European Medical Writers Association

The Write Stuff

The Journal for European Medical Writers

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Perspectives

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 emwatws@associationhq.com 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

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Behind the press

Cover picture

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European
Medical Writers
Association

27th EMWA Conference
20-22 November 2008, London

You are invited to participate in 2 days of training, discussion, and networking at the the 27th EMWA Conference to be held between 20th and 22nd November 2008 at the Holiday Inn London, Kensington Forum, 97 Cromwell Road, London, UK.

The conference will again provide members with opportunities to continue 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.

London was chosen for this autumn meeting for its ease of accessibility, dynamism and cultural diversity, and range of good hotel options. Which makes it ideal for popping into for a 1-2 day meeting.

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

Julia Forjanic Klapproth
EMWA President

From the editor's desk:

Perspectives

by Elise Langdon-Neuner

'Perspective' is an enormous word. Perspectives stretch back as far as we can see, allow us to view a thing in one of many possible ways and give us an understanding of how important one thing is in relation to others. Sometimes there would seem to be only one perspective—the one that is most familiar to us, and which corresponds to our own opinion—but there are always more viewpoints if we look at things 'in perspective'.

An extreme example of this is provided by the drug thalidomide, which caused the tragedy that more than anything else was responsible for the escalