and friends, and meeting new faces. Whether it's a round table lunch discussion about patient information leaflet readability, talking medical communication over breakfast, discussing freelancing matters over a drink in the bar, there is always something to talk about. I rarely travel as part of my freelance business and most of my work is done via email and telephone from home. I don't feel isolated because of this because I have a very full work and home life. However, for me life as medical writer would be less inspiring without a conference. So I really hope to see you in Barcelona next spring so we can communicate some more.

**Margaret Bray**

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A question is raised at EMWA's Annual General Meeting in Vienna

**Report from the Freelance Business Forum in Vienna**

*by Alison McIntosh*

This was the 5th meeting of the EMWA Freelance Business forum, and we had the largest number of freelance members attending to date with about 55 attendees—a very good turnout despite the late hour of the day and the imminent prospect of evening walking tours of Vienna in superbly warm weather. The meeting this year was co-chaired by Alistair Reeves and Sam Hamilton.

Alistair started the meeting by giving us a sneak preview of the Freelance Business Survey which is being carried out by EMWA. The survey was last carried out in 2003, so this new information will provide a more up to date snapshot of what members are currently charging for their work, as well as highlighting the types of work EMWA freelance members (and a few others who responded) are undertaking for clients.

Although the full results of the survey will not be available until the September issue of *TWS* this year, we were given an indication of what to expect using the preliminary data available in mid-April. At that time there had been 80 respondents (63 in 2003), with the largest group coming from the UK followed by Germany, as in 2003. The majority were working full time, with key activities being medical writing, editing and translation. Most written documents were for the drug approval process, scientific papers and marketing material.

There is still time to take part in the survey, which can be completed online and takes only a few minutes. Your responses are confidential, as there is no way of identifying who has responded. As a medical writer, you know: the more people who respond, the more robust the data! The survey is open until 13 July 2007. You can complete the questionnaire by pasting the following link into your browser <http://www.surveymonkey.com/s.aspx?sm=kLNS3CdA%2bzd24JHK0mE8%2fw%3d%3d>. So, please, if you have not yet responded, make sure you do before the deadline!

A second topic for discussion was the possibility of providing templates for legal documents. A show of hands indicated that in most countries writers depended on receiving documentation regarding confidentiality agreements and contracts from their clients. These were read very carefully and any inappropriate clauses discussed and hopefully removed. This was not true in some countries, including France, where some writers had each contract looked over by a lawyer before signing. After some discussion it was concluded that it would probably be too difficult to have appropriate wording suitable for every EU country. However, Sam together with Linda Liem volunteered to put together a useful checklist of what needs to be considered in contracts. In addition, a list of general tips for business set up and conduct was suggested as a potentially useful resource. Helen Kulesza and Elaine O'Prey offered to help with compilation of this list. This list will be published in the September issue of *TWS* and on the website.



## What's news at EMWA?

Further topics of discussion concerned the question of sharing information about late or non-payment, as well as issues new freelance members need to look out for when beginning. Although a few members had experienced non-payment from individual clients, it did not appear to be widespread. Late payment was more common, but most freelance members reported that payment eventually comes through without resorting to lawyers. A request was submitted for a bulleted list to be provided on the website concerning "Freelance Pitfalls," but this would cover only general concerns and not information about specific clients<sup>1</sup>.

Thanks to Alistair (a.reeves@ascribe.de) and Sam (sam@samhamiltonmwservices.co.uk) for organising and chairing the meeting, and also undertaking the new survey. And (from Alistair and Sam), thanks to Alison for preparing this report on the meeting.

If you would like to help Sam with the checklist, she will be pleased to hear from you. And if you have any questions, concerns or comments about any of the issues reported here please let us know. Alistair received several requests for a similar forum at the EMWA Autumn meeting, as it is often easier for freelance colleagues to attend the shorter meeting, so we will be making sure that the programme at future autumn events also includes a Freelance Business Forum.

### Alison McIntosh

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<sup>1</sup> Post meeting note: It was suggested that an e-mail list of freelancers was set up to circulate information. All freelancers would receive the mails and it would be up to the individual to participate in the e-mail dialogue. This possibility is currently being explored with EMWA.

The Photographs on pages 47 and 48 were taken by Crispin Hodges (webadmin@emwa.org)



Virginia Watson with the bouquet she received at the Spring Conference in Vienna as a token of EMWA's gratitude for her hard work and dedication as Education Officer for the past 2 years and the many years before this that she contributed to developing EMWA's Professional Development Programme.



The five Nick Thompson Award fellows on the occasion of the presentation of the fifth award to Marion Hodges in Vienna at the 16th Annual Spring EMWA Conference. The fellows are (from left to right): Art Gertel, Geoff Hall, Marion Hodges, Barbara Grossman, and Barry Drees. The Nick Thompson award confers on the recipient lifetime honorary membership in EMWA and is awarded to EMWA members on the basis of extraordinary contributions and service to EMWA. It honours the late Nick Thompson, one of the founding members who played a key role in the establishment of EMWA. Nominations for a Nick Thompson Award can be made by any EMWA member (other than existing recipients). The nomination is submitted to the president of EMWA, who, provided he or she feels that the nomination is not frivolous, then passes it on to a panel comprising existing Nick Thompson award holders, who discuss the nomination in private. If the panel decides unanimously in favour, the president is informed and the award is presented at the following spring conference. *TWS* and all EMWA members would like to extend hearty congratulations to the newest Nick Thompson fellow, Marion Hodges, who can be seen below (right) receiving the award from EMWA's new president Julia Forjanic Klapproth (left).



## The decimal comma-point conundrum

Amelia Williamson, intern at *Science Editor* (the Council of Science Editors periodical), has been preparing an article about the style differences in decimal notation. Most of Europe uses the comma as a decimal separator, while the United States uses the period. The article discusses the history of decimal notation and the style difference as well as potential problems the difference could pose for writers and editors. The article is expected to appear in *Science Editor* in late 2007 or early 2008.

## Moral dilemmas

*Do medical writers face moral dilemmas and if so what role does intuition play in resolving them? For a job that has the image of working in a backroom poring over complex data and compiling documents all day, medical writers if you go by reports about ghostwriters in the popular press are faced with an alarming number of moral dilemmas on a daily basis....*

"Nothing captures human attention more than a moral dilemma. Whether we are soap opera fanatics or not, we can't help sticking our noses in other people's affairs, pronouncing our views on right and wrong, justified or not." These words introduce the MST (Moral Sense Test) website [1] created by the psychology department at Harvard University. The website is part of research the university is conducting into the role of intuitive responses in ethical reasoning. Visitors to the site are asked to participate in the research by completing the test.

The tens of thousands of responses that have already been received show a high degree of consistency regardless of the participants' nationality, ethnicity, religion, age and sex. Joshua Greene working at Harvard has shown by functional magnetic resonance imaging that when people are asked to make a moral judgement about 'personal' violations, like pushing a stranger off a footbridge, activity increases in the brain areas associated with emotions. A similar increase was not seen with 'impersonal' actions, like throwing a switch that diverts a train. His explanation is that it has only recently become possible to harm other people through remote rather than personal contact. The evolution of emotional responses is still lagging behind this development. The consistency in moral intuitions does not necessarily make them right. Peter Singer, a professor of biometrics at Princeton University, suggests on the contrary that we should be sceptical about relying on our intuitions [2]. Blowing up people with bombs is no better than clubbing them to death. We should think for ourselves and not just listen to our intuitions.

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### References:

1. <http://moral.wjh.harvard.edu>
2. [www.project-syndicate.org/commentary/singer21](http://www.project-syndicate.org/commentary/singer21)

(NB: the Project Syndicate website is excellent for anybody interested in world politics).

## MedDRA 'preferred' terms

For anyone involved in writing up the findings of clinical trials for study reports or preparing summary documentation for market authorisation dossiers, the advent of the Medical Dictionary for Regulatory Activities (MedDRA; <http://www.meddrasso.com/MSSOWeb/index.htm>) was certainly a great leap forward.

Since clients have been using MedDRA, however, I have noticed a phenomenon which was not so marked when they previously used other classification and coding systems: insisting on using 'preferred terms' in the 'logical' order they are used when coding with MedDRA when writing up results, i.e. 'term' and then 'modifier', when the actual 'expected' word order in English is the reverse, because most terms are nouns and most modifiers are adjectives.

Good examples are 'rash' and 'dermatitis', which are often modified. I can live with 'rash morbilliform', 'rash maculo-papular' or 'dermatitis contact' in lists in frequency tables, but I think we should make the extra effort in the accompanying text to supply the reader with the expected word order, viz 'morbilliform rash', 'maculo-papular rash' or 'contact dermatitis'. Tables are probably generated from the database where the terms are stored with the modifier as some sort of subset to the condition, and it would be an inordinate amount of work to go through every table switching them around. But text is a different matter. To me, leaving the modifiers after the terms is doing a disservice to the reader. Recently a client insisted on saying 'One patient developed hallucination auditory' and the reason was 'because this is the order in MedDRA and this is how it is listed in our tables'. Is there really any likelihood that the informed reader (and I assume that authority reviewers can be regarded as such) might think that the 'auditory hallucinations' in the text accompanying a table were different from the 'hallucination auditory' listed for a patient in a table just above, or in a table in the report appendix? Would you prefer to read 'Atrioventricular block first degree was observed in 2 subjects' or 'First-degree atrioventricular block was observed in 2 subjects'?

Am I making a mountain out of a molehill? It would be interesting to hear what others think about this.

**Alistair Reeves**

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## Call for Applicants for EMWA Professional Development Committee

The EMWA Professional Development Committee (EPDC) would like to invite applications from EMWA members for two positions on the committee.

As a committee member you will be involved in all aspects of developing and maintaining the EMWA Professional Development Programme including the quality and type of workshops that are offered and aiding the development of new workshops through the mentoring system. The core of EMWA is the EPDP and by serving on the EPDC you can help to shape and guide the future of this vital programme. Remember, there is more to EMWA membership than just leading or attending workshops and networking; the chance to gain experience in a planning or managerial role is also invaluable.

If you would like to contribute to the work of the EPDC by applying for this post, or are tempted but would like to know more, please contact the Education Officer, Stephen de Looze (Stephen.deLooze@accovion.com) or any member of the EPDC (details on the EMWA website) who will be happy to provide more details.

## Komma Kummer<sup>1</sup> in Berlin



This photograph of a façade from the palace of Sanssouci in Berlin was taken by Rainer Bischoff. Sanssouci was the summer residence of King Friedrich II. Apparently he called it Sanssouci (which is French for 'without sorrow') as a reminder of the blissful days of his youth before he became weighed down with the duties and responsibilities which come with being a king (or for us ordinary folk 'growing up'). What Rosie Bischoff (RCB@clinwrite.com), who sent the photograph for *TWS*, would like to know is what possessed Friedrich to put a comma between sans and souci. She has sent an email to the palace management to ask them to explain the comma. To date she has not received a reply leading her to the conclusion that "some people just do not understand what is important in life!"

<sup>1</sup> The German 'Komma Kummer' translates as 'Comma distress' in English.

## Call for manuscripts

A special issue of *Panace@* asks, "Should the entire protocol of every clinical trial be translated into the researchers' local language?"

In Spain the time to approval for a multicenter clinical trial was shortened substantially by skipping some steps in the approval process. The Spanish drug regulatory agency and co-ordinating centre's clinical trials ethics committee agreed to the abbreviated process because the trial (of an avian flu vaccine) was considered a high public health priority [Dal-Ré R, García-Corbeira P, Morejón E. ¿Cuál es el tiempo mínimo necesario para iniciar un ensayo clínico multicéntrico en España? *Medicina Clínica* (Barc) 2007;128(7):275].

One of the steps that was skipped to save time was translation into Spanish of the trial protocol. Only the summary, the application to the national regulatory agency, and the patient consent form were translated into Spanish.

Because medical writers in Europe are also frequently translators, readers of *TWS* may have experience with similar situations. Is the entire protocol usually translated in your setting? If not, why not? Have unsatisfactory translations in the past led to the conclusion that translation is not worth the cost? Do all clinical researchers read English well enough to follow the protocol correctly? Has requiring clinical researchers to use documents in English ever compromised the quality of the data they collected?

*Panace@* ([www.medtrad.org/panacea](http://www.medtrad.org/panacea)), an on-line, multilingual, open access journal read mostly by medical, pharmaceutical and life science translators and editors, publishes articles in Spanish, English, and other main European languages. The journal enjoys high access and download rates, and the guest editors hope this special issue will reflect views from many countries because policies and practices may differ.

If you'd like to submit an article for the upcoming special issue of *Panace@* on clinical trials, please contact me at [kshashok@kshashok.com](mailto:kshashok@kshashok.com). The deadline for manuscript submittal is 1 April 2008.

## Elsevier withdraws

June started well with the announcement on 1 June that Elsevier is to withdraw from its exhibitions for the weapons industry. The company's chief executive officer said, "It has become increasingly clear that growing numbers of important customers and authors have very real concerns about our involvement in the defence exhibitions business".

<http://www.reed-elsevier.com/index.cfm?articleid=2084>:

## “No point to PowerPoint, says professor”

This is the title of an article written by Richard Alleyne [1]. He accompanies the article with a photograph of a lady yawning to illustrate Professor John Sweller’s scientific explanation for why a room full of PowerPoint viewers yawn within a couple of minutes of seeing the first slide. We illustrate things slightly differently in *TWS*.



[Photo credit: Marlies Kari Neuner]

Sometimes I get the impression that the executives I work with spend most of their time presenting what other executives in the company are doing to yet other executives in the company. That is on the assumption that there is somebody (apart from me) doing some work rather than presenting about work. All these presentations are given with the aid of PowerPoint. But wait, what did John Sweller say?

“The use of the PowerPoint presentation has been a disaster. It should be ditched.”

*John Sweller, April 2007*

This could leave a lot of my executives without a job and the statement predictably caused a ripple through Web forums [2]. So we need to look at it a bit seriously.

John Sweller is a professor at the School of Education,

University of New South Wales in Sydney. He founded the Cognitive Load Theory in the 1980s. The theory relates to ‘working memory’. The part of the brain responsible for this memory provides temporary storage and manipulates information necessary for complex cognitive tasks, such as language comprehension, learning and reasoning [3]. According to Sweller everything we are aware of goes through working memory, which has a limited capacity of only three to four items of information that can be held for only three to four seconds. Almost all information goes after 20 seconds, unless there is rehearsal.

Working memory is impaired by bombardment by redundant information. This is where the PowerPoint thing comes in. If one form of instruction is intelligible and adequate, providing the same material in another form has a redundancy effect which impairs understanding. Therefore rather than presenting words as text on a screen and reading from the screen the words should just be said. Alternative we could all get on with doing some work and just send our words as a PowerPoint presentation to colleagues without wasting time giving the presentation.

If you do feel compelled to give a presentation then you should think about what you put on the slide. Sweller concluded that using different modalities—audio and visual—increases the capacity of working memory and understanding. He says it is effective to speak to a diagram because this combines the audio modality of hearing the words with presenting the information in a different form by the visual modality. Surely then PowerPoint should not be ditched but used effectively to present illustrations rather than repeat your spoken text.

**Elise Langdon-Neuner**

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1. <http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2007/04/19/nppoint19.xml>
2. [http://www.presentationzen.com/presentationzen/2007/04/is\\_it\\_finally\\_t.html](http://www.presentationzen.com/presentationzen/2007/04/is_it_finally_t.html)
3. [http://www.unsw.edu.au/news/pad/articles/2007/mar/Cognitive\\_load\\_theory.html](http://www.unsw.edu.au/news/pad/articles/2007/mar/Cognitive_load_theory.html)

## 500 words are not enough

Beate Wieseler [see box entitled ‘Meeting the final goal of trial registration’ *TWS* 15(1), 2006 page 61] is disappointed by the ICMJE’s statement<sup>1</sup> that abstracts of more than 500 words can be considered a prior publication of results by journals and preclude publication of a full article in the journal. While the ICMJE confirms that results presented as an abstract of less than 500 words will not be considered to be a previous publication, the editors clearly state that “Researchers should be aware that editors may consider more detailed deposition of trial results in publicly available registries to be prior publication.” An abstract of 500 words cannot include sufficient informa-

tion for use of a study in a systematic review and cannot sufficiently explain the methods and results of a study. The rosiglitazone results reports in the GSK registry, which are based on a study synopsis according to ICH E3, generally were longer than 500 words and hardly had enough information. There is clearly a need for further debate to reach the final goal of trial registration.

<sup>1</sup> Laine C, Horton R, De Angelis CD, Drazen JM, Frizelle FA, Godlee F, Haug C, Hebert PC, Kotzin S, Marusic A, Sahni P, Schroeder TV, Sox HC, Van Der Weyden MB, Verheugt FWA. Clinical trial registration. Looking back and moving ahead (editorial). *JAMA* 2007; June 4: E1-E2.





## Message from the President

By Julia Forjanic Klapproth

Wow, what a conference. This year's conference in Vienna was the second in a row to have a theme. As Vice President I developed the theme idea to expand upon what EMWA offers at its conferences in order to reach out to a broader scope of writers—both advanced writers and writers in non-regulatory areas. And the popularity of this conference, in my opinion, is the clearest indication that the theme idea is working. Most of the workshops and events at this conference sold out within the first 3 weeks, some within 5 days. We have never had such a rush on registrations as we had this year, which shows that we are offering things that interest a lot of people. Not only that, the rapidness with which people sent in their registrations this year is now comparable to the way the events at the AMWA annual conference sell out—an organisation of much larger dimension. We are moving onto a new stage of size and calibre. This is exciting for me, personally, because I see that the idea of the themed conference is achieving what I had hoped for. EMWA is attracting a larger audience and becoming a forum for wider discourse.

***EMWA's new EC structure will be described in detail in September's TWS***

But I am aware that growth like this can also be overwhelming at times. I have a 3 ½-year-old son and it is so rewarding to watch him grow and develop. He is at that age when he is adamant about wanting to show me how big he is and how he can do everything on his own. And to a large extent I give him as much independence as I can. But there are moments, for example when I turn around and see him standing precariously on top of a high fence over a chunk of asphalt yelling "Mommy, Mommy, look at me", when I realise that it is important to take control of the situation. Leading a rapidly growing organisation like EMWA is a similar experience. It thrills me to see how successfully it is growing. But I realise that to meet the expectations of its rapidly growing membership, processes and systems need to be brought into place to keep up with the pace.

During our annual general meeting (AGM) this year the members made it clear that we need to work on the logistics of coordinating EMWA behind the scenes. With our improved economic situation we are now able to invest in electronic systems that will allow us to manage our databases and conference registration online. We intend to have such a system in place for the Basel conference this

Autumn. However, while such an electronic system will help us sort out many of the problems discussed during the AGM, electronics alone will not solve everything. We will need to look at all aspects of how EMWA is run and come up with a system that includes clear processes for communicating to members and workshop leaders to avoid misunderstandings. We will need to make sure conference programmes are finalised further in advance of the conference date to give more time for registration. The full conference brochure will be reintroduced by popular request. And I am sure as we assess the situation we will find other processes that need to be optimised. Improving these things will be crucial to maintaining the quality of what EMWA offers as well as our credibility as a professional organisation. And it is our foremost priority.

In the next issue of *The Write Stuff* I will write an article describing the structure of the Executive Committee that has now been elected into place. I realise that there are several points that people are unsure about and I hope to clarify these so that the membership has full transparency around what the new structure is and how it is meant to function.

Outside of these logistical issues, however, only positive feedback on the conference was received. This was the first conference I have seen in years where the advanced writers were as enthusiastic about the conference programme as the new writers. There was once again a great social atmosphere, which was aided by the wonderful social programme developed by Head Office. It is this sense of community that I love about EMWA and which makes EMWA conferences so special.

I have to say I have arrived home from this conference tired but content. As a parting word I again want to thank everyone, especially the workshop and seminar leaders, plenary speakers, and discussion panel members who volunteered their time and without whose enthusiasm a conference like this could never be realised.

**Julia Forjanic Klapproth**

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## If in doubt, leave them out—or maybe not? Subtitle: Do the best you can!

by Alistair Reeves

It is impossible these days to write anything about punctuation in English without Lynne Truss' phenomenally successful 'Eats, Shoots and Leaves' hovering in the background [1]. Some would say: 'She did it all. Why bother to write more?' As far as I am qualified to say this, I think she did a very good job on the comma and other punctuation marks, but went overboard on the apostrophe (but then we all have our bugbears). When the book was launched, she did give EMWA much free publicity, because in a newspaper article (I have been unable to locate which, although I saw it at the time) she publicly criticized an entry in our conference programme. The entry was 'New Members Welcome Drink', and she felt that there should be an apostrophe after the 's'. This is also immortalized in her book (p. 51), although the source is not quoted there—and the point will remain controversial. I had reviewed the programme in question and taken out the apostrophe, as I felt that the new members would not be bringing their own drinks.

We did not come in for any criticism with regard to our use of commas, however. This is surprising because the comma is as controversial as the apostrophe, and variants on the question 'Should I put a comma here?' are amongst the most frequent I hear.

Lynne Truss closely observed and analysed the *popular* use of punctuation (where transgressions prevail: *tea's + cakes', ladie's toilet, do-nut*) and did not cast her eye specifically over usage in scientific texts. There is much overlap, of course. I shall try to pick out here some situations where particular attention should be paid to comma usage in our context. Otherwise, the following websites (and there are many more) make illuminating reading and describe the basic rules and conventions much better than I can:

[http://owl.english.purdue.edu/handouts/grammar/g\\_comma.html](http://owl.english.purdue.edu/handouts/grammar/g_comma.html)  
<http://www.grammarbook.com/punctuation/commas.asp>  
<http://www.stpt.usf.edu/pms/comma.html>

If English is your first language, you have probably been surprised that some writer colleagues with English as a second language have an inordinate interest in the comma. Apart from a general interest in 'getting it right', they are probably used to incontrovertible rules in their first language that determine when a comma is needed or not. The grey area in English is—unfortunately—enormous. This is why even those whose first language is English also struggle with the comma—as I do.

Apart from the few rules we have, an effective way of deciding where to put a comma in English is to read your

sentence out loud, or ask someone else to read it out. Without realizing it, writers often use commas for one of two purposes: to set off an element of a sentence from an introductory clause or introduce a new idea with a slight pause (*Although 225 samples were taken, only 22 had been properly fixed, and 2 of these were contaminated*), or to separate two or more elements when you would pause when speaking, or the voice would rise. This is only an effective way of deciding if you are very familiar with usual English intonation (and this varies from region to region and country to country anyway). Another common situation is when deviating from normal or expected word order (subject-verb-object interposed with adverbials usually after the verb) to obtain stress.

This means that we have to have some 'rules' or 'conventions', even if—like so much in the English language—they will never be reliable. One of the main things is to avoid overuse, even if it is not strictly *incorrect*, because I think that overuse of the comma is more disconcerting to the reader than underuse. My main advice with the comma is 'If in doubt, leave it out', but there are definitely many instances where it is indispensable.

First, a few basics (not exhaustive):

### *What do commas actually do?*

Like all other punctuation marks, they send out messages to the reader, facilitate comprehension, awaken expectations, and contribute to *meaning* and *sense*. Some punctuation marks in English send out very strong messages, such as the em-dash (—) or the colon (:), and others a weak message, such as the semi-colon (;) or square brackets ([ ]). The problem with the comma is that it sends out mixed messages and can be used either singly or in pairs, and, specifically in our area in medical and scientific writing in Europe, speakers of English as a second language may be used to the comma in their first language giving the reader a very much stronger message than in English. When used in pairs, they separate off information in some way, but so do brackets (parentheses) and em-dashes. These three devices often appear interchangeable, and there is a hierarchy: brackets are weakest and em-dashes strongest, with commas in the middle. Some examples are given below. Whatever: the comma should be used *only* when it helps the reader to understand your sentence, and not only because you are observing a 'rule' or a sometimes spurious convention (e.g. you must have a comma before 'too' at the end of a sentence or after 'i.e.' [see below]).



## Some instances where commas are definitely wrong

**Decimal separators.** Very basic and should be easy, but even these days I still see this error almost weekly: the comma is *not* a decimal separator in English: 8,9 mg/dL is incorrect; 8.9 mg/dL is correct<sup>1</sup>. 10.000 for ten thousand is not correct, it should be 10,000. The raised comma (10'000) may appear on some calculator displays or be used in the IT world, but it has not caught on yet, and people seem to be strangely resistant to this sort of change. Even though 10<space>000 is recommended from some quarters, the space is too soft a character to catch on quickly, so we are stuck with the comma. As boring as it is, you just have to change all those commas to decimal points (or vice versa) in your texts and tables.

**Used before 'that' and 'if' (when 'if' is erroneously used to mean 'whether').** A comma is not used before 'that' when 'that' is used after an introductory clause (*The EMEA claimed that ...* or *She said that ...*) or as part of a defining clause (*The samples that we received today were all spoiled*) (see below). If you feel you have to write: *The investigator enquired if we could send her...*, do not be tempted to put a comma before the 'if'. In any case, it should be 'whether' and not 'if' when you are writing, and there is no comma before 'whether' either.

**After 'both', when it is used as an adverb.** 'Both' is both an adjective and an adverb. A comma would be incorrect after 'both' in the following sentences: *Similar findings were made in both the elderly and young subjects*; *Both the cats and the rats showed considerable weight loss*. Both when used as an adjective (*in both groups*) is also obviously not followed by a comma.

**Between non-coordinate adjectives.** Non-coordinate adjectives are adjectives that cannot be exchanged in position or cannot be separated by 'and' (the above websites give good help on this one). The adjectives in the following sentence are non-coordinate: *Insert the long white plastic tube into the base of the device*. You cannot reasonably say: *Insert the long and white and plastic tube...*, nor can you say *'the plastic white long tube'*, and commas are therefore not needed. The adjectives in the following sentence are coordinate: *Expensive, labour-intensive studies are a thing of the past*. This is because you could also say: *Labour-intensive, expensive studies are a thing of the past*. And you could replace the comma by an 'and'. The problem is that many instances of this involve mixtures of non-coordinate and coordinate adjectives, use is not consistent, and sometimes it is just a matter of feeling.

**Before 'because'.** A sweeping statement: there is never a comma before 'because' (1), unless it is used after the second of a pair of commas (2). Examples: (1) *The subject was*

## If in doubt, leave them out—or maybe not?

*withdrawn because she developed pneumonia*; (2) *Dairy products must be avoided, even if the patient has tolerated them well before, because they can inactivate the active substance ...*. If, however, the second sentence read *Dairy products must be avoided, even if the patient has tolerated them well before because they were taken in moderation*, there is no comma before 'because' because the 'because' clause is explaining why they were well tolerated and not why they must be avoided.

## Some instances where commas are definitely right

**When they are necessary to avoid confusion.** This covers a multitude of issues. Sometimes it just makes things easier to read and understand, so the reader does not have to backtrack. Making a reader backtrack is never desirable. Examples: *If the adverse event is serious details of concomitant medications taken over the past two weeks must be documented*; or *Despite this new information on genetic alterations changed our opinion*. In the first example, the mind automatically reads 'serious' as a modifier of details, and it is actually the complement of the verb 'to be' in this clause, so 'serious' should be followed by a comma. In the second example, it is not until you reach 'changed our' that you realise that something is wrong here and that there should be a comma after 'this'. In both cases you have to backtrack because of the omission of a comma.

**When the clauses in a sentence have different subjects.** This is explained in more detail below and does not apply to 'if clauses' at the beginning of a sentence: *If the samples are out of date, they must not be distributed*. Here a comma is needed, but *The samples must not be distributed if they are out of date* does not need a comma.

**When they are used in pairs around commenting clauses.** The 'which' clause in the following sentence is called a commenting clause: *The blood samples, which will be analysed on 24 June 1996, must not be deep frozen for longer than 1 week*. This actually means that all blood samples concerned will be analysed on 24 June and that none of them must be deep frozen for longer than 1 week. What happens when we delete both commas? *The blood samples which will be analysed on 24 June 1996 must not be deep frozen for longer than 1 week*. The sentence now means that only the blood samples scheduled for analysis on 24 June 1996 must not be deep frozen for longer than 1 week. The 'which' clause here is called a defining clause. Speakers of British English have been tending for years now towards 'that' instead of 'which' in defining clauses: *The blood samples that will be analysed on 24 June 1996 must not be deep frozen for longer than 1 week*. This is OK. What is impossible is: *The blood samples, that will be*

<sup>1</sup> If you use the English version of Word and have not changed any of the language settings and have the grammar check switched on, you will note that if you write '8,9 mg/dL' the comma and the '9' are underlined with a zigzag line, indicating that this has been recognized as an error, because the system expects a space after a comma. I generally like to think that I am better at grammar than Word, but in this case it is a good indicator that something needs correcting!

>>> **If in doubt, leave them out—or maybe not?**

*analysed on 24 June 1996, must not be deep frozen for longer than 1 week.* Commenting clauses always have to be constructed with ‘which’ and always need commas, and if you leave out the commenting clause, you must be left with a complete sentence.

**In verbatim quotes.** Whether you write “*That’s when I tripped and cut my head*”, the patient said or *The nurse said, “I gave her the injection at 10 o’clock”*, you need a comma. In the first example, I have used typical European positioning of the comma after the inverted commas; typical US positioning would be the reverse (,). This does not apply to the comma after ‘said’ in the second example.

**Before ‘or’ when there are more than 2 choices.** No comma is needed in: *Patients usually respond to amoxicillin or cefixime.* A comma is needed in: *Patients usually respond to amoxicillin, cefixime, or ofloxacin* (at least that’s my opinion). This is like the use of the serial comma before ‘and’ [2].

**What about the grey area?**

I have dealt with two regions in this grey area in previous TWS articles on myths about English: the supposed obligatory use of a comma after ‘e.g.’ and ‘i.e.’ (I am against it) [3], and the use of the comma before ‘and’ in lists (I am for it) [2]. There are many others, e.g.: should there be a comma before ‘respectively’ after subsequent running lists to establish relationships in a sentence, or should there be a comma before ‘too’ when used to mean ‘also’ at the end of a sentence. Brief answers to these: unfortunately, respectively is often grossly overused—and inappropriately—by many writers who confidently hope that the addition of this encumbrance will disentangle their sentence for the reader; whatever, it never needs to be preceded by a comma, as far as I am concerned. ‘Too’ at the end of sentences should occur only very rarely in scientific texts, as it is very much a spoken, literary or journalistic device; if you do use it, you don’t need a comma before it. The comma does not improve comprehension whether it precedes ‘respectively’ or ‘too’. ‘Too’ in the middle of a sentence should be surrounded by commas, but it is really only suited to informal or journalistic use: *NHS trusts, too, have been feeling the pinch since the new regulations were introduced.*

To illustrate various other points with commas, I chose a short paper from the *BMJ* about forest plots [4]—not because I felt that the comma was used particularly well or particularly badly in the paper. I have recently been dealing with forest plots and liked the way it briefly summarised their evolution. Steff Lewis, one of the authors, permitted me to tear her sentences apart.

The following two sentences appear in the summary of the article: *Forest plots, in various forms, have been published for about 20 years. During this time, they have been improved, but it is still not easy to draw them in most standard computer packages.*

**Why did the author put commas around the prepositional phrase ‘in various forms’?** Because it draws the reader’s attention to the phrase by introducing two pauses. To achieve this, the author deviated from the expected word order in English. The message is similar if you write: 1) *Forest plots have been published in various forms for about 20 years*, or 2) *Forest plots have been published for about 20 years in various forms.* The phrase ‘in various forms’ before the verb in the original sentence modifies the subject (forest plots) and immediately makes the reader aware that forest plots can take different forms. This information is, of course, also provided in sentences 1) and 2), but it is not stressed in 1) because it uses the expected word order in English when no emphasis is intended on any element (subject-verb-object-time interposed with adverbials). Sentence 2) adds some stress to ‘in various forms’ because the time is not at the end, but it is not as strong as before the verb with commas. Note that the omission of ‘in various forms’ in the author’s original sentence still leaves a *complete sentence*: this is a **must** when using pairs of commas to surround any phrase or clause in this way.

**Are commas actually necessary around ‘in various forms’?** The addition of commas adds extra emphasis, but they are not *necessary*. But this is definitely an instance where I would support the use of commas. Ultimate stress would be achieved by writing *Forest plots—in various forms—have been published for about 20 years*, but the use of the em-dash seems exaggerated here.

**Do I need a comma after ‘During this time’?** This is a matter of personal preference. If I start a sentence with a time clause or phrase (precise or imprecise, e.g.: *On 26 June 1963*, or *At Visit 6*, or *Recently*), I am deviating from the expected word order in the English sentence (time at the end), and I like to add a comma. Many people don’t. Hence, *During this time they have been improved* would also be fine.

**Do I need a comma before ‘but’?** Yes. If you introduce a new idea into a sentence with a conjunction, you need a comma before the conjunction. This is not always observed when people use ‘and’, especially in short sentences. If I have a long sentence (for these purposes a long sentence is about 1.5 lines of 12-point text on an A4 page with 2.5 cm margins), with two or perhaps three clauses, I will almost always separate these with commas before the ‘ands’ or other conjunctions, and definitely do so if the subject changes. My sentence above: *I have recently been dealing with forest plots and liked the way...* has the same subject in each clause, so a comma is not needed. A comma is needed in the following sentence: *The patient was found dead in the bathroom, and her husband reported that she had been complaining of breathlessness for about 2 hours.* And in this one: *The patient then developed acute renal failure and became unconscious, and later a creatinine clearance of ... was determined.*



An extract from the introduction of the forest plot article: *In a typical forest plot, the results of component studies are shown as squares centred on the point estimate of the results of each study. A horizontal line runs through each square to show its confidence interval—usually, but not always, a 95% confidence interval.*

**Do I need a comma after ‘plot’?** Again, you don’t actually need a comma here, but because the author wanted to stress the idea of ‘the typical forest plot’, it is appropriate to pull the idea forward in the sentence and add a comma, as this underlines the deviation from the expected word order. Consider this rearrangement: *The results of component studies in a typical forest plot are shown as squares centred ....* The idea of ‘typical’ gets a little lost in the middle of the sentence.

**What about the punctuation in the second sentence—is it OK?** For me, no. The em-dash before ‘usually’ is too strong, and the commas around ‘but not always’ are too weak. The important information here is that the horizontal line does **not** always represent a 95% confidence interval. I would have edited this sentence as follows: *A horizontal line runs through each square to show its confidence interval, usually—but not always—a 95% confidence interval.* By transposing the punctuation here, the stress is clearly on ‘but not always’ because it is surrounded by em-dashes, and the comma before ‘usually’ is necessary to tell the reader that a new idea is coming.

When describing the history of forest plots, the author says: *However, smaller studies, with less precise estimates of effect had larger confidence intervals and, perversely, were the most noticeable on the plots. (New §) Means of focusing attention on the larger, more precise, studies were sought.*

**Do I need a comma after ‘however’?** Yes, always, at the beginning of a sentence (and yes, you can use ‘however’ at the beginning of a sentence). You do not need a comma if it is used to mean by whatever method’: *However you managed to make that mistake, I’ll never understand!* You need a comma before ‘however’ if it is used at the end of a sentence (much rarer when writing, but often spoken). And what about ‘therefore’ at the beginning of a sentence? I try to avoid using ‘therefore’ at the beginning of a sentence, but I do think that it should be followed by a comma in this position.

**Is ‘however’ always surrounded by commas when not used at the beginning or end of a sentence?** Yes. What about ‘therefore’? No—either with or without commas as far as I am concerned.

**Is the comma after ‘smaller studies’ appropriate?** I don’t think a comma is needed here.

**There is no comma before ‘and, perversely’.** Right. Both clauses have the same subject and so this is not necessary. Had the sentence read *However, smaller studies with less precise estimates of effect had larger confidence intervals, and forest plots were therefore heavily criticized because*

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*such studies were the most noticeable*, a comma before the ‘and’ would be needed. A change of subject in a sentence means that a comma is appropriate before the ‘and’ (or whatever other conjunction—‘and’ is just about the most common) introducing a new clause. This is illustrated by the following sentence from later in the paper: *The plot was not called a ‘forest plot’ in print for some time, and the origins of this title are obscured by history and myth.*

**What about the commas around ‘perversely’?** These are appropriate, and I might even have been tempted to replace them with em-dashes: ‘perversely’ is a strong word and carries the message in this sentence. The commas are weak here.

**Is the comma between ‘larger’ and ‘more precise’ appropriate?** Yes. But only if the author meant that the studies that were more precise, were also larger. This would mean that these modifiers (adjectives) of the word ‘studies’ are coordinate, or interchangeable, and the comma could be replaced by ‘and’. If this is what she wanted to say, she could also have said: *Means of focusing attention on the more precise, larger studies were sought.* Without a comma, it would mean that there may have been many more precise studies, but not all of them were larger, as she wished to focus only on the larger ones. But this was not the case.

**And what about the comma after ‘precise’?** The comma after ‘precise’ is incorrect. The inappropriateness of the comma becomes obvious if we add the ‘and’ between the coordinate adjectives: *Means of focusing attention on the larger and more precise, studies were sought.* It is immediately obvious that it is wrong—we have two modifiers with nothing to modify because the phrase is curtailed by the comma, and ‘studies’ immediately looks like a new subject in the sentence. The author’s use of the comma here was influenced by the comma between the coordinate adjectives (and—by the way—this error was also missed by the *BMJ* editors!).

After all of this, you will probably be tempted to ‘leave the comma in’—just in case. There are plenty of clever examples where a comma or a couple of commas change meaning entirely, even in a very short sentence, and apparently millions have been lost and won because of the presence or absence of a comma. Some authors still ask me: ‘Does it really matter?’ Sometimes it doesn’t, and it’s very unlikely that your marketing authorization application will be turned down because of inappropriate commas, but this doesn’t mean that we shouldn’t try to do the best for our readers and keep ourselves happy at the same time by doing the best we can.

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# Commas

by Valerie A. Elliston

Commas are often scattered like confetti: in a kind of cheerful abandon but without any particular purpose beyond a feeling that they will somehow enhance the writing purely by their presence. However, they have several clear functions and, in some instances, can change the meaning of a sentence.

We can assume that the main purpose of grammar and punctuation is to make a piece of writing clear and unambiguous so that the reader understands the writer's intention at once, and does not have to re-read phrases or sentences in order to grasp their meaning. To help in achieving such clarity, the comma has four distinct uses: listing, joining, indicating gaps, and bracketing or isolating. (Note the Oxford comma after the word 'gaps'; this use has been covered by Richard Clark's article 'The fatal comma' on page 7 of this issue) Each group will be considered in turn, with badly punctuated sentences indicated by an asterisk (\*).

The **listing comma** is used when three or more words, phrases or sentences could be linked by the words *and* or *or*. This substitution avoids clumsiness and helps the smooth flow of the language.

*Spanish is spoken in Spain and in Central America and in most of South America and in many other parts of the world.*

This sentence is correct, but sounds rather clumsy and repetitive.

*Spanish is spoken in Spain, in Central America, in most of South America and in many other parts of the world.*

The comma improves the flow here and in the following example.

*We can fly to Mumbai via Moscow or via Athens or via Cairo.*

*We can fly to Mumbai via Moscow, via Athens or via Cairo.*

*They spent the mornings shopping in Bond Street and enjoying coffee in Fortnum's and wandering around the Wallace Collection and trying to hail taxis.*

This could be improved by the use of commas. Note that each activity is mentioned in a phrase, not a complete sentence. The listing comma is therefore correct.

*They spent the mornings shopping in Bond Street, enjoying coffee in Fortnum's, wandering around the Wallace Collection and trying to hail taxis.*

Note: two complete sentences must **not** be joined with a comma, but three or more complete sentences can be linked with listing commas plus *and* or *or*.

*\*Julia speaks Spanish, Rose speaks German.*

*Julia speaks Spanish, Rose speaks German and John speaks French.*

Note: in British usage it is not usual to put a listing comma before the word *and* or *or* (the Oxford comma again) but it is usual in American English. However, the comma should be added if it makes the meaning clearer, as in

*This applies to the London boroughs of Barnes, Wandsworth, and Kensington and Chelsea.*

Here, the comma before the first *and* shows that Kensington and Chelsea form one borough, not two. However, this use of the listing comma can convey a meaning that is the opposite of what is intended, as in

*\*Treatment consisted of exercises, appropriate drugs, avoiding fatty foods, and alcohol.*

In this instance, the final comma implies that alcohol is part of the treatment! Omit the comma and the meaning becomes clear.

A listing comma is also used in a list of modifiers which all modify the same object. In each case, the comma could be replaced by the word *and*.

*Her short, fair, curly hair expressed her lively personality.*

*Her short and fair and curly hair expressed her lively personality.*

Replacing the commas by *and* does not alter the sense.

*I discovered an ancient gold coin in the field.*

In this case, we cannot insert *and* between *ancient* and *gold* because the word *ancient* modifies the *gold coin*, not simply *coin*. It would sound odd to say

*\*I discovered an ancient and gold coin in the field.*

To sum up the use of the listing comma:

**Use one in a list wherever the word *and* (or *or*) could be used.**

**Put one before the word *and* or *or* if this is essential to make the meaning clear.**

> > >

>>> **Commas**

The **joining comma** can be used to join two complete sentences into one, but it must be followed by an appropriate connecting word such as *and*, *or*, *but*, *while*, *yet* (and *for* when this means *because*).

Note the construction of the above sentence: there are, in fact, two complete sentences joined by a comma plus the word *but*. The same two sentences could be written like this:

*The joining comma can be used to join two complete sentences into one. However, it must be followed by an appropriate connecting word such as ...*

Or like this:

*The joining comma can be used to join two complete sentences into one; however, it must be followed by an appropriate connecting word such as ...*

Note that, in these alternative examples, the connecting word is *however*, because the punctuation marks being used are the full stop (full point) or the semicolon.

The use of the joining comma relates to two different types of clauses: subordinate and coordinate. Here are some examples of the former:

*She was late because the bus had already left.*

*He'll bring the car if it rains.*

The main clauses here are *She was late* and *He'll bring the car*.

The **subordinate**, or less important, clauses are *because the bus had already left* and *if it rains*. The comma is not needed between the two clauses here because the main clause is written first and the complete sentence runs smoothly to the end. However, if the subordinate clause comes first, the comma is needed. So far, we have been considering the smooth flow of the sentence, but there are instances where this joining comma can affect the meaning and force the reader to stop and re-read for sense. For example,

*Heavy damages had to be paid to a man who fell off his garage roof and sustained head injuries because a doctor in A & E had failed to diagnose skull fracture.*

This man did not fall because of the doctor's failure. First, he fell, *then* he was taken to hospital, *then* the doctor failed to diagnose skull fracture. Finally, damages had to be paid because of that failure. A comma before the word *because* would help to clarify this. It would be even clearer if the subordinate clause came first:

*Because a doctor in A & E had failed to diagnose skull fracture in a man who fell off his garage roof, heavy damages had to be paid.*

(Of course, it would be clearer still to write *a man who had fallen* etc. using the past perfect tense to show the correct sequence of events.)

A **coordinate** clause is of equal, not subordinate, importance to the main clause, as in the following example:

*The risks of staging a musical are considerable, and the backers are afraid of sustaining huge losses.*

Here are two equally important clauses, main and **coordinate**. They are linked by the joining comma and the word *and*. Compare with

*The risks of staging a musical are considerable because there are so many factors to take into consideration.* Here, we have a main clause followed by a **subordinate** clause introduced by the word *because*. No comma is needed. However, if the subordinate clause comes first, the comma is needed.

*Because there are so many factors to take into consideration, the risks of staging a musical are considerable.*

Say these sentences aloud to hear the difference. Here are some more examples of the joining comma with **coordinating conjunctions**:

*Millions of pounds have been poured into this project, yet we still have nothing to show for it.*

*You must meet the deadline for your essays, or they will not be considered for marking.*

Be careful of using *nor* as a coordinating conjunction.

*The doctor could not use thiopental in this case, nor could he use methohexital.* Note here that the use of the negative conjunction *nor* forces a change in the word order in the coordinate clause. It would be clearer to write:

*The doctor could not use thiopental or methohexital in this case.* Or

*The doctor could use neither thiopental nor methohexital in this case.*

Here, we do not have a main clause plus a coordinating clause. A clause (as opposed to a phrase) requires a verb. Hence, the joining comma is not required.

*The English are bad at learning other languages, while the Dutch are particularly adept at it.*

Note: *while*, not *whilst*. *Whilst* means *although*, as in

*Whilst I disagree with you, I must defend your right to speak out.*

Joining two complete sentences with a comma but without a coordinating conjunction is one of the commonest of all errors in punctuation. The rule to remember is:

**Use a comma to join two complete sentences only when also using one of the words *and*, *or*, *but*, *yet*, *while*. Do not use a joining comma in any other way.**

The **gapping comma** simply shows that one or more words have been omitted to avoid repetition. However, if a sentence is clear without a gapping comma, do not use it. If you have a doubt, put it in.

*Some of the patients showed signs of distress; others showed signs of nausea.*



## Commas

*Some of the patients showed signs of distress; others, of nausea.*

The comma after *others* indicates that the words *showed signs* have been omitted but can be taken for granted. Note the semicolon between the two parts of the sentence. This is because, when the omitted words are included, the second part forms a complete sentence; therefore, a comma cannot be used here.

The **isolating** or **bracketing commas** are the most often used. A pair of commas encloses an interruption that does not interfere with the smooth flow of the point being expressed. One should be able to remove all the words between the two bracketing commas without changing the sense of the sentence.

*These findings, we suggest, make us doubt his hypothesis.*

*These findings make us doubt his hypothesis.*

*He was, needless to say, absolutely exhausted.*

*He was absolutely exhausted.*

*The children were, in spite of everything, still full of energy.*

*The children were still full of energy.*

*Gordon Brown, it would seem, will become Prime Minister.*

*Gordon Brown will become Prime Minister.*

*We have been obliged to conclude, after careful study of all the evidence, that the result, despite all their efforts, is unsatisfactory.*

*We have been obliged to conclude that the result is unsatisfactory.*

Note that there are two interruptions in the last sentence, each enclosed within a pair of commas. In each of the examples, the words within the pairs of commas can be removed without changing the sense of the whole. This is a useful way of checking. If the whole sentence fails to make sense, something is wrong. Note the following:

*\*Yet, over the horizon, lay the enemy ships.*

If the words between commas are removed, the sentence fails to make sense: *Yet lay the enemy ships.*

It should read:

*Yet over the horizon lay the enemy ships.*

The phrase *over the horizon* is not an interruption but an essential part of the whole sentence.

Bracketing or isolating commas are also relevant when considering defining and non-defining relative clauses. I have covered this topic in a previous issue of *TWS* [see 15 (1):31].

Here are some interruptions that occur at the beginning or at the end of a sentence when only one isolating comma is required:

*Having lived most of her life in France, Julia is fluent in French.*

*The pronunciation of English is changing by the day, or so we are told.*

The words isolated by the single comma could be removed without changing the sense of the whole. When checking, make sure that the words isolated by commas are true interruptions and not an essential part of the meaning.

*\*Just before leaving the bus caught fire.*

The reader registers *just before leaving the bus* and has to re-read to catch the real meaning:

*Just before leaving, the bus caught fire.*

To sum up the use of bracketing or isolating commas:

**Use a pair of commas to enclose a mere interruption which could be omitted from the sentence without changing its meaning.**

**Make sure the words enclosed by the commas form a true interruption.**

**If the interruption occurs at the beginning or end of a sentence, use only one comma.**

To sum up the use of commas in general:

**Use a *listing* comma in a list when *and* or *or* could be used instead.**

**Use a *joining* comma before *and*, *or*, *but*, *yet* or *while*.**

**Use a *gapping* comma to show that words have been omitted.**

**Use a pair of *bracketing* or *isolating* commas to separate an interruption.**

**Valerie A. Elliston**

*Colchester, UK*

Valerie A. Elliston is a freelance writer and registered indexer. She was formerly an adult education lecturer in English language and literature.

## The importance of proofreading

Notice in a British Sarova Hotel:

‘When you stay with Sarova Hotels, whatever your experience, please take a moment to fill in one of our comment cards and leave with our receptionist. On your departure.’

I chose not to leave with the receptionist, but if anyone would like to give this a try, I’d be happy to tell you which hotel it was.

**Alistair Reeves**

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## The fatal comma

By Richard Clark

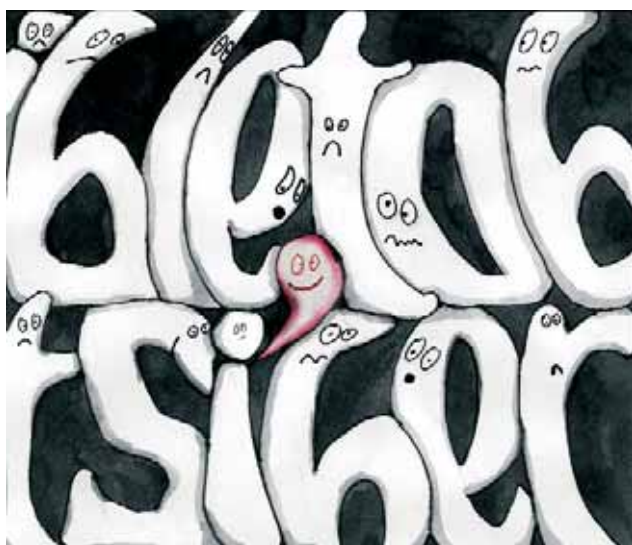
### Saved from death

I am not sure if this story is true or not, but it illustrates the power of commas. Czarina Maria Fyodorovna once saved the life of a man by transposing a single comma in a warrant signed by her husband, Alexander III, which exiled a criminal to imprisonment and death in Siberia. On the bottom of the warrant the czar had written:

“Pardon impossible, to be sent to Siberia.”

Maria Fyodorovna changed the punctuation so that her husband’s instructions read:

“Pardon, impossible to be sent to Siberia.” The criminal was set free.



Quick, move it! None of us want to go to Siberia

### Hanged on a comma

Sir Roger Casement was said to have been ‘hanged on a comma.’ In 1914 he sailed to Germany and enlisted German support to help Ireland gain its independence from Great Britain. This included his unsuccessful attempts to recruit Irish prisoners to form an ‘Irish brigade’ to fight against Britain and drafting an unofficial treaty with Germany to support an independent Ireland. On his return to Ireland in 1916 he was arrested and charged under the Treason Act of 1351. His barrister argued that because the mediaeval act did not contain any punctuation and was written in Norman French, that it seemed to apply only to activities carried out *within* the realm (i.e. on British soil). In translation the act read:

“If a man be adherent to the King’s enemies in his realm giving them aid and comfort in the realm or elsewhere...”

Casement’s allegedly treasonable activities were all carried out in Germany, so this argument could have saved him. Nevertheless it is fair to say that this defence was very weak! In any case, the judges claimed to find a faint *virgule* (a sort of prototype comma, signifying a short pause) after the second ‘realm’ in the original act, and so he was condemned to death by hanging. If you want to be pedantic you could say he was ‘hanged on a virgule’, but 99% of people wouldn’t know what was meant—so hanged on a comma it remains.

### A costly comma

The placement of a comma in a contract between Rogers Communications Inc. and Aliant Inc. looks like it will cost Rogers dearly—an extra \$2.13 million. Rogers thought it had a 5-year deal with Aliant to string Rogers’ cable lines across thousands of utility poles in Canada for an annual fee of \$9.60 per pole. But early last year Rogers was informed that the contract was being cancelled and the rates were going up. Impossible, Rogers thought, its contract was iron-clad until the spring of 2007, and could potentially be renewed for another 5 years. The construction of one sentence in the contract allowed the entire deal to be scrapped with only a year’s notice, Aliant argued [1].

The contract states that the agreement “shall continue in force for a period of 5 years from the date it is made, and thereafter for successive 5 year terms, unless and until terminated by 1 year prior notice in writing by either party.”

Rogers’ intent in 2002 was to lock into a long-term deal of at least 5 years, but the regulators with the Canadian Radio-television and Telecommunications Commission (CRTC) stated that the validity of the contract came down to the second comma in the previous sentence. Had it not been there, the right to cancel wouldn’t have applied to the first 5 years of the contract, and Rogers would be protected from the higher rates it now faces. The regulator stated that the comma in question “allows for the termination of the [contract] at any time, without cause, upon 1-year’s written notice.” Rogers intention was to shield itself from rate increases, but now it will see its costs increase to up to \$28.05 per pole. Rogers will probably have to pay \$2.13 million more than expected, based on rough calculations.

## The fatal comma

### Some plain words

We all know how to use commas don't we. (That was a statement, not a question!) Just in case though, the venerable Sir Ernest Gowers summarises the key issues regarding comma usage pretty well:

"The use of commas cannot be learnt by rule. Not only does conventional practice vary from period to period, but good writers of the same period differ among themselves. Moreover, stops have two kinds of duty. One is to show the construction of sentences—the 'grammatical' duty. The other is to introduce nuances into the meaning—the 'rhetorical' duty"[2].

I like this sort of attitude! Maybe this is because of my deep-rooted mistrust of grammatical 'rules' taught as taught at school. The grammar pedant can sometimes put too much emphasis on the grammatical duty of commas (see the next section) at the expense of the nuance and phraseology of the writer, and writers often just spray commas all over the place. Nevertheless, I do think that grammar rules are important, though commas are a special case for which the rules need to be bent a bit now and again.

### Zero tolerance to zero tolerance

An article by John Mullan in *The Guardian* reports the views of a New York-based critic, Louis Menand, on Lynne Truss's book *Eats, Shoots & Leaves: The Zero Tolerance Approach to Punctuation* [3,4], Menand was not happy with Truss's "strange grammar." For example, the dedication mentions "The striking Bolshevik printers of St Petersburg who, in 1905, demanded to be paid the same rate for punctuation marks as for letters." Here, Menand seems delighted to find "a nonrestrictive clause [that] is not preceded by a comma. It is a wild ride downhill from there." (In normal English this means he wants a comma after St Petersburg.) I think he has a point, but firstly I would never construct this sentence in the same way such that it needed so many commas, and secondly, the lack of a comma doesn't change the meaning of the sentence to me. To Menand, presumably, it does:

"Without that comma, the dedication is to some striking printers who made the demand, as opposed to some other striking printers who didn't. Only with a comma is the dedication to all the striking printers (as Truss presumably intends)."

This level of sophistry is beyond me, I'm afraid. I don't really like the dedication—with or without an extra comma. But, non-restrictive clauses aside (yes, I would hyphenate non-restrictive, unlike Mr Menand), if you were to read the dedication aloud with the intention of dedicating the book to the striking printers, then you would pause briefly after St Petersburg. That's as good a rule as any.

### The dreaded 'Oxford'

Here we come to another example of a cross-Atlantic clash between the British and North Americans, which also illustrates the importance of not following rules slavishly. At

school in the UK (in the long-gone days when *some* English grammar was taught) we were told to put commas between items in a list of three or more items, but that a conjunction (such as 'and') took the place of a comma between the last two items. So in the UK, most people write 'red, white and blue'. In the US—with the exception of newspapers—the Oxford (or serial) comma is just about mandatory. The argument is that as this comma is sometimes necessary to remove ambiguity, there had better be one there always. The Oxford comma appears after the conjunction in this list, thus: 'red, white, and blue'. Personally, I prefer not to use an Oxford comma, but I *don't* mind using one *if it removes ambiguity*.

I'm not sure what the situation is like in the US, but here in the UK many people would rather cut off their own arm than use an Oxford comma! But if you never use an Oxford comma you can sometimes get into trouble. For example, consider:

"The sea, the perfume of wisteria, or a summer lunch: any of these revived memories of an easier time."

The removal of the Oxford comma would change the meaning such that the perfume of a summer lunch brought back memories of an easier time. Likewise, trouble lies in wait for those who always use Oxford comma. Here the 'toast, juice, ham and eggs' rule comes into play. A comma after 'ham' would make it a separate item from the eggs (which may be the case), but if ham and eggs are served together then the Oxford comma has to go."

### Common sense, observation and taste

I'm a simple person. I don't know all the rules of grammar, and all the grammatical terms used to describe them. However, the words of Sir Ernest ring true, and provide some comfort:

The correct use of a comma—if there is such a thing as 'correct' use—can only be acquired by common sense, observation and taste."

The use of commas is not usually a life or death matter, though sometimes it can feel like it is. Thus, do we all need a bit more common sense, observation and taste?

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## Gertrude Stein on degrading commas in the prose alas

by Mary Ellen Kerans

My writing took a small turn for the better in the 1970s after a friend mentioned that Gertrude Stein thought we could manage very well without commas. We were of a generation whose teachers had given us beat poets alongside Dickens and Eliot so when we opened the *Village Voice* every week to read a column with no trappings of capital letters or punctuation beyond periods we were open to it, attended to content and found it witty not silly. In New York publishing at that time we kids just out of college knew how to punctuate but could appreciate purposeful rule breaking.

I picked up a bit of Stein to read to see how she managed. Hers were well formed sentences where sounds and order helped me glide from images to thoughts. Reading felt like swallowing honey. It was easy and intuitive and left me open to surprises in content. I'm not remembering pigeons on the grass alas or a rose is a rose but rather the Toklas *Autobiography* and bits of Stein's writing on writing.

Stein's sentences invited critical thinking about punctuation and grammar. Minimalism was more than a modernist stylistic trick it was a discipline to ensure words were useful and structure optimal. Punctuation was no quick fix for lame clauses with nested afterthoughts however correctly marked up they might be.

Reading Stein herself makes the point better, but the Internet gives me few examples available open access to recommend. Someone must still sit on copyright. Only excerpts quoted by others: a wonderful article by filmmaker and feminist academic Kay Armatage (2007) [1] on Stein's attitude toward sentences is a good place to start. Armatage expresses the same feelings I remember that Stein's writing on writing combines thoughtful liberation exploration and good sense. Some of the quotes Armatage provides give the flavor of Stein's own sentences better than my imitations can:

### On names and nouns:

People if you like to believe it can be made by their names. Call anybody Paul and they get to be a Paul call anybody Alice and they get to be an Alice.

That is the reason that slang exists it is to change the nouns which have been names for so long.

### On editing:

Of course the first thing that anybody takes out of anybody's writing are the adjectives.

### On how commas weaken writing:

A comma by helping you along holding your coat for you and putting on your shoes keeps you from living your life as actively as you should lead it . . . the use of them was positively degrading.

A longer quotation from Stein on commas was available on a US community college support website on punctuation (<http://grammar.ccc.commnet.edu/grammar/commas.htm>). It expresses Stein's main message as I discovered it in the 1970s. Good writing needs few commas. We will understand sentences if the writer has involved us in their content because knowing that content will 'force itself' upon us:

And what does a comma do, a comma does nothing but make easy a thing that if you like it enough is easy enough without the comma. A long complicated sentence should force itself upon you, make you know yourself knowing it and the comma, well at the most a comma is a poor period that lets you stop and take a breath but if you want to take a breath you ought to know yourself that you want to take a breath. It is not like stopping altogether has something to do with going on, but taking a breath well you are always taking a breath and why emphasize one breath rather than another breath. Anyway that is the way I felt about it and I felt that about it very very strongly. And so I almost never used a comma. The longer, the more complicated the sentence the greater the number of the same kinds of words I had following one after another, the more the very more I had of them the more I felt the passionate need of their taking care of themselves by themselves and not helping them, and thereby enfeebling them by putting in a comma.

So that is the way I felt about punctuation in prose, in poetry it is a little different but more so . . .

Gertrude Stein, from *Lectures in America*

Would Gertrude concede that punctuation is a little different but more so in medical texts too? She didn't have to deal with strings of odds ratios, confidence intervals and the like and alas feel a need for all the punctuation she could get. But the crux of Stein's lesson transcends genres: that well chosen words in good order will be all the stronger if we weed out some of the clutter that obliges us to use commas.

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## Using some comman sense

by Ursula Schoenberg

What's a comma—just an apostrophe that's fallen low, right? Wrong. These little specks of ink on a page are a far more potent defining element of your cultural identity than you think. Take English and German, for example. When I hear the word 'comma', I smile. Not so when I hear the word 'Komma'. This is because, when I write English, the comma offers itself as a charming and useful option to make my text more readable. I can flirt with an English comma. A German 'Komma' is a much more serious thing. It hovers over a sentence at the prescribed place, and you ignore it at your peril.

To a certain extent, my reaction is an artefact harking back to school days. German spelling and punctuation rules used to be a mirror of the Germanic mind-set: authoritarian, logical (more or less), and rigidly enforced. We spent hours learning where to place 'das Komma' or taking down oral dictation to practice spelling. In the upper forms, bad spelling and punctuation could lower your grade by a substantial margin—I shudder to think how many potential physics and math geniuses' careers were nipped in the bud due to their lousy punctuation.

Of course, much of this pedantry does indeed have a rationale. German words and sentences are, on average, longer than English ones (ask any translator). There is also the pesky German habit of sticking verbs at the end of sentences. An English text with sloppy punctuation may be annoying, but you can usually figure out what the author is talking about in spite of it. In German, failed punctuation will almost certainly leave you helplessly marooned in the text, reading and re-reading a sentence to glean its meaning.

Several years ago, someone decided to 'reform' the spelling and punctuation rules in the German-speaking countries. Initially, some sensible i.e. logical punctuation rules were turned into 'options' and other spelling and punctuation rules changed altogether. However, these changes caused so much upheaval and protest, that the 'reform' was 'reformed' again, several times, making the ensuing chaos in everyone's head and on the page truly staggering.

The unfolding linguistic anarchy has been interesting, if not exactly amusing, to watch. We have now reached the point that at least three national newspapers in Germany have their own 'house rules' for spelling and punctuation. I find it deliciously ironic that most Germans have completely given up trying to follow the undulations of these

so-called 'reforms' and have relinquished control to their (American!) Microsoft spell-checker.

In truly Germanic style, these 'reforms' were decreed from above, with an astonishing amount of hubris. What were the reformers hoping to achieve? Had they really no inkling of the gargantuan nature of the task they were undertaking? Had they gone about their job a little more skilfully, German speakers might have been able to 'humanize' their relationship with the once-feared 'Komma'. Instead, we have a full-blown identity crisis on our hands, which manifests itself in mutiny on our linguistic flagships.

In contrast to this top-down approach, shifts in language have a grass roots character in English-speaking countries. I doubt not that in some distant future we will be writing 'rite' and 'nite', but no one is going to be obsessing about it on the way there. English happily absorbs 'foreigners' like 'Kindergarten' and 'Angst' without getting its knickers in a twist like the French, who have a special committee to keep the French language 'clean'. I don't believe anyone would dream of setting up a global committee to dictate new rules for English—can you picture a Brit, an American and an Australian hotly debating where to place a comma? No, English speakers will continue to approach punctuation with a sort of breezy lightheartedness that is totally endearing. You really just have to use some comman sense.

### Ursula Schoenberg

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## No sense in missense

According to the *Oxford Dictionary of Biochemistry and Molecular Biology* a missense codon is a codon that has been altered so that it codes for an amino-acid residue different from the one for which it normally codes. The report I was editing, however, referred to Miss Sense amino acid coding sequences. The dictionary completely missed this sense.

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# Clinical Trial Disclosure: The ongoing debate on public registers for clinical trials

by Kathy B. Thomas and Claudia Tesch



## Introduction

In recent years, there has been a great deal of discussion in the professional press and general media on the need to restore public trust in our politicians, teachers, doctors—just to name a few. Five publicly available Reith Lectures 2002, entitled “A question of trust” have been broadcast on BBC Radio 4, capturing the widespread public mood on this topic [1].

The loss of public trust in the clinical research community, particularly in the pharmaceutical industry, came after a series of allegations focusing on selective reporting of clinical trial data by the pharmaceutical industry [2,3]. Of particular concern were instances in which sponsors disclosed positive results from clinical trials while leaving out the negative ones. This contributes to publication bias and can seriously impact the interpretation of data, both at the individual study level and for large data sets in meta-analyses on published studies [4-9]. In an effort to address the situation, the stakeholders, including the governmental agencies, trade associations, journal editors, the WHO, ICH, and Cochrane collaboration (Fig. 1), became proactive regarding the increased transparency of the data on clinical trials—however without always coordinating or fully anticipating consequences of their efforts. Unluckily for those affected in the clinical research community, some of

the proposed or implemented actions by the stakeholders were conflicting, making compliance towards increased transparency difficult.

Clinical trial registration and transparency of clinical trials has been the subject of previous articles in *TWS* [10,11]. Here we follow up on those reports and summarize some of the latest developments on this fast-changing topic and the way these developments potentially affect all patients, pharmaceutical companies, clinical research organizations, universities or government institutes, and other individuals involved in testing of and reporting on investigational products<sup>1</sup> in humans. We also share some of our own experiences gathered while setting up the processes associated with ‘Clinical Trial Disclosure’ at an internationally operating pharmaceutical company.

## ‘Clinical Trial Disclosure’

The term ‘Clinical Trial Disclosure’ refers to activities surrounding the public, electronically available registers<sup>2</sup> that are used to present information on i) *new* clinical trials at their inception, and ii) *results* of completed clinical trials. For this purpose several publicly accessible Internet registers (repositories of information) that cover all disease areas and geographical locations and which are open to all sponsors have been established by non-profit organizations (Fig. 2).

Figure 1: Stakeholders in the ‘Clinical Trial Disclosure’

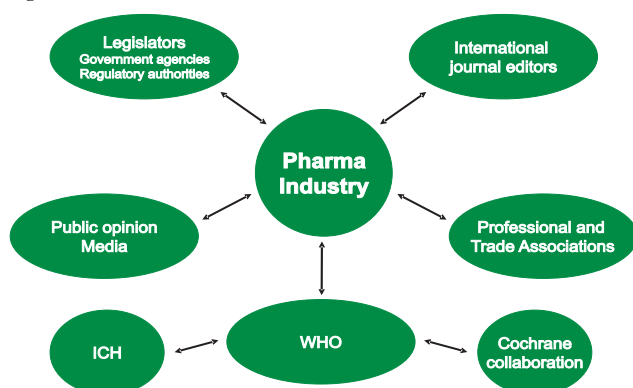
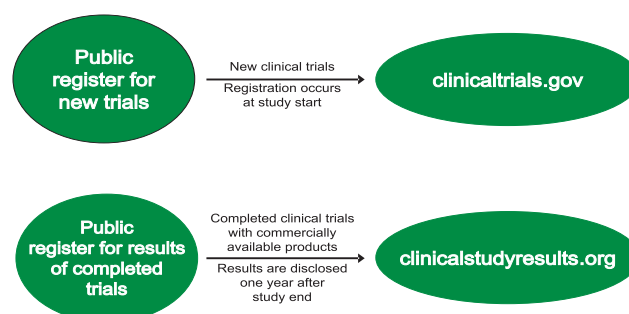


Figure 2: Examples of public registers used for new clinical trials and for trial results; both registers are repositories. On-line search portals scan all collaborative registers worldwide ([www.ifpma.org](http://www.ifpma.org); [www.who.int/trialsearch](http://www.who.int/trialsearch)).



1 Investigational products include drugs, biologics, or devices.

2 ‘Clinical Trial Disclosure’ differs from the EudraCT database. The EudraCT database is a compulsory regulatory provision for all clinical trials performed in the European Union; the information submitted to EudraCT is accessible only to the competent (regulatory) European Authorities. ‘Clinical Trial Disclosure’ implies electronic information on clinical trials, open to the public free of charge.

3 The US state of Maine has established reporting regulations for all prescription drugs marketed in Maine (State of Maine Law, effective from October 2005), which require all trials and results of these trials to be registered on a publicly accessible register. Other US states have proposed similar state legislations: California, Hawaii, Michigan, Minnesota, New Jersey, New York, Pennsylvania, and Rhode Island.

## Clinical Trial Disclosure

## Legal Aspects

At the legislative level, several US and international incentives have stimulated registration of *new* clinical trials in public registers. In the USA, federal law requires, since 1997, the registration of any trial, involving “serious or life-threatening diseases” (FDA Modernization Act, Section 113, 1997 [12]). Additional US federal draft bills and safety acts, as well as state-by-state<sup>3</sup> laws have been introduced and debated at various legislative levels, calling for public disclosure of information for *all* clinical trials at their inception and completion (Table 1).

Outside the US, some countries<sup>4</sup> have already established national laws requiring registration of *new* clinical trials in public registers; other countries are at the stage of guidelines that encourage voluntary disclosure of new trials; in some countries, institutional review boards/independent ethics committees require clinical trials to be registered as a condition for approval. For the European Union specifically, the European Commission plans to release some elements of the EudraCT database to the public via EuroPharm—the Community database on medicinal products. To date, the guideline (ENTR/CT 6) is at a draft stage and no final details have been announced.

## Pharmaceutical trade associations and American Medical Association

In the absence of pertinent legislation, the pharmaceutical industry has put forward its own recommendations. In 2005, the pharmaceutical trade associations (IFPMA, EFPIA, JPMA, PhRMA)<sup>5</sup> released the ‘Joint Position Paper’, committing their members to increased transparency standards and thereby affecting the disclosure of potentially *all* clinical trials [13]. The American Medical Association (AMA) published similar recommendations in their public statement on this topic [14].

Through the ‘Joint Position Paper’, companies involved in the development of investigational products were encouraged “to make public how they will adhere to these standards”. In response, many companies now have a statement on their Internet websites regarding their policies on ‘Clinical Trial Disclosure’; the stated policies, however, differ among the individual companies.

Standards set down by the ‘Joint Position Paper’ are:

- Registration of all *new* clinical trials (other than exploratory trials<sup>6</sup>, e.g. Phase 1) in a free public registry within 21 days of initiating patient enrollment.
- *Disclosure of results* for all clinical trials (other than exploratory trials<sup>6</sup>) conducted with drugs that are *approved for marketing and are commercially available in at least one country*, within 12 months of study completion (suggested format: synopsis of the clinical study report according to the ICH E3 guideline) (Fig. 3)<sup>7</sup>.

Table 1: Important events for ‘Clinical Trial Disclosure’

|      |   |                  |
|------|---|------------------|
| 1997 | <b>FDAMA Law, Section 113</b><br>Register studies with serious or life-threatening diseases and conditions.   | LAW              |
| 2005 | <b>Maine Regulations</b><br>Register all trials; disclose results on all trials with the product. Publicly disclose ...“information about clinical trials of ...products...that are or have been FDA-approved for marketing and are or have been dispensed, administered, delivered or promoted in Maine”.  | LAW              |
| 2002 | <b>PhRMA Principles</b><br>Disclose trial results of all hypothesis-testing trials.   | GUIDANCE         |
| 2005 | <b>IFPMA Industry ‘Joint Position Paper’</b><br>Register new hypothesis-testing trials and disclose trial results from completed trials with products that are approved for marketing and commercially available in at least one country.   | GUIDANCE         |
| 2007 | <b>Enhancing Drug Safety and Innovation Act (reintroduced)</b><br>Enzi/Kennedy Bill, Waxman-Markey<br>Register new trials and disclose all trial results.<br><br><b>FACT Act (reintroduced)</b><br>Register new trials and disclose trial results of studies with serious and life-threatening diseases.  | GUIDANCE         |
| 2004 | <b>ICMJE Editorial 01</b><br>Register new clinical trials (hypothesis-testing trials) on a publicly available register to qualify for publishing. Exploratory trials (e.g. Phase 1) may be excluded from registration.  | EDITORIAL POLICY |
| 2005 | <b>ICMJE Editorial 02</b><br>Register hypothesis-testing trials is a prerequisite for publishing. Specify required 20 data fields for an adequate registration.   | EDITORIAL POLICY |
| 2007 | <b>ICMJE Editorial 03</b><br>Register all new clinical trials as a prerequisite for publishing (adopting the expanded definition of required clinical trials by the WHO).<br>Allow pre publication of results in a suggested format and site (abstract or table format <500 words, posted in the same clinical trial register where the original registration resides). | EDITORIAL POLICY |

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## &gt;&gt;&gt; Clinical Trial Disclosure

**International Committee of Medical Journal Editors**

In September 2004, and again in June 2005, the International Committee of Medical Journal Editors (ICMJE) announced an unprecedented editorial publication policy. As a prerequisite for publication, the policy required authors or sponsors to submit new clinical trials (*excluded at that time were preliminary trials* e.g. Phase 1) in a public register at, or before, the time of patient enrollment (effective from September 2005) [16,17]. The ICMJE policy specified criteria for acceptable registers as well as for a minimal set of information that would need to be disclosed. Trial registration with missing fields or fields that contain uninformative terminology would be considered inadequate.

In their latest editorial (June 2007), the ICMJE expanded its definition of clinical trials [adopting to the World Health Organization (WHO) definition], requiring *all* clinical trials (*including preliminary trials* e.g. Phase 1) to be registered so as to qualify for future publication [18]. The editors said they were expanding the definition of trial types that must be registered to include preliminary trials in the public domain. This latest policy comes into effect for clinical trials starting on or after July 2008.

In addition, the updated policy states that ICMJE will not consider a posting of results as “pre publication” *only* if

it is structured as an abstract or a table not exceeding 500 words—and posted in the original registry where the study was registered [18]. This could imply that results disclosure would occur on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and *not* on PhRMA’s [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org).

Many other journal editors have adopted the recommendations of ICMJE on publication policy. Indeed, since the initial announcement of their publication policy on clinical trial registration in a public register in 2004, a substantial number of other journals accepted the ICMJE Uniform Requirements for Manuscripts standards. A link to the list of these journals can be found on the ICMJE homepage or by checking the ‘Instruction for authors’ for the journal of interest.

**Registers for new clinical trials**

Currently, the largest and most commonly used international clinical trial register is the [www.clinicaltrials.gov](http://www.clinicaltrials.gov). It was created following the enactment of the FDA Modernization Act of 1997, and is operated by the US National Library of Medicine of the National Institutes of Health. The register fulfills the criteria specified by ICMJE and the ‘Joint Position Paper’. Other acceptable registers are summarized elsewhere [18,19].

Originally, the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) register was intended to help patients and their physicians locate clinical trials in which to enroll. However, due to recent developments in clinical trial disclosure, the register serves many other users such as journal editors, granting agencies, the research community, ethics committees, and institutional

Table 2: Abbreviations

|                |   |
|----------------|---|
| <b>AMA</b>     | American Medical Association  |
| <b>CRO</b>     | Contract Research Organization  |
| <b>EFPIA</b>   | European Federation of Pharmaceutical Industries and Associations         |
| <b>EudraCT</b> | European Clinical Trials Database   |
| <b>FDAMA</b>   | Food and Drug Administration Modernization Act                            |
| <b>ICH</b>     | International Conference on Harmonisation                                 |
| <b>ICMJE</b>   | International Committee of Medical Journal Editors                        |
| <b>ICTRP</b>   | International Clinical Trials Registry Platform                           |
| <b>IFPMA</b>   | International Federation of Pharmaceutical Manufacturers and Associations |
| <b>ISRCTN</b>  | International Standard Randomised Controlled Trial Number Register        |
| <b>JPMA</b>    | Japanese Pharmaceutical Manufacturers Association                         |
| <b>NIH</b>     | The US National Institutes of Health                                      |
| <b>PhRMA</b>   | Pharmaceutical Research and Manufacturers of America                      |
| <b>UTRN</b>    | Universal Trial Reference Number  |
| <b>WHO</b>     | World Health Organization   |

Table 3: Important Websites

|  |   |
|--|---|
| <b>FDA Modernization Act of 1997 Section 113 (FDAMA)</b> | <a href="http://www.fda.gov/cder/guidance/4856f.n1.htm">http://www.fda.gov/cder/guidance/4856f.n1.htm</a>   |
| <b>ICMJE</b>   | <a href="http://www.ICMJE.org">http://www.ICMJE.org</a>   |
| <b>Joint Position Paper</b>                              | <a href="http://clinicaltrials.ifpma.org/">http://clinicaltrials.ifpma.org/</a>   |
| <b>PhRMA</b>   | <a href="http://www.phrma.org/clinical_trials/">http://www.phrma.org/clinical_trials/</a>   |
| <b>Registers</b>   | Hosted by National Institutes of Health<br><a href="http://clinicaltrials.gov/">http://clinicaltrials.gov/</a><br>Hosted by ISRCTN<br><a href="http://www.controlled-trials.com/isrctn/">http://www.controlled-trials.com/isrctn/</a><br>Hosted by PhRMA<br><a href="http://www.clinicalstudyresults.org/">http://www.clinicalstudyresults.org/</a> |
| <b>IFPMA search portal</b>                               | <a href="http://clinicaltrials.ifpma.org/">http://clinicaltrials.ifpma.org/</a>   |
| <b>WHO search portal</b>                                 | <a href="http://www.who.int/ictip/en/">http://www.who.int/ictip/en/</a>   |

4 Mandatory registration of new clinical trials in national public registers: Israel, Italy, South Africa, Taiwan.

5 For abbreviations see Table 2; for important websites see Table 3.

6 Exploratory trials “serve to set direction (i.e. to generate hypothesis) for possible future studies” [13].

7 If a peer-review journal publication for a particular study is announced, an additional 12 months is granted for an interim period as a round-about to allow for the journal editors’ review and approval process [15] (Fig.3).

## Clinical Trial Disclosure

review boards [5,19]. By May 2007, more than 40,000 trials<sup>8</sup> had been registered; for the industry, 1,054 pharmaceutical companies and Clinical Research Organizations posted information on 14,786 clinical trials, of which 5,788 were in the process of recruiting patients.

The register [www.clinicaltrials.gov](http://www.clinicaltrials.gov) represents a wealth of information on clinical development. The site is easily accessible, with consistent, user-friendly, and focused search possibilities (by disease, location, age group, study phase, or sponsor). For registrants, clear on-line instructions show how to register a new clinical trial; uncertainties and questions are promptly answered by the helpdesk staff [19,20].

### Registers for completed clinical trials (disclosure of clinical trial results)

Although the disclosure of clinical trial results is required by law only in the US State of Maine<sup>3</sup>, many companies disclose clinical trial results voluntarily. This is partly because of the commitment of the pharmaceutical trade association and its members, partly due to individual companies' own declared transparency policies, and partly due to continued pressure from the professional media [18,20,21]. Some companies disclose clinical trial results on their company's websites (e.g. Boehringer Ingelheim, Forest Laboratories, Eli Lilly, Merck, Novartis), while others use a third party vendor (Roche), or the publicly available register [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org) hosted by PhRMA.

By May 2007, more than 60 pharmaceutical companies have used [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org) (e.g. ALTANA Pharma, Sanofi-Aventis). It is a central, widely accessible, web-based register for clinical study results. The database contains the results from "hypothesis-testing" clinical studies (mainly Phase III and IV studies) completed since October 1, 2002, largely for drug products that are approved in the United States (although in recent years results on drugs with non-US approval are also being posted on this site). Results of studies include both published articles and unpublished study summaries.

At present, there is no formal consensus on international norms and standards for results reporting. The format of disclosed entries differs even at an individual company level. Many entries are scanned documents, which precludes electronic search. Because of the way the register is organized, the number of individual entries is difficult to assess, as this would require manual counting.

The implementation dates suggested by the 'Joint Position Paper' for results disclosure is "within one year after the drug is first approved and commercially available in any country, or for trials completed after this initial approval, within one year of trial completion, unless such a posting would compromise publication in a peer-review journal". One of the implications of this statement is that in order to

comply with that request, clinical studies conducted with commercially available products will require tightly coordinated efforts on the part of clinical departments, investigators, biostatisticians, medical affairs, and medical writing.

Publishing a study in a peer-review journal is an important goal for all involved. If timely publication is not realistic, study results should be released in a format such as that of the ICH E3 summary [13]. An alternative way to present clinical trial results without compromising future publication of the original data in a peer-review journal has been proposed by the ICMJE (see section above on the ICMJE editorial June 2007) (Fig. 3).

In addition to the above recommendations regarding the disclosure of clinical trial results, recent regulatory requirements by the European clinical trials directive (ENTR/CT2, 2006) specify the conditions for the disclosure of clinical study results to the ethics committees, competent authorities, and the clinical investigator responsible, as follows: "At the end of the trial (on all sites in a multi-centre trial) the sponsor should provide the ethics committee with a summary of the clinical trial report. To be responsible for his/her part in the report writing, the investigator should have access to the recorded and reported data to ensure accuracy, completeness and timeliness. This report should be the same as the one forwarded to the competent authority..." [22]. For the EU countries, at least, this should encourage concordant disclosure of results to all parties mentioned by the regulatory guidance, as well as to the public registers.

Overall, it is clear however, that when it comes to the disclosure of clinical trial results there are still numerous open issues that need clarification, agreement, and commitment by all stakeholders [20].

### WHO and the universal trial reference number

Several different public and non-public registers of clinical trials exist. Some contain information only on *new* clinical trials; others contain *results* of completed trials, and still others contain both. Some registers operate internationally and others at a national level; some are run by non-profit others by for-profit organizations. This means that there are many registers available which can (and does) lead to multiple entries of the same clinical trial in different registers—a situation that should be avoided because it is misleading and lowers the credibility of the registers.

To reduce duplication of entries, facilitate unique identification of clinical trials, and promote transparency, the International Clinical Trials Registry Platform, based at WHO, has announced on their website the allocation of a universal trial reference number (UTRN). It is planned that such a number will be available soon and shall be used to track *all* activities of a particular trial, including the study protocol, ethics committee's advice, regulatory submission documents, posting of results and journal publications [23,24].

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<sup>8</sup> The unwary user performing a search of the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) register please note that only the 'recruiting' trials appear automatically; a box in the top left screen has to be checked to also view trials that are 'no longer recruiting'.

>>> **Clinical Trial Disclosure****Universal search portals for registers**

IFPMA and WHO provide on-line portals, which search the collaborative primary registers worldwide, thus, providing a single point of access to information about ongoing and completed clinical trials ([www.ifpma.org](http://www.ifpma.org); [www.who.int/trialsearch](http://www.who.int/trialsearch)).

**Our experiences and recommendations**

From our own experience, the implementation of the 'Clinical Trial Disclosure' in a pharmaceutical company represents a challenging but very exciting set of tasks. The job requires knowledge of the latest relevant regulatory laws and guidelines, their sources, and applicability. In our case, the tasks were cross-functional, inter-departmental, inter-continental, and very communicative at all stages. For someone getting involved in this field, we suggest to keep the following points in mind:

1. Inform upper management (corporate level) about the requirements and implications of the 'Clinical Trial Disclosure' tasks; ensure commitment from upper management for the project.
2. Assign a responsible person/group of persons ('Clinical Trial Disclosure Managers') to coordinate activities of the project and integrate all involved functions and departments in the decision-making (clinical, clinical affairs, legal, intellectual property, regulatory, public relations, medical writing).
3. Establish company guideline(s), with a 'decision tree' for responsibilities and processes.
4. Include all clinical trials from all subsidiaries.
5. Establish agreements regarding the responsibilities with co-developing and marketing partners, as well as with investigators (multicenter trials, investigator-initiated trials).
6. Insist on reliable information of planned new trials and completed trials.
7. Coordinate the preparations to register a *new* clinical trial with the review and approval of the *clinical study protocol*.

8. Coordinate the preparation of the *results disclosure* with the review and approval of the *clinical study report*.
9. Consider publication strategy soon after the study outcome is known.
10. Establish a procedure for updating entries in the public registers.
11. Establish a procedure for responding to public enquiries (e-mail, phone).
12. Maintain a sense of humor!

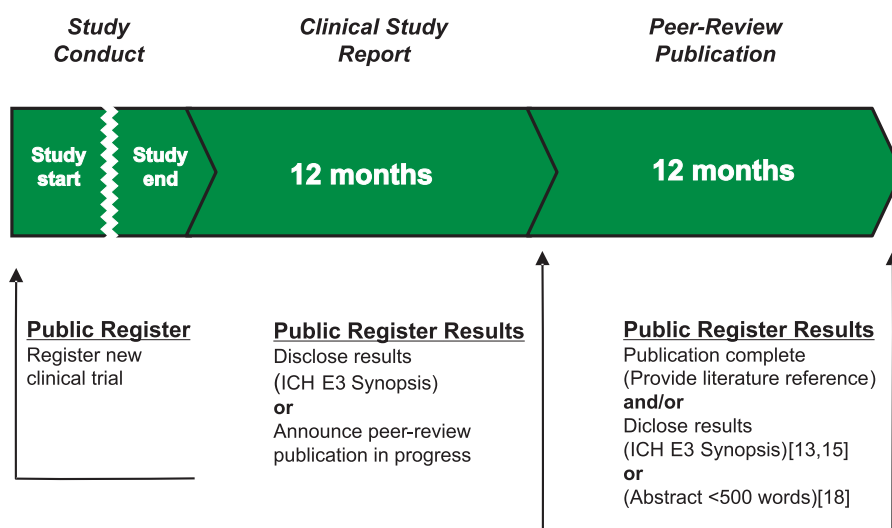
**Conclusions**

Restoring public trust in the clinical research community is the most important aim of the 'Clinical Trial Disclosure'. This is a complex task and it is up to all stakeholders to realize the aim without excessive or uncoordinated regulations. There is still plenty of work to do to restore public trust by sensibly coordinating and harmonizing the various proposals designed to increase transparency and accountability. Pharmaceutical companies, which have been at the center of attention for not being trusted, are overwhelmingly responding to the new requirements, guidelines, and suggestions. For those involved in, and affected by, the 'Clinical Trial Disclosure' it is indeed no longer a matter of 'whether', but rather 'when' and 'what' to disclose. The debate on public registers for clinical trials is definitely going on.

**Affiliations/Competing interests**

Kathy B. Thomas and Claudia Tesch are employees of ALTANA Pharma (Member of the Nycomed Group), located in Konstanz, Germany. Both are medical writers and as part of their tasks they coordinate entries for registers (new clinical trials and results of completed trials) applicable to the 'Clinical Trial Disclosure'. Both have presented the topic regularly to company internal audiences and actively participated in several external meetings.

Figure 3: Proposed timelines for posting information on new clinical trials and results of completed clinical trials on public registers.





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## GSK experience first consequences of a study results database

GlaxoSmithKline which has a very extended results registry has experienced the first consequences of these databases. Data from GlaxoSmithKline's study results database have been used by independent scientists for a meta-analysis that has just been published in *The New England Journal of Medicine (NEJM)*. The meta-analysis is entitled 'Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes' and was conducted by Steven E. Nissen and Kathy Wolski (<http://content.nejm.org/cgi/content/short/NEJMoA072761?resourceType=HWCIT>).

This analysis found that the diabetes drug rosiglitazone manufactured by GSK significantly increases the risk of myocardial infarction. The study was limited by a lack of access to original data source data which the authors state would have allowed a time-to-event analysis. The authors conclude that

"The manufacturer's public disclosure of summary results for rosiglitazone clinical trials is not sufficient to enable a robust assessment of cardiovascular risks. The manufacturer has all the source data for completed clinical trials and should make these data available to an external academic coordinating center for systematic analysis. The FDA also has access to study reports and other clinical-trial data not within the public domain. Further analyses of data available to the FDA and the manufacturer would enable a more robust assessment of the risks of this drug."

Three editorials accompany the report in the *NEJM*. It has caused concern among doctors and diabetes patients and it has been suggested that it will involve the US Federal Drug Agency in a new scandal.

On 16<sup>th</sup> June 2007 *The Economist* reported that GSK's shareholders have brought a lawsuit against the company for failing to adequately disclose the studies it had conducted into rosiglitazone.

For more information about the drug see <http://search.medscape.com/all-search?queryText=rosiglitazone>

## Elise Langdon-Neuner

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The following boxes are also relevant to clinical trial disclosure: '500 words is not enough' (page 51) and 'The PPP Survey' (page 92).



## **Saving a brain drain: The Norwegian-Russian Centre for Medical Studies and a medical writer's role in grant applications**

by Kari Skinningsrud

### **How it all started**

I first heard about the Norwegian-Russian Centre for Medical Studies from a Norwegian professor in radiology, Frode Lærum, who had the idea that started it all. He wanted to help Russia maintain good scientific functions after the Soviet Union collapsed in 1993, and to help avoid a complete brain drain to the United States and other countries in those difficult times. A cooperation agreement between the Russian Academy of Sciences (RAS) and the University of Oslo was signed in Moscow 30 June 1993, an event covered by Russian television. The Norwegian broadcasting company's correspondent in Moscow, journalist and historian Hans Wilhelm Steinfeld, became one of the members of the first board. Steinfeld gained international recognition for his interviews with Gorbatsjov, Jeltsin and prime minister Rysjkov in the period 1991-1994.

### **The initiators and funding**

Professor Sjur Olsnes, an acknowledged researcher at the National Cancer Hospital in Oslo, had kept in touch with fellow researchers in the Russian Academy of Sciences since he worked there for the renowned professor Engelhardt in 1968. Olsnes has been a key partner for Lærum from the Centre's beginning, and so has Olsnes' good friend and colleague from RAS, professor Jurij V. Kozlov. In 1996 the staff in Oslo was increased with a Russian-speaking project manager, Julia Ferkis, who has been responsible for administration of the Centre since. The Centre's main grant providers are the Norwegian Ministries of Foreign Affairs, Health and Education and Research, totalling 625,000 euros.

The Centre has financed 168 researcher working years at the Institute of Gene Biology and the Engelhardt Institute of Molecular Biology at RAS since 1993. The fellows have published 184 articles during the past 13 years, quite a few of them in acknowledged western journals such as *Nature*, *Science* and *Cell*.

### **Co-operation in practice**

Symposia have been important educational and networking occasions for the Centre and an equal-basis cooperation has been emphasized to facilitate efficient transfer of knowledge. A Russian and a Norwegian Programme planning Committee are responsible for each symposium. The

aim is to have an equal number of Russian and Norwegian presentations. About half of the 50 symposia that have been arranged since 1993 have been joint ventures with Sechenov Medical Academy, the Centre's major medical partner and Russia's oldest and largest medical university. Topics have varied from laparoscopic surgery and health legislation to medical ethics and oncology. More than 10,000 Russian physicians, nurses and other health personnel have attended the symposia-programme so far, and approximately 400 Scandinavian and West-European specialists have presented their lectures in Russia. Russian and English programmes and abstract books have been published for each symposium. It is a goal to keep costs low, so none of the invited lecturers to the symposia receive any financial compensation.

The Centre has a diverse programme for specialist exchange. There is an ongoing collaboration on mini-invasive surgery with the Moscow State University of Medicine and Dentistry, the Sechenov Academy and the Interventional Centre at the National Hospital (Rikshospitalet) in Oslo. An interesting aspect of this collaboration is that the Interventional Centre has bought some practical equipment for mini-access liver surgery from Russian colleagues in Yekaterinburg. Professor Babill Stray-Pedersen at Rikshospitalet, Oslo (WHO's European advisor for reproductive health in their Scientific Technical Advisory Group [STAG]) plans to develop locally adapted guidelines for reproductive health and birth care for the St. Petersburg area in cooperation with the Regional Clinical Hospital of St. Petersburg (if the application I sent 15 April this year is successful). Haematological diseases, drug abuse, urology, management and health legislation are other topics of collaboration with Russian hospitals and Universities.

There are large differences in competence within the Russian health system; some groups are fully at height with western university standards, while others are far behind. The aim from the start was to cooperate with those of a middle-standard, but also to learn from environments with more expertise. Their fields of expertise are typically those associated with areas that were of special interest to the Soviet Union; such as defence and space technology and protection against radiation.

Equality and reciprocity are more and more replacing the former humanitarian profile, and the Centre's activities reflect the interest not only of the Russians but also of the Norwegian partners. Only those projects where all parties involved feel they have something to win are likely to succeed.

## Saving a brain drain

**The medical writer's role**

So, how did I become involved? Professor Lærum was the principal investigator in the first clinical study I was responsible for in Nycomed Imaging many years ago. When he visited Nycomed in 2001 to tell us about the Centre for Norwegian-Russian Medical Studies, I gave him my card and told him I was about to become a freelance medical writer. The years passed, I forgot all about having given my card to him, but in 2005 he contacted me and said he had a job for me. They needed help to write applications for funding. At first I wondered if that was something a medical writer could do, as it had not been mentioned in any EMWA course I had heard about, and I had never actually written such an application myself. After a meeting with the three people working at the Centre at Rikshospitalet (administrative head, professor and secretary), I started to work for them as a freelancer two days a week from March 2005.

Involving an external writer in the process of applying for funding was an arrangement new to all implicated personnel, and practical approaches suitable to each individual team were sought. My contribution varied from brushing up the language to writing most of the project description, all according to time available and wishes from the teams. I also spent some time trying to find funding sources. My engagement expired after 7 months. The Centre decided to see if the applications I had assisted with generated funding before they considered renewing my contract. It had been quite controversial to pay someone to write applications, and it was necessary to give the senior UiO managers some proof of the usefulness of my work before it could continue. It turned out that quite a lot of money was granted from the applications, so I was invited to come back—to be employed half-time—and I continued to work for them from September last year.

I had the interesting experience of giving a course on grant-writing to the Centre's researchers in Moscow for two days in March this year. The process of preparation was valuable for my own work, and looking at notes from EMWA workshops I have taken was really useful, even though none of them were on grant-writing. The main theme of the course was translating ideas into projects and selling them to different target groups. I understand that writing an application for funding is quite often the first attempt to describe the research idea in writing, i.e. structure the work process, define areas of cooperation, write objectives, endpoints,

***Professor in radiology, Frode Lærum, wanted to help Russian scientists after the Soviet Union collapsed***

milestones and measurements and plan timelines and budgets. It was challenging for me to speak to people who do basic research and find relevant examples of endpoints etc. It is very different from doing clinical studies, but planning a project is still quite generic and many aspects of protocol writing and quality control are relevant in basic research as well. All project descriptions should spell out clearly why the methods and endpoints are the best ones in that specific context and why the variables measured are appropriate in relation to the stated objectives. Quality assurance measures should be included to ensure that the data produced will be reliable and accurate, even if and especially because GLP is not required in basic research. There have been some articles about grant-writing in the past issues of TWS. However, when I offered a short workshop on this topic for EMWA's Vienna conference only a few delegates were interested in joining the course. I am convinced that grant-writing is a field where medical writers have great opportunities and can make substantial contributions, but we still have a job to do to alert medical writers to this potential and convince those who apply for grants that it is worth paying a medical writer (and not just anyone) to do it.

***I am convinced this is a field where medical writers can give substantial contributions***

My job in the Centre for Norwegian-Russian Medical Studies is rewarding in many

ways. I have experienced that my years in the pharmaceutical industry have given me competence that is welcomed in arenas where I did not think I would have anything to contribute with. The work I do in the Centre is also rewarding in the sense that I meet many grateful researchers who have never been offered any help with applications and who appreciate the collaborative process in itself. It was good to hear one of the more experienced researchers in Moscow express her gratitude to Norway and the Centre for Norwegian-Russian Medical Studies for helping them in difficult times, and to continue to do so in times that are still not easy.

**Acknowledgement**

Much of the information in this article is taken from the Centre for Norwegian-Russian Medical Studies' annual reports from 2005-06, written by the Centre's administrative head Julia Ferkis.

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## Teaching English to the medical profession Developing communication skills and bringing humanities to medicine

by Jonathan McFarland

*"The scientific importance of English is such that, whenever I have a meeting with my residents—and I have many, both residents and meetings—I find myself emphasizing, over and over again, the need for them to learn English." [1]*

(Dr Javier Lucaya, Chairman of Radiology, Vall d'Hebron, Barcelona)

Five years ago when visiting an English family member in the reference hospital for the Balearic Islands, Son Dureta Hospital, I recognised the enormous necessity for English for Medical Purposes, as stated above by Dr Javier Lucaya. Dr Lucaya later says: "I may be exaggerating...." He is not. He is understating. English is essential at all levels of the health system in Spain for communication with the enormous influx of foreign visitors taking vacations in the country in summer. Doctors must also write articles in English for international journals and take part in conferences held in English to advance in their careers. Needs were there, but were not being addressed. I saw an opportunity to merge my interests in teaching and medicine and begin to fill this gap.

Jim Scrivener [2] notes that there are three kinds of teacher: the explainer, the involver and the enabler. I see myself as the last of these three. Scrivener states, "This kind of teacher is confident enough to share control with the learners, or to hand it over to them completely". Carl Rogers, an American psychologist (1902-1987), considered authenticity to be the most important characteristic for a teacher [2]. It is vital to be yourself, and not the 'teacher', and to build up a rapport with the students. I agree with both. I try to share control and be myself. When I start a course, the first thing I say is: "I am the teacher and the student, and you are the students and the teachers. My aim is to teach you English and I hope to learn about your different specialities".

I started teaching at Son Llatzer Hospital on Majorca in 2003. It is a provincial hospital, with in the region of 400 beds and not all the specialities. I had the great luck to begin working there about 6 months after its inauguration and was therefore there from the beginning. I taught groups of 25, and very often, especially with the low levels, I needed to give them grammar lessons. But even at the low levels I made them give 'presentations'. The groups were very mixed. There were doctors, nurses, auxiliary nurses, pharmacists, porters, lab technicians, computer staff, receptionists, and administrative staff. This enormous variety of people all working in the same hospital was a great advantage both for me and for them. The classes were a way of allowing hospital staff to interact, who in the normal course of events would not do so. Hospitals are very cliquey places, and porters do not often have the possibility to speak to the head of the Psychiatric Department.

You can never 'learn' a language, but you can develop your knowledge to a sufficient level to be able to achieve different things such as speak to patients, give an explanation of illness to the mother of a sick boy, give directions to a lost relative, or give a presentation to the American Society of Nephrology.

I have since focussed on teaching in particular departments, such as ENT, Gynaecology, Paediatrics, or Dermatology. I have continued with the presentations, as they are integral to the life of a doctor. My students give 'talks' in the classes, later to be criticised by me, for the linguistic content and by their peers for the scientific content. They learn from me about the use of the definite article and I learn from them about 'dermoscopy of pigmented facial lesions'.

In 2005, the ENT Department of Son Llatzer Hospital gave a symposium about the importance of image-guided surgery. Originally the meeting was going to be conducted in Spanish with me interpreting, but I suggested that they should give their talks in English. It seemed the ideal situation, and it worked well. I sat at the front of the lecture hall and took notes on my students. The following day I went into class and explained where they had slipped up with their use of language and pronunciation.

As readers of this article you might begin to think that I have misled you with the title. I have talked about my experiences as a teacher of English to members of the medical profession, but where does the subtitle come in? Isn't bringing the humanities to medicine seemingly an oxymoron?

I have no medical training, but the medical world fascinates me. I am drawn to it, but my training is in the arts, therefore medicine is a field I find difficult. Many people are interested in both arts and science, but there is a crucial difference. If you study the sciences, you can delve into the arts, but the opposite is not really true. This is why I have been drawn to a speciality called the 'Medical Humanities'.

This speciality was given two formulations by the then editors of the journal of the same name [3]:

"The first is concerned with complementing medical science and technology through the contrasting perspective of the arts and humanities, but without either side impinging on the other. The second aims to refocus the whole of medicine in relation to an understanding of what it is to be fully human; the reuniting of technical and humanistic knowledge and practice is central to this enterprise. We have described these two approaches to medical humanities as "additive" and "integrated" respectively."

This field is little known in Spain, even amongst doctors. It has been around for a lot longer in the USA and the UK, and is part of the medical training in many universities, such as

## Teaching English to the medical profession

New York University, University of Texas, and University College, London. It is not an easy discipline to integrate into the courses in hospitals, but since the beginning it has infiltrated into my teaching, both in content and in style.

I have tried to instil it into my courses in more concrete ways, especially since 2005 when I began to teach at Son Dureta Hospital, where the groups have been smaller, and more focussed on the clinical side of medicine. In relation to the above quotation, I have made literature prominent in tackling the first 'additive' point, by using texts with a direct interest to medical professionals, such as Jean-Dominique Bauby's poignant description of the 'locked-in syndrome', or Raymond Carver's honest poem "What The Doctor Said", which is an account of the writer's doctor telling him he has lung cancer [4]<sup>1</sup>, or Chekhov, himself a physician, who treats medical topics with cool precision.

I have used the second 'integrated' point—'an understanding of what it is to be fully human'—as a kind of foil to the ever growing trend in medicine to specialisation or maybe over-specialisation. In the medical profession it is essential never to lose sight of the overall picture because if you do, sometimes grave errors will arise. I have worked on the 'patient-centred approach', with texts, video work and roleplays. We have had debates about whether medicine is an art or a science and on how to break 'bad news' to the family. We spent a few weeks working on the 'art of dying', and looked at this from many angles: the medical, the ethical, the religious, and the philosophical. Here, I was indebted to an interesting website put together by Kings College, London [5] based on a year-long symposium addressing a range of questions associated with death and dying.

This term we have begun to work on the question of the role of the doctor, what they can do apart from curing and caring, and how conversation, can help them to be better doctors. As a source text, I used the article entitled "How Work can be Made Less Frustrating and Conversation Less Boring" [6] by Dr Theodore Zeldin in which he writes

"The healthcare profession contains a vast reservoir of potential going to waste, of talents which are not properly appreciated, and of conversations which never take place."

The article is directed towards doctors and written for a medical journal. It led to essays by my students, with those essays being sent to the author and commented on by him, which in turn led to further debate amongst the students. This was a vital experience of opening out the enclosed 'classroom', and only became possible with modern technology, e-mails, and web-links. Technology plays its part, but human interaction is the core. This on-line conversation between students and Dr Zeldin is a thread for this year's course, and perhaps epitomises my ideas about how to try and use the humanities in a classroom full of scientists.

"Good communication skills are integral to medical and other healthcare practice. Communication is important not only to professional—patient interaction but also within the healthcare team." [7]

This is integral to what I have been trying to install in both hospitals in Majorca: good communication skills in the English language, both oral and written. I have paid a lot of attention to the writing of abstracts, articles, presentations

and posters. I have also set writing assignments, the latest being a term project concentrating on an idea picked up from the *British Medical Journal*. At the beginning of this year, the journal chose the 15 most important medical milestones since the first publication of the journal in the 1840s. The topics ranged from immunology to the Pill, sanitation to chlorpromazine, and smoking to vaccines. First my students had to choose the topic they thought had made the biggest impact and write an essay on it. Then they had to give an oral presentation with PowerPoint slides on the same theme. In this way they practised both oral and written communication skills.

As I explained earlier I have always seen presentations or 'talks' by the students as a way of furthering their ability to use the language and at the same time impart information of interest to the rest of us. In June 2006 to conclude the first year of the English course at Son Dureta Hospital, accredited by the Local Health Ministry for the Balearic Islands, I set my students the task of giving presentations in the lecture hall of the hospital. There was a mixture of medical and non-medical topics, "The Eating Disorders Unit" alongside "Photography: A technique to relive a magic instance", and "News from the lab" next to "Dreams", with "Popular architecture" combining with "Team building". It was a fitting culmination to a year's work, but only the beginning of what will hopefully become an annual event in this teaching hospital.

There are many plans for the future, but one is already a reality: a translation and linguistic unit has already been announced for Son Dureta Hospital, essential for a hospital looking to be an important contributor in the field of research and investigation. Soon I hope that English may be the language for clinical sessions, which may happen sooner than expected as I have been asked to attend weekly oncology sessions at Son Llatzer Hospital. These will be held in English and my role will be to give the oncologists feedback on their English. Another plan is to set up a blog for professionals from different hospitals to communicate with each other in English. I am beginning to do this with my students from both hospitals but I think it can be carried further as a means of inter-hospital communication. My hope is that English will become an integral part of hospital training and life. A big hope but attainable.

*I wish to dedicate this article to Dr Antoni Obrador (the late Head of the Digestive Unit, Son Dureta University Hospital), who was a great support in setting up the English course.*

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<sup>1</sup> After writing his last story, "Errand", about Chekhov's death, Carver learned that he had cancer.



## Reading round your therapeutic area

by Alison McIntosh

Often when you accept a medical writing job you begin the task by researching the therapeutic area concerned. This can mean a quick update to remind you of any changes, or researching for several days to try to get a feel for a new disease area. I often employ an additional method, which is effective, does not involve delving into text books, or surfing the net, and feels much less like 'work'. Perhaps you already use it?

A while ago I found myself writing a couple of hundred very detailed case narratives for Parkinson's disease. For large phase III studies this can involve trawling through many hundreds of pages of listings to extract key data points to populate narratives. In this instance, considering the amount of information required by the client, each narrative was taking over three hours to write, contained masses of information about drugs with unknown names, and procedures that were not familiar to me.

Writing narratives can be a very laborious exercise, and unsurprisingly deal with many negative aspects associated with a disease area. For me, to keep the task invigorating it can help to put the disease in context, not just from a scientific perspective, but also from a patient perspective.

To help me understand Parkinson's disease from a patient's view I began to read 'Lucky Man: A Memoir by Michael J. Fox' In his autobiography he deals with his career and also the discovery that he had young onset Parkinson's disease [1].

He describes the symptoms of the disease first hand, writing, "Every time my most recent dose of Sinemet would wear off the disease presented me with a concise history of my symptoms—first the tapping of the pinkie, then the dancing hand, and within fifteen minutes or so, the whole of my left arm would be tremoring. Tremoring, actually, is too subtle a word—the tremor would start my whole arm bouncing." This kind of detailed description brought to life the 'increase or worsening of tremor' written in a listing as an adverse event.

Concomitant procedures undertaken during the course of the trial were also listed and in the book he describes having to undergo 'thalamotomy' providing a very detailed description of exactly what the procedure involved. This was no longer just a word written in a listing, and given a definition by a medical dictionary, but a complex procedure that patients underwent in an attempt to increase their quality of life.

In 1986 when I was investigating HIV-1 for my PhD, many new scientific discoveries were being made about a recently isolated virus. There were no licensed antiretroviral treatments and the outcome for those infected with the virus was considered dire. The media was full of extreme stories concerning HIV/AIDS and any celebrities reportedly dying from the disease. During this time I saw a performance of 'Torch Song Trilogy' by Harvey Fierstein [2] in a West End theatre. I remember I was incredibly moved by this seminal production which allowed the public examination of how AIDS had affected the gay community during the late seventies and early eighties in a more measured and productive fashion. It had absolutely no scientific content but what it did for me was place HIV-1 into a human context.

I know I am not alone in using personal accounts to help work through medical writing tasks. Last year I was asked to review oncology literature, a task I wanted to finish as quickly as possible. Another writer also assigned to the job approached the subject differently and began to read 'Cancer: C: Because Cowards Get Cancer Too' by John Diamond [3]. The author had been a journalist in the UK who recorded, in his newspaper column, his battle with throat cancer. This book recounts his life, his cancer and all the treatments he underwent and has very uplifting reviews on Amazon.

In the UK in recent months there has been much discussion around the outcome of the NICE review regarding availability of new dementia treatments. For those working in this therapeutic area who want to find out more about what this harrowing disease is like to live with on a day-to-day basis, John Bayley's memoir would be a good place to start [4]. In this book he recounts the way normal life with his wife of 45 years slips further, and further away from him as the disease tightens its grip on her brain, ultimately destroying her ability to function as a person.

Interested in the moral issues science throws at us? Why not try reading the novel by Kazuo Ishiguro: 'Never Let Me Go'. This book will leave you thinking about the moral dilemma of human cloning and all its implications [5]. Although not to be classed as a 'light holiday read' I thought it was an exceptional book.



## Reading round your therapeutic area

Where 'reading round your therapeutic area' is written from a very personal perspective, Anne Hudson Jones has written a series of academic articles on the contribution of literary narrative to medical ethics. If you would like to examine the moral and ethical issues this poses in greater detail then accessing the articles would be a pertinent place to begin [6].

Perhaps you have used this 'tactic' in reading round your therapeutic area? Do you have any recommendations? If so please let us know. Maybe we could post them on the EMWA website, or maybe we could start an EMWA 'book group' with discussions at each of the Spring conferences?....Or maybe I'm just a freelance medical writer who needs to get out more!

### Alison McIntosh

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The *Lancet* published a special issue entitled 'Medicine and Creativity' in December 2006 (vol 328). This included an excellent article by Anne Hudson Jones on the beneficial effects of writing about illness (Jones AH. Essay Writing and healing. *Lancet* 2006;368:S3-S4). The article covers some of the well-established literature on patients' narratives of illness and is a helpful general reference to this literature.

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## Oxymoron

The Merriam Webster on-line dictionary defines:-

Oxymoron: plural *oxymora*

Function: noun

Etymology: Late Greek *oxymoron*, from neuter of *oxymoros* pointedly foolish, from Greek *oxys* sharp, keen + *mos* foolish: a combination of contradictory or incongruous words (as *cruel kindness*); broadly : something (as a concept) that is made up of contradictory or incongruous elements.

Roget's Thesaurus does not list oxymoron in common every day usage. However, moron is listed as a person with a learning disability. Very recently oxymoron seems to have become an 'in' word. There was even discussion at the EMWA Spring conference about its meaning. Clearly some clarification is called for. Paul Dunne (pdunne@iol.ie) researched the word and found the daily

usage of the term oxymoron may refer to a person who, in trying to be clever, may end up appearing foolish in the presence of their peers. He found no reference to this possibility in a present day dictionary or other references. On asking people about their experiences with the word Paul collected the following examples:

|                  |                     |                |
|------------------|---------------------|----------------|
| wise fool        | warm freezer        | legal murder   |
| plastic glass    | adult children      | good morning   |
| pretty ugly      | questionable answer | alone together |
| dangerously safe | fun run             | civil war      |

With all deliberate speed (go quickly, slowly)      Festina lente (Latin), hasten slowly  
'So foul and fair a day, I have not yet seen.' (Shakespeare, Macbeth, Act I, Scene III).

Oxymoron is quite often used in jokes, e.g. 'military intelligence': intelligence (1) meaning intellect or use of brain, and (2) knowledge about enemy country. Another oxymoron joke might be 'honest politician', which implies there are no honest politicians!



## A personal account of my first year as a freelance medical writer

By Samina Hamilton

In the last issue of *The Write Stuff* (TWS), you heard about my journey to freelance medical writing and my first three months in business. The next three have been no less interesting, with new challenges presenting themselves, sometimes on a daily basis! I have gained new clients, and diversified my portfolio to take on training roles within my local university. Read on for an insight into the highs and lows I have experienced during my second quarter in business.

### Months 3 to 6

#### January 2007

The seasonal holidays were well and truly over with the children back at school and the decorations boxed up in the loft. I was eager to pick up on two projects where I left them in late December 2006. I was expecting final statistical output for one study, enabling me to begin draft reporting, and I was to begin front-ending another report. January looked set to be a busy month, or so I thought... A couple of days after I received efficacy output for the draft report, it became clear from ensuing discussion that the safety output 'was not quite ready yet'. There were also some issues with the efficacy data which would require further statistical review, however, the required resource would simply not be available for what could be several weeks and possibly a few months. As for the front-end report I was supposed to be preparing, that completely disappeared into the ether. Suddenly, my packed January was looking a little freer.

I took advantage of the immediate gap in my writing fortunes by embarking on the new year exercise plan I had vaguely considered over the holidays. Exercise is great for allowing space and time to think. Having recognised that the reality of unmet milestones meant payment delays, sometimes long ones, I made a mental note to build in an extra assumption for milestone contract bids. I would reduce my risk by stating that I would invoice for the work done to date where milestones were delayed by the client, and deduct that amount from the eventual milestone payment. I also saw that I was going to need several more contracts ongoing simultaneously to absorb potential delays and apparently contracted work.

The rest of January 2007 was therefore spent on intensive business development activities. I went back to square one and trawled the internet, applied for several contract posi-

tions of interest via InPharm.com and got back in touch with old contacts to ask if they were in need of writing services. I re-examined some of the e-mail applications I had sent out before the holidays. I restructured them by comprehensively stating my experience and capabilities in the covering e-mail, rather than relying on the reader to actually make it to my web link and CV to review this key information. It was a simple enough presentational change, but amazingly, it appeared to do the trick. Within a few hours, requests for information and invitations to bid for projects started to appear in my in-box. I had learnt the valuable lesson of gaining the attention of potential clients within the first few lines of an e-mail.

I was delighted to be invited by Alistair Reeves, EMWA Freelance Coordinator, to help out with the set up, conduct and reporting of the Freelance and Small Business Survey planned for 2007.

#### February 2007

I updated the material for my website and had a few information technology glitches I was experiencing, ironed out. With ongoing business development activities, but no billable work as yet, it seemed like a good time to get away for a few days to celebrate our 15th wedding anniversary. With the children's Gran installed at home, Paul and I escaped to Krakow, Poland, for what was an impromptu break in a cultured jewel of a city. Paul reminded me that had I still been a paid company employee, I would never have had the requisite annual leave in hand to make this trip.

***I had learnt the valuable lesson of gaining the attention of potential clients within the first few lines of an e-mail.***

My return to work heralded the beginning of an absolute onslaught of enquiries, and more importantly, contract wins. I sent out a total of eleven requests for information and bids in as many days. I had also been concentrating on developing longer term relationships with some companies, so that the work

would not completely dry up once I had closed out individual project contracts. That strategy was paying dividends. I signed three separate contracts for periods of 6 to 12 months to provide medical writing services, on an 'as-needed' basis. I also won several individual pieces of work, not all associated with the 6 to 12 month contracts. Three of these clients were hoping to use my first piece of work to decide if they wanted to develop a longer term relation-

## A personal account of my first year as a freelance medical writer

ship with me. For the first time since starting out on my own, I had what I considered to be a healthy backlog of work that would occupy me until the end of June 2007. I had breathing space in early July before our scheduled family holiday in late July/early August, and I was in discussion with two clients about work for my return from holiday.

Another interesting opportunity arose during February which really caught my imagination. My good friend, Helen, with whom I had done my PhD, had called me to discuss 'something big'. We had both ended up as freelance medical writers and she now lived with her American husband and two children in the US. We had stayed in touch over the years and were now enjoying more regular contact, mainly because our working lives now allowed it. Helen had been invited to bid for a very large contract with a major pharmaceutical company. It was for a programme of early phase protocols and there

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***...had I still been a  
paid company  
employee, I would  
never have had the  
requisite annual  
leave in hand to  
make this trip.***

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were enough of them to keep several writers busy for a period of 18-24 months. She asked for my counsel during the bidding process and for me to be part of her team, should she secure a win. I was delighted to be included and we had fun working together on her bid. I spoke with several UK-based freelancers to ensure that I would be able to resource the UK end of the operation in the event of a win. With the bid safely with the client, Helen and I both put it to the back of our minds. So far, we have been lucky enough to be able to subcontract small pieces of work to one another from time to time, and we both hope to nurture this working relationship as our businesses develop.

### **March 2007**

At the EMWA Brussels conference, I had realised from talking to experienced freelancers, that it would be pertinent to contact my local university and hospitals trust, as this could unearth potential business from an alternative sector. I decided to try a multi-pronged approach to make the quickest possible in-roads. I approached parents at my children's school whom I knew were hospital consultants associated with groups involved in clinical research. I also joined the Healthcare Network North East England ([www.hcnetnee.com](http://www.hcnetnee.com)), a local organisation which works with companies, including those involved in clinical research, to increase sales and market opportunity through networking. Both approaches initially drew a blank. It then occurred to me that I should make the best of existing, albeit dormant, contacts. My next, and best move so far, was to contact my old PhD supervisor, who was now not without professorial clout, and was still based at the University of Newcastle Upon Tyne. I updated him on the last 15 years of my life and then asked him to spread the word about my services at the university and within the

hospitals trust. He very kindly facilitated some key introductions for me and I soon had enquiries and two contracts in process from a newly formed hospital-based group overseeing the conduct of clinical trials in the region. Great! I had broken into the local market, and my breathing space in early July started to shrink. It was rather fun to be going out and meeting local researchers, not to mention revisiting the medical school where I had studied and worked for so many years. Oh, did I forget to mention that I agreed to present a postgraduate training seminar in July 2007 to talk about my career to date, and the possibilities for careers in clinical research? I'm not sure the promise of a buffet lunch and university car parking permit for the day sold it to me though; I think it was more the opportunity to show that a fulfilling career, via the path I had chosen, can be a viable and achievable alternative to a career in academia.

Alistair and I were in touch over the survey and Freelancers' Forum planned for the Vienna conference. I registered for EMWA Vienna, or rather two days of the whole, as the conference was unfortunately scheduled right in the middle of my reporting two studies.

I was writing again too, to my relief. I began reporting for two new clients, in addition to updating the report which

had stalled in January. I also won three unexpected, smaller pieces of work which I wrote and closed out during the month.

Late March was a very busy period for me, as I hit critical path on a large clinical study report. I luckily remembered to submit my second value

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***I luckily  
remembered that my  
second value added  
tax (VAT) return  
was due just in the  
nick of time...***

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added tax (VAT) return just in the nick of time. Never a dull moment... I now look forward to a slight breather over the Easter holidays (or at least part of them) with the family.

I will continue to update you as I navigate my way through my first year in business, so look out for my articles in future issues of *TWS*.

### **Samina Hamilton**

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## Internet healthcare

Rumour has it healthcare is the most searched topic on the Internet. MedHunters.com<sup>1</sup> tells us that searching healthcare is more popular with teenagers than online games. The site outlines how to find healthcare information on the Internet and lists some useful sources.

1. [www.medhunters.com/articles/healthcareOnTheInternet.html](http://www.medhunters.com/articles/healthcareOnTheInternet.html)



## Reflections on jargon

### Dear TWS

As past issues, the December 2006 issue of *TWS* has a very engaging mix of items—instructive, provoking thought and discourse, and humorous. For me, your brief on jargon (page 137) created the critical mass that would overcome my reticence and unleash an outpouring of resentment and opinion on the use of jargon. I'd like to share them with you. But first, a couple of comments:

1. Jargon is not limited to American businesses. In fact, American bureaucratized bodies (especially governmental ones) and entities that have hierarchic structures, accountability, and spheres of influence are hotbeds of jargon. In my work I frequently come across jargon also in the initial, unedited drafts of medical articles from both English and non-English speaking countries, or in the published copy of less rigorously edited clinical journals; and I am puzzled and irritated by their authors' ritualistic and unabashed use of tumescent single words, disorderly telegraphic contractions, or pompous phrases—which seem like cars that are designed to look deceptively substantial, but which are dressed with frangible sheet metal around weak engines and unsteady mechanisms.
2. Single- or multi-word jargon takes a variety of forms. The speeches of lay circles—in-speak, slang, colloquialism, clichés, youth-speak, rap-speak, hip-speak—are full of the plebeian relatives of professional jargon. Euphemisms, clichés and the like are not too distant. The examples of jargon you gave in *TWS* are mainly buzzwords—contrived and after the limelight but practical for economically conveying broad and complex concepts.

Listed below randomly are some very subjective thoughts I have had over recent years on why jargon thrives though simpler language is preferable. They are conjectural; and perhaps combined linguistic, sociological and psychological studies might debunk my suspicions—or on the other hand, elevate their stature.

- Jargon is a stand-in for passwords for admission and verification of belonging to fraternities or regiments. It substitutes for some rites of initiation and recitations of pledges of allegiance.
- It is the verbal vestment of ritual. Its use has liturgical quality and is the invocation for pomp (therefore “pompous” language). At times it is no more than mantra, its effect not much different from the touch that spins prayer wheels.
- The user of jargon is kowtowing verbally, is validating the reverence-worthiness of a hierarchy and the office at its summit, and consciously or unconsciously, but oftentimes imitatively, is striving to demon-

strate to others, and simultaneously confirm to one-self, arrival, belonging, fealty, and obedience, and subservience in one direction and rank in the other.

- Given the opacity of content that it masks, the deliberate use of jargon cannot but be accompanied by some conscious compromise of the self. Its unconscious use implies another type of intellectual deficit.
- It is possible that because American society and culture have not had a history of monarchy and elitism (the latter is not all that unrelated to the former), and because, most would agree, the level of education and literacy that most American schools provide is generally weak, jargon thrives because it has survival value. It helps cover up faults in its user's thought processes. It supports pretensions of being hip, savvy and branchée. It helps create illusions of the consequentiality, inaccessibility, and indispensability that a pseudo-expert or an arriviste “authority” strives for. Perhaps the use of jargon in America is a sublimation of unspoken attractions to elitism and virtual royalty.
- Despite the preceding, organizational or professional jargon might be seen also as a tool that, on a very subliminal level, helps distance the arena where jargon is used from the user's personal/“private” life. Jargon may be a way of asserting individual independence and maintaining separation between work and obligation, on one hand, and the self, on the other.
- Why do the French, chauvinistic and resistant to the adulteration of their language and culture, accept the use of foreign words (especially English ones) in their day-to-day affairs? One possibility is that they use those words as jargon—to capitalize on the easy handle that the alien words provide of alien concepts, but at the same time to impede the full integration of the concepts themselves into conservative French hearths and life. In other words, if it is foreign keep it foreign.
- In oral communication, simple words or phrases could be articulated in ways to make them sound as jargon. If one were to spend a little time observing some prominent contemporary politicians one could conclude that the most simpleminded of them have the inborn talent to make jargon out of 8-graders' language.

Having risked being accused of jargon-mongering myself, I finish with an open message, cast out in the bottle of *TWS*, to all aspiring medical authors out there: it takes resolve and effort (and sometimes the intervention of an editor) to check the urge to imitatively use jargon based on the assumption that it is expected of you and you need it for professional acceptance. And if you're resorting to stilted language to mask weaknesses in arguments or of trivial information in search of publication, shame on you all!

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## Eureka!

When you find a good solution for expressing a particular idea after searching for years, you feel like Archimedes jumping out of the bath! This may not have the same repercussions as the testing of Hiero's crown, but I have finally found a reasonable way of solving the problem described below.

In German, and I suspect other related languages, it is quite acceptable to write the following, for example, as a withdrawal criterion: *If patients require treatment with an NSAID, **especially** aspirin, they must be withdrawn.* German-speaking authors writing in English also often use this type of formulation, which is nonsense in English. 'Especially' and 'in particular' (and similar terms) are the problem: directly from 'insbesondere' in German. Does this mean that there may be less of a reason to withdraw a patient treated with the NSAID ibuprofen? Certainly not because the exclusion criterion states that patients treated with NSAIDs must be withdrawn. Discussions with authors over the years have revealed that this formulation is used when they want to give an example of what may frequently happen: in this case, aspirin, as a very commonly prescribed NSAID, is **particularly likely** to be prescribed, but no treatment with any NSAID is allowed.

We have to accept that this does not appear to be objectionable to German speakers, but it clearly doesn't work in English, so we have to find a passable solution. The solution I have recently come across is to say in such cases: *Patients requiring treatment with aspirin or other NSAIDs must be withdrawn.* Not literally what the German says, but it conveys exactly the same idea. (The astute reader will still wonder why the author didn't simply say: *Patients requiring treatment with NSAIDs must be withdrawn*, but let's not get picky.)

A further possibility is to say: *Patients requiring treatment with NSAIDs, for example aspirin, must be withdrawn.* But this solution sounds strange in the following situation (as an exclusion criterion): *Patients with a history of circulatory disorders, for example peripheral vascular disease, are not eligible.* Here 'Patients with a history of peripheral vascular disease or other circulatory disorders are not eligible' is definitely preferable.

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## Lost Property Office

What will be the European Union's standard for a 'lost property office' which in French, German and Polish translates as a 'found property office'? Only found property is in the office but people who have lost property come to claim it.

## Why -ing forms can be confusing, and the power of hyphenation

Version 1: *These molecules are designed to resist protein binding and would be interspersed with the specific protein binding molecules of the protein array (e.g., antibodies, fusion proteins, etc.).*

Does the protein bind molecules of the protein array, or do the molecules bind the protein?

Version 2: *These molecules are designed to resist protein binding and would be interspersed with the specific protein-binding molecules of the protein array (e.g., antibodies, fusion proteins, etc.).*

Now we know that it's the molecules which bind specific proteins.

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## Mixed metaphors

Having been asked to edit a short document on the prevention of hepatitis B I was astounded by the metaphors in the short passage that follows:

"Thirty years ago, the outlook for the prevention of hepatitis B looked bleak.<sup>a</sup> However, the advent<sup>b</sup> of hepatitis B vaccines provided hope throughout the world<sup>c</sup> that this disease would one day be conquered. Since that time, great strides have been made in preventing the spread of hepatitis B. We still have a long way to go before this disease can be confined to the history books, but the future looks bright!<sup>d</sup>"

<sup>a</sup>I'm not sure if an outlook can look bleak. Alternatively, perhaps hepatitis B itself has an outlook, in which case these viruses are a lot cleverer than I realised.

<sup>b</sup>Advent always makes me think of Christmas.

<sup>c</sup>Are we back in Christ's birthday territory? Can be really rule out that hepatitis B vaccines would not provide hope in a galaxy far, far away?

<sup>d</sup>Though not the author.

I felt physically ill after reading this, with the final exclamation mark the (metaphorical) dagger in my guts. Bear in mind that this was written by a medical writer with years of experience in medical writing, so there are no mitigating circumstances (Mixed metaphor disease must be contagious as now I'm starting to write in that style too.)

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Turning vision into reality







## 5 more myths about English (4)

by Alistair Reeves

Here are 5 more myths about English (if you would like to know why I wrote '5' here and not 'five', see Myth 1 [1]).

### Myth 16: 'Localisation' is more precise than 'site'

It is not. At first sight, the simplest and best reason to prefer 'site' over 'localisation' is that it has only 1 syllable and not 5, and does not put you in the quandary of wondering whether it should be written with an 's' or a 'z' (see Myth 5 [2]). But there is an even better reason not to use 'localisation' when you mean the place on the body where a patient developed a rash: quite simply, *it is wrong, and does not mean 'site'*. 'To localise' means 'to restrict or assign to a particular place' (hence 'local' anaesthetic), 'to invest with the characteristics of a particular place' or 'to decentralise' something [4]. 'Localisation' (noun) is derived from 'localise', and it is the activity of localising, and *only* that.

Etymologically close relatives of 'to localise' are 'to locate' and 'location': 'to locate' is 'to discover the place of something' or 'to put something in a particular place' [4]. 'Location' means where something is or happens, and is therefore a possible substitute for 'site'; but because monosyllabic 'site' is just as good, it should be given preference. 'Location' also means the act of locating (like 'finding'), and does have other meanings too, e.g. 'a film location'. If you can't quite manage to make the transition to 'site', 'body site' is fine too.

### Myth 17: 'Contralateral' is a useful word in our context

In most cases, plain old 'other' or the opposite of 'left' or 'right' does a better job, because everyone understands these, and they are much shorter. Contralateral (the one on the other side), and the rarer ipsilateral (the one on the side you are not talking about when you refer to the other side), are used for body parts that occur in pairs on either side of the body—and there are quite a few such parts. Examples of the use of 'contralateral': *'If blood samples are taken from the right arm, the blood pressure should be measured on the contralateral arm'* or *'The contralateral breast should also be closely inspected for changes'*. But why bother with such a mouthful, even if it sounds good? 'Left' would have been just as good in the first instance, and 'other' in the second. Still worse is the 'contralateral side of the body'—a tautology, because 'lateral' already includes the concept of 'side'. It is often astonishing how

writers will leap to use a complex word in written scientific texts when a simple one will do: after all, if you came into a room with two doors, one on either side, would you ever write: *'I came in through that door and she came in through the contralateral door'*?

The use of contralateral is justified in the following and similar instances (title of a journal article): *Are men with testicular cancer at risk of developing a contralateral tumour?*

### Myth 18: 'Post' is acceptable as a preposition in our context

I thank Chris Priestley of Accovion GmbH, Eschborn, Germany for drawing my attention to this one.

Using 'post' as a preposition in the following way is jargon, and should be reserved for speaking or medical notes:

- Post dosing, the animals showed ...
- Post hysterectomy, the patient had ...
- Patients should be mobilised within 24 hours post surgery
- Post end of treatment, 7 patients reported ...
- Post mixing, the malleable mass is transferred to a 450 L bowl.

We all know that post means 'after' and that the above examples will never be misunderstood, but 'after' is the preferable solution for all similar constructions in written English ('After the...' in number fourth). Watch out for the use of 'following': see Myth 9 [2]. In all the above cases, 'post' would never be hyphenated—and this is perhaps a good indicator of whether you can use it or not in formal writing: if you are not tempted to hyphenate it (i.e. are not using it as a prefix but a preposition), you will usually be able to substitute 'after'. 'Post' has not yet entered the realms of written prepositional use, but is used as a prefix indicating 'after' or 'behind'. Well-accepted examples are (hyphenation is up to you; I usually write them as one word): posttreatment, postinfusion, postpartum, postprandial(ly), postpubertal(ly), postnatal(ly), and anatomical terms such as postnasal(ly), postsplenic and postganglionic. Many instances where 'post' is used as a prefix cannot be found in medical dictionaries. Formulations like 'The patient had post-dialysis concentrations of ...' have been taking hold for years now, and it is beginning to sound pedantic to insist on: 'After dialysis, the concentrations of ...'. But: 'It is important to measure the blood pressure post dialysis' is still not acceptable.

>>>

## &gt;&gt;&gt; More myths about English

**Myth 19: ‘and/or’ has to be used to allow for all possibilities**

Described very fittingly by Anne Jones [5] as a ‘term of unfathomable meaning’, ‘and/or’ is always difficult to justify, and it is better to avoid it altogether.

The ‘and’ is almost always superfluous. This is one instance in English where native speakers have it easier: because we spontaneously just say and write only ‘or’, and this is almost always all that is needed (listen out for ‘and/or’ in conversation—you will hardly ever hear it). Many non-native speakers of English cannot render this with plain old ‘or’ in their own language (because ‘or’ is used ‘exclusively’ [see below], or they have other words), and this makes it difficult for them to cross the threshold of just using ‘or’ in English.

Consider the following: *‘If the patient develops vomiting or dizziness, the infusion will be stopped immediately’.*

Which brute is going to leave this poor woman on the infusion if she develops vomiting and dizziness?

And the following: *‘Space should be provided for the study participant and/or investigator to make notes.’* (in the instructions on the preparation of an informed consent form).

What does this actually mean? It means that we should allow for the following possibilities:

- The investigator might want to make notes, and we should provide white space entitled ‘Investigator notes’.
- The study participant might want to make notes, and we should provide white space entitled ‘Study participant notes’.

It is highly unlikely that we wish to provide for the ridiculous situation that the study participant and the investigator will actually want to hold the same pen and write the same note together on an area of white space entitled ‘Investigator and study participant notes’. The ‘and’ is therefore superfluous, and *‘Space should be provided for the study participant or investigator to make notes’* is quite adequate.

Another example (from an SOP): *As sponsor of a clinical trial, the University has the overall responsibility for the trial and may use the services of third parties (such as pharmaceutical companies, associations, foundations, and others), e.g. for the supply of trial medication and/or financial support.*

A daft ‘and/or’, if ever I saw one. Why? First, there is an ‘e.g.’, so you’re giving examples and there could be countless other ‘ands’ and ‘ors’. Second, why allow for the possibility that you may have only the trial medication from one source, only the financial support from a different

source, or both from the same source (if this what the ‘and’ is supposed to mean here—probably not, I think it’s just sloppy and ‘overprecise’ use)<sup>1</sup>. Third, even if you just said ‘or’, it is so obviously not exclusive here, and clearly does not mean that the sponsor has to choose between either trial medication or financial support, or that there would be problems if the source of both were the same.

Finally, the daftest of all, which I leave without comment: *Narratives are provided for all patients who died on study treatment and/or within 30 days of the last dose of study medication.*

Dispensing with ‘and’ and just using ‘or’ is called using the ‘inclusive or’, and obviates the use of ‘and/or’ completely. Most misused ‘and/ors’ fall into this category.

Why do so many native speakers use ‘and/or’ then, when writing, if we spontaneously use just ‘or’? I surmise that it is because they think it sounds more precise and have so often been bullied into writing this by pernickety colleagues from the ‘Ah-yes-but-what-if’-school that they feel the ‘and’ makes things clearer or ‘covers everything’. But it does not.

If the exclusivity of ‘or’ is important, it is either obvious from the context: *‘You can pay for lunch or dinner’*—faced with this choice, who would pay ‘inclusively’ for both? Or there are linguistic devices available. This is why we have ‘either’ and ‘or’: *‘If patients develop headache, they may be treated with either paracetamol or ibuprofen’*. Whilst it would be impossible to prevent a patient being treated with both, implicit here is that a choice has to be made. If the converse is the case and combination treatment is allowed, you can always add ‘or both’: *‘If patients develop headache, they may be treated with paracetamol or ibuprofen, or both’*. To add an ‘either’ before the ‘paracetamol’ in this case would not be wrong, but is unnecessary. This, of course, means the same as: *‘If patients develop headache, they may be treated with paracetamol and/or ibuprofen’*, and is one instance where some may try to argue for ‘and/or’. Not me: I still prefer the ‘or both’ solution, because the reader does not have to backtrack: I bet most people reading ‘and/or’ backtrack a little to be sure that they have understood the sentence properly: to make readers backtrack is to be unkind to them.

Is trying to avoid ‘and/or’ a lost cause? I hope not.

This use of ‘and/or’ also calls into question the use of the ‘slash’ in general, and its almost always ambiguous use. It is worth reading Stephen de Looze’s *TWS* article on this; Ann Jones also discusses this point [5, 6].

<sup>1</sup> The sloppiness and inconsistency of this text—although in an SOP—is shown by the author’s failing to use ‘and/or’ in the brackets before ‘others’ because it was felt necessary in exactly the same situation in the next clause. ‘Others’ is superfluous, anyway, because of the ‘such as’, and this only makes it worse.

## More myths about English

**Myth 20: The correct abbreviation for litre is now 'L'**

Thanks to Anne Bartz, freelance translator and medical writer, Hamburg, Germany for telling me that she recently heard this was now a 'rule' in British usage and asking whether this is a myth, although not specifically a myth about English.

It may surprise you to read this (I was surprised, anyway), but litre is not an official *Système International d'Unités* unit [7]. This means there is no 'official' abbreviation for 'litre', so we can do what we want (Oh dear! No rule again!). There has been a trend towards writing 'L' for litre for a few years now, I suspect because of the possibility of confusion between 'l' and '1', and this is probably due to all the fonts we have in word processing (i.e. the distinction used to be clear with the typewriter). The difference is obvious with 'sans serif fonts'—Arial: 'l' or '1'—but not so obvious with 'serif' fonts (i.e. Times [Roman]-like fonts)—Times New Roman: 'l' or '1'. Sometime someone probably started using 'L' and it has gradually caught on. I responded to the trend and often now use 'L'. Message as usual: be consistent in one text.

**Note on Myth 11: No comma after 'e.g.' and 'i.e.':**

I thank Diana Taylor, Parexel International, Berlin, Germany for supporting me in spurning the use of the comma after 'i.e.' and 'e.g.' [3]. Diana pointed out that this is also supported by Fowler's *Modern English Usage* [8], except for the following situation: 'He attacked reactionaries, i.e., it would seem, those who opinions [etc.]...'. I am pleased to hear this, as I do not frequently consult Fowler (perhaps I should), but had I consulted Fowler on this one, this example would not have increased by readiness to revise my opinion.

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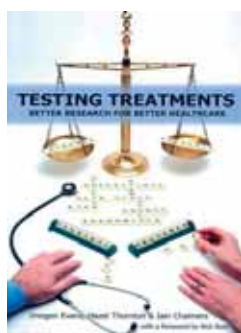
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## In the Bookstores...

## A Call to Make Patients Effective Partners in Medical Research

Imogen Evans, Hazel Thornton, Iain Chalmers. *Testing Treatments. Better Research for Better Healthcare*. London: The British Library, 2006. ISBN 0-7123-4909-X (Paperback). GBP 12.95, EUR approx. 19.00. 116 pages.



This book can be highly recommended to general practitioners and users of healthcare services (all of us!), because it is enlightening about how clinical trials are designed, how their results are analysed and communicated, and how biases in the creation of new medical knowledge can influence treatment decisions, and thus the quality of healthcare. By targeting

the book to both healthcare users and healthcare providers, the authors hope to teach both how to tell the difference between biased and trustworthy information, so that they can more confidently judge the reliability of data, research reports, advertisements, and other sources of information.

In clear, sensible prose (a credit to the authors' writing skills and to the adroit copyeditor), the three authors show "how the existing 'drivers' for research—commercial and academic—have not done enough to identify patients' priorities" (p. 96). Their goal is to convince readers that "better testing of treatments in the future should come from productive partnership between researchers and patients" (p. 80). The topics chosen for inclusion, the straightforwardness of the authors' reasoning, and the evidence from medical journals, the lay press, and patient-advocacy groups, make for a convincing read. The information sources are rigorous, and the information itself, some of which involves complex concepts related to research study design and methods, is explained in a way that is not at all condescending, but rather encourages readers to learn more. The authors' successful transfer to a wider audience of information usually intended for specialists in biomedical and pharmaceutical research is a lesson for writers and editors who aspire to publish effective consumer outreach and education materials.

The book starts with an Acknowledgements section, a Foreword and an Introduction, which are followed by eight chapters that identify specific shortcomings in current medical research, explain why these problems make the research less useful than it could be, and suggest ways in which the problems could be overcome. At the back of the book are an up-to-date reference list, a brief list of additional resources (some of which are worth investigating for medical writers, translators and editors), and an index.

Chapter 1 explains why "too much medical decision-making

is based on poor evidence" (p. 2)—a claim that might surprise readers who assume that all researchers, medical affairs managers, journal editors, and government agencies know what they're doing. In subsequent chapters the authors explain the basic principles of testing treatments, and tell readers how reliable evidence of treatment effects can be obtained. Chapter 2 lays out the dangers of using treatments that, despite their widespread acceptance by healthcare professionals and patients, are not based on sound evidence. The authors then explain how "fair" (i.e., unbiased) experimental or comparative studies should be designed (Chapter 3), and lift the veil on clinical trials by explaining the ideal methodological characteristics of this "gold standard". The examples of how blinding, double-blinding, and randomization are used to overcome potential sources of bias in study design and interpretation are especially helpful. In Chapter 4, strategies that clinicians, patients and researchers can use to reduce uncertainty in making treatment decisions are described, and consumers are encouraged to participate more actively in treatment decisions. Problems that can compromise the trustworthiness of the results of clinical trials are analysed in Chapters 5 and 6.

Especially instructive is the authors' explanation of how the choice of research topics is influenced by pharmaceutical firms' commercial interests and researchers' need to obtain professional recognition—two powerful socioeconomic factors that can prevent certain health problems from receiving the attention they deserve. The book concludes (Chapter 7) with a strong plea for patients to organize and become more actively involved in setting the medical research agenda. The authors then give us a seven-point "blueprint for a revolution" (Chapter 8), and an action plan for users of healthcare services who wish to become better informed about the quality of care and of the evidence it is based on.

The text itself is highly readable, and the way the book is organized into short chapters is also reader-friendly. The layout was probably chosen on the assumption that reading will be frequently interrupted (as is likely for most general practitioners and other busy people), so readers can come back to the text later without losing the thread. Boxed quotes provide referenced examples and supporting material for readers with a bit more time, and each chapter ends with a short list of key points that summarize the main messages.

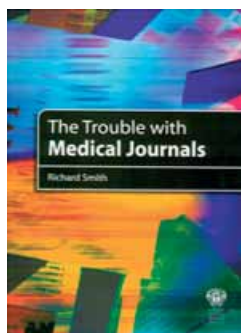
To help improve the quality of medical research, the authors advocate active participation by patients and user groups in designing research and evaluating the evidence, and recommend that clinicians and patients improve their ability to critically evaluate research to detect biases and

## In the Bookstores...

inaccuracies. In addition to its didactic value as an introduction to biomedical research methods, the book contains both an effective consumer-enabling message and important insights (for clinicians as well as patients) into how research can fail to meet the goal of providing better healthcare. This short, educational book encourages users and providers of healthcare to question assumptions, detect biases, raise questions about the quality of the evidence if they find it unconvincing, and work together to ensure that the right research questions are asked, and the right research is used to find the answers.

## Can You Trust What You Read in Medical Journals?

Richard Smith. *The Trouble with Medical Journals*. London: The Royal Society of Medicine Press, Ltd., 2006. ISBN 1-85315-673-6 (Paperback). GBP 19.95, EUR approx. 29.25. 292 pages.



As editor of the *BMJ* from 1991 to 2004, Smith witnessed many types of misconduct and questionable practice by researchers, reviewers, editors, clinical trial sponsors, and medical journal publishers, and he remains at the forefront of efforts to professionalize medical journal editing. In this book the author describes some of the challenges the *BMJ*

faced during his tenure as editor, examines how other journals have dealt with their own challenges, and explains why the trouble with medical journals should matter to everyone. He melds his first-hand experiences with a non-systematic but wide-ranging review of the editology literature pertaining to biomedical journals, and the result is a spicy story of the factors that conspire to make journals less effective, less reliable, and less accountable for their errors than Smith, for all his pungent criticisms, passionately wishes they could be.

The contents are divided into seven sections comprising one to five chapters each, with no illustrations or tables. Section 1 consists of a single chapter titled 'Introduction: medical journals are probably a force for good but need considerable reform'. This statement is supported by evidence presented in the subsequent six sections, 'The nature of medical journals', 'The processes of publishing medical research', 'Problems in publishing medical research', 'Important relationships of medical journals', 'Ethical accountability of researchers and journals', and 'The future'. A total of 418 references are cited; it would have been helpful to place them at the end of each chapter rather than list them all at the end of the book, where they are harder to check as one reads (especially as no headings

were used to identify which chapter the references belong to). The index at the back of the book is helpful but not as thorough as it might have been given the very large range of topics mentioned; some cross-references and pages on which entries and subentries are mentioned seem to have been missed. But interested readers will nonetheless find much to make the book worth reading cover to cover.

Smith gives us the human side of journal editing, and emphasizes that problems with journals are unavoidable because many of the decisions that reviewers and editors make are based as much on judgement and opinion as on fact. Sources of pressure and conflicts of interest that can bias decisions about what to publish are also identified and discussed with reference to cases in the *BMJ* and elsewhere. The mixture of case histories of editorial mishaps and Smith's analysis of their implications for the trustworthiness of journals makes the book a valuable educational resource for editors and reviewers, and a gold mine of data for journalologists.

The author is careful to point out that the *BMJ* and *The Lancet* (mentioned several times for purposes of comparison) are not typical medical journals, because their editors were (or are, in the case of Richard Horton, Editor-in-Chief of *The Lancet*) unafraid to publish provocative articles, try innovative editorial policies, and embroil their journals in controversy. These journals are well-off financially and highly respected, and so can afford to be bolder than most others, whose editors may consider discretion, rather than risk-taking, as the better part of valour. Both of the UK's top general medical journals have enjoyed huge successes and survived painful mistakes, but as Smith has declared more than once with regard to the journal he edited, "the *BMJ* is not in the truth business but the debate business" (p. 30).

A couple of chapters are not directly relevant to Smith's analysis of the trouble with medical journals, and the writing is, in a few places, so impetuous that passion has over-ridden clarity. The rather critical review of the book that was published in the *BMJ* [1] took issue with Smith's views on specific issues, while overlooking the book's timeliness and usefulness. Smith is indeed opinionated, but is nonetheless one of the world's experts in peer review and good professional practice for editors. Even if your job does not involve gatekeeping responsibilities, his analysis and opinions are worth reading as a record of how well medical journals are performing now that the media, the public, and regulatory institutions have become aware of the abuses that can undermine their reliability as sources of information.

So, can you trust what you read in medical journals? The author would answer, "Sometimes, but not always". Journals document advances in basic and clinical research, and perform the necessary roles of screening information, improving how the research is reported, and disseminating the results. As filters, journals are not one hundred percent accurate at distinguishing between good and bad research; as a manuscript review and editing service, peer review is

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## &gt;&gt;&gt; In the Bookstores...

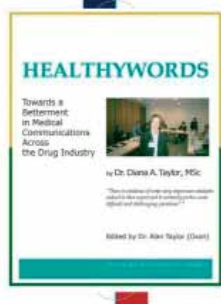
only partly effective in improving how accurately and transparently the research is reported; as information transfer tools, journals are not always published in ways that facilitate access to the information in resource-challenged settings. To make journals more useful sources of information, editors and reviewers need more support in learning how to make their journals better. Smith's book helps by educating gatekeepers, researchers, health care users, and ethics experts alike about the limitations of medical journals. In showing which processes are most vulnerable to abuse or incompetence, the author has done all users of medical journals a huge favour by suggesting how to avoid many of the pitfalls that arise from the human efforts needed to publish them.

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## Medical Writing for Managers

*Diana A. Taylor. Healthywords. Towards a Betterment in Medical Communications Across the Drug Industry. An Operational Handbook for Managers. Alan Taylor, ed. Marburg: Tectum, 2006. ISBN 3-8288-9083-0 (Paperback). EUR 24.90. 187 pages.*



Taylor has made a career of advising medical information and medical affairs (MI/MA) managers on how to develop their staff's collaborative writing skills and use them effectively to support pharmaceutical firms' goals. In this book the author has set herself the ambitious task of using research in text readability and her knowledge of current European regulations

aimed at protecting patients' rights to explain why MI/MA managers need to develop medical writing teams that function as a "knowledge-creating community" within the company.

*Healthywords* goes part of the way toward explaining the processes road-mapped in book's Summary and Outlook section:

- How data becomes information, becomes knowledge
- How issues of literacy have a bearing on the writing of texts by corporate scientists
- How these texts are to be fully understood and acted upon by their assumed audiences/readers
- How the same corporate scientists are to be trained as collaborative corporate rhetors
- How the company is itself constructed as a text to be 'read' in the competitive market.

To explicate how these different processes can be optimized, the author has combined research on text usability,

commentary on postmodern research in text analysis, and discussions of the medical writers' place within their corporate culture. The mixture of scholarly and applied information, and the frequent switches between knowledge-oriented and practice-oriented content, make *Healthywords* somewhat less effective as a handbook (which should provide specific guidance for decision-making and problem-solving) than it could be for managers. Readers must work hard to find the author's useful advice about writing better documents that will satisfy patients' needs and comply with current regulatory requirements.

The book is nicely printed and attractively laid out, apart from some gaps of white space after a few sections and tables. The Acknowledgements, Preface and General Introduction lead into four chapters that deal with working practices within the pharmaceutical industry, rhetorical considerations in the field of medical communication, collaborative environments in medical communication, and the role of pharmaceutical industry managers' training, education, and social responsibility. The chapters and their sections are clearly sign-posted, and the book concludes with a Reference section and a Bibliography for those interested in further reading. The typesetting reflects a sometimes odd combination of English and non-English conventions, but most readers would probably not be too distracted by this.

Busy managers in highly competitive pharmaceutical and communications industry environments could benefit from the knowledge and insights compiled in this book—but their information retrieval task would be made much easier by a careful revision and restructuring of the text to highlight the elements of practical guidance. Perhaps a second, revised edition will allow Taylor's valuable contributions to shine through the rest of the intriguing but less useful content on postmodern rhetorical analysis.

**Karen Shashok**

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## Call for contributions

*TWS* welcomes articles (800-2800 words) or boxes (up to 800 words) on topics of interest to medical writers, particularly on the future themes: 'perception vs proof' (where there is no evidence to support what is rightly or wrongly accepted as fact) and titles (article titles or academic titles). Ideas for future themes are very much appreciated as are letters commenting on anything you have read in *TWS* or would like to say to or about EMWA. Please submit to Elise at [langdoe@baxter.com](mailto:langdoe@baxter.com).





**Webscout:**

## Caution—foodies everywhere!

by Joelyn Flauaus

After attending a couple of EMWA conferences, I noticed that a lot of medical writers share the same addiction—the love for food (and wine of course). Good news is that we are not the only ones. There are a lot of foodophiles (so called “foodies”) around the globe who genuinely love food, who love dining out, who love cooking, who get excited about trying out new recipes etc. The perfect platform to exchange your experiences with fellow foodies is a food blog. The world of food blogs is as diverse as the world of medical writing. You can easily explore the world of food myths and cultures and eventually come across new recipes.

Below you find a small selection of my favourite food blogs from around the world. Visit the forums to chat about food and to discuss recipes, restaurants, and everything else with fellow food lovers. Join me in exploring new culinary possibilities by getting inspirations from around the world.

### <http://chocolateandzucchini.com>

Chocolate & Zucchini: this blog is written by one of the biggest stars in the food blogging community, Clotilde Dusoulier, a Parisian who shares her passion for all things food-related including thoughts, ideas, recipes, and restaurant experiences. She recently published her own cook book.

### <http://www.deliciousdays.com>

Delicious days: this food blog from a couple in Munich lets you take a peek into their steamy kitchen. This blog reflects the authors’ passions: Munich, the Bavarian city they live in, their travel experiences, cookbook reviews and the pursuit of all things delicious. Check out their mouth-watering recipes!

### <http://orangette.blogspot.com>

Orangette: a very addictive food-literature blog. This blog of a Seattle-based foodie provides you with an interesting collection of stories, often autobiographical and always gastronomical. The fun-to-read stories are often accompanied by recipes.

### <http://annesfood.blogspot.com>

Anne’s Food: this is a blog from a Swedish girl living in Stockholm who is obsessed with food and cooking. Get the latest recipes (in English or Swedish) and discover insider tips for nice restaurants and bars in Stockholm.

### <http://brandoesq.blogspot.com>

Kuidaore—cooking & eating to surfeited collapse: this Singaporean food blog provides an insight into the blogger’s obsession with macaroons and also provides you with tips to prepare high-level multi-course dinners.

### <http://nami-nami.blogspot.com>

Nami-Nami: this blog of an Estonian foodie returning to her hometown Tallinn after living in Edinburgh for seven years is about cooking and eating in Estonia and beyond. The blogger shares recipes and insights to the Estonian way of living with us.

### <http://cupcakeblog.com>

Cupcake Bakeshop: this San Francisco-based blog is about a true obsession with cupcakes. Everything you ever wanted to know about cupcakes (and how to bake them) but were afraid to ask. Learn how to make the most incredible and delicious cupcakes. Choose from an infinite number of recipes, from savoury to sweet.

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If you find a page that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at:  
[joeyn@trilogywritng.com](mailto:joeyn@trilogywritng.com).

## Facilitating comprehension?

- The laboratory *facility* was instructed to use the new device from 1 September 2006 onwards.
- We have just opened up a new laboratory *facility* at our Philadelphia site.
- The laboratory *facility* is staffed by 27 specialist technicians.

Does *facility* actually add anything here?

**Alistair Reeves**

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**Journal watch:**

# Transparency of medical writing assistance and misleading composite end points in clinical trials

by Nancy Milligan

## Transparency: the key to an ethical relationship between medical writers and journals

In an editorial recently published in the *Journal of Investigative Dermatology*, a freelance medical writer and the managing editor of the journal have come together to continue the debate on the role of medical writers in biomedical publishing [1]. In the article, Heather Yarnell Schultz and Elizabeth Blalock recognise the increasing use of medical writers in biomedical publishing (apparently the market for medical writers grows by about 15% each year [2]) and examine the ethics of recognising writing assistance in published material. They suggest that ‘the problem is not with the use of medical writers per se, but the use of unacknowledged medical writers or the use of medical writers to prepare articles that list authors who have not contributed to the intellectual process of the article’. They also highlight the problem of authors concealing funding sources for writing services. The authors go on to describe the viewpoints of various organisations who have published standards or guidelines for authorship and writing assistance (the International Committee of Medical Journal Editors [ICMJE; 3], the American and European Medical Writers Associations [AMWA and EMWA; 4, 5], and the Pharmaceutical Research and Manufacturers of America [6]). They conclude that it is generally accepted that most medical writers would not qualify for full authorship, but that medical writers should at least be acknowledged in the manuscript and therefore that the role of any writing assistance should be transparent. In response to the various guidelines, the GATE principles were put forward by Daskalopoulou and Mikhailidis to guide the ethical conduct of professional writers and authors [7]. GATE stands for: *guarantee* (are the authors guarantors of the work?), *advice* (did the authors advise the writer?), *transparency* (is the writer acknowledged?), and *expertise* (did the writer have sufficient expertise to draft the article?). Yarnell Schultz and Blalock conclude that ‘clearly, transparency is the key to a harmonious relationship between medical writers and the biomedical peer-reviewed journals’. Encouragingly, the article finishes by putting forward expectations of the *Journal of Investigative Dermatology* for corresponding authors; they suggest that authors should guarantee that: (1) authors in the by-line of submitted manuscripts meet ICMJE standards, (2) the contributions of medical writers not meeting the ICMJE standards are stated in the acknowledgements, (3) the funding for such writ-

ers, either through employment or through other sources, is stated in the acknowledgements, and (4) authors are willing to take public responsibility for the scientific merit of the published work. This type of guideline supports an ethical relationship between journals and medical writers, which can only be a good thing for the future of our industry.

## Problems with the use of composite end points in cardiovascular clinical trials

Composite end points, a method of combining multiple single end points, are often used in cardiology clinical trials to increase event rates and statistical power (a common composite may consist of cardiovascular mortality, myocardial infarction, and revascularisation outcomes). However, composite end points can be misleading if one component is overrepresented in the results, which can lead to an overestimation of the impact of the treatment on the other outcomes. A recent systematic review investigated the characteristics of composite end points in 114 cardiovascular randomised controlled trials in six major journals [8]. The researchers were interested in the extent to which the individual components of composite end points varied in importance to patients (categorised as fatal, critical, major, moderate, and minor), the frequency of events in more or less important components, and the extent of variability in the relative risk reductions across components. Reporting of composite end points was often inadequate. 68% of studies ( $n = 77$ ) reported complete component data for the primary composite end point, and 98% of composite end points included fatal end points, usually ‘all cause mortality’. 56% ( $n = 64$ ) of composite end points showed either a large (10%;  $n = 11$ ) or moderate (47%;  $n = 53$ ) gradient in importance to patients. Of the 84 composite end points that reported data for at least two of their component end points, 45 (54%) of the component end points showed large or moderate gradients in both importance to patients and the effect of treatment across components. When analysed by categories of importance to patients, less important components showed higher event rates (with medians of 3.3% for both fatal and critical outcomes, 3.7% for major outcomes, 12.3% for moderate outcomes, and 8% for minor outcomes) and larger treatment effects (relative risk reduction of 8% for death and 33% for minor outcomes). For example, mortality outcomes provided the lowest event rates and showed the smallest treatment effects even though they were present in most of the cardiovascular composite end points. This study highlights

## Journal watch:

the challenge medical writers face when writing up trials that report composite end points. The main advice should be to interpret composite results with caution to avoid overestimating the treatment effect of certain outcomes, and to ensure you report results for the separate components, if available, as well as the overall results.

### Nancy Milligan

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## UK vs US spelling pitfalls

You knew that UK spelling requires ‘programme’, not ‘program’, for ‘conference programme’ and most other usages, but did you know that according to the *Concise Oxford Dictionary*, ‘program’ is usually the preferred spelling for ‘computer program’?

The preferred spelling of the element S is ‘sulfur’ with an ef in both US and UK spelling. IUPAC adopted the spelling ‘sulfur’ in 1990, as did the Royal Society of Chemistry Nomenclature Committee in 1992 (<http://en.wikipedia.org/wiki/Sulfur>). But the journal *Nature* is not alone in continuing to uphold British custom by spelling it ‘sulphur’. Googling on ‘sulfur spelling’ brings up 161 thousand hits, and googling on ‘sulphur spelling’ finds 267 thousand.

Doctor Moroneh of Edinburgh is a practising endocrinologist with a private practice who needs to practise his golf swing. His colleague Doctor Tolisembam of Chicago is a practicing endocrinologist with a private practice who needs to practice his baseball swing.

### Karen Shashok

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## Why I don’t like using ‘using’

Version 1: *Identifying active transcription factors and kinases from expression data using pathway queries*

Do the data use pathway queries, or do human beings use the queries?

Version 2: *Identifying active transcription factors and kinases from expression data-using pathway queries*

Now it’s the queries which use expression data. But is that what the authors meant?

Version 3: *Identifying active transcription factors and kinases from expression data by using pathway queries*

That’s better—clear and unequivocal. But why not say ‘with pathway queries’? Or ‘Using pathway queries to identify active transcription factors and kinases from expression data’?

### Karen Shashok

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*Pharmaceutical industry publishing practices of clinical trial results:*

## The ‘PPP’ Survey

There is an increasing demand for greater transparency in the publication of clinical trial results because trust in the pharmaceutical industry is low. Little research on publishing processes in the pharmaceutical industry is available. In the course of research being conducted by Helena Korjonen-Close at University College London School of Library, Archive and Information Studies (UCL SLAIS), a survey will to be launched on the UCL SLAIS website (<http://www.ucl.ac.uk/slais/research/>) in September 2007. The survey will target medical writers and marketing people involved in publishing processes in the pharmaceutical industry and its service agencies (clinical research organisations and medical communications agencies).

The aim of the survey is to

- identify current methods of dissemination of clinical trial results
- identify how those involved in disseminating results understand the new methods in publishing, including open access and requirements of biomedical journals when submitting articles
- explore how the selection is made on what results are disseminated and why
- explore the pharmaceutical industry’s understanding of its reputation and transparency
- understand how a journal is selected when wishing to publish
- find out the importance of timeliness of the dissemination of results; early release vs end of trial.

UCL SLAIS is a leading centre for research in librarianship, information science, archives and records management, especially in the areas of health informatics, research evaluation, and scholarly communication.

### Helena Korjonen-Close

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# The Comma

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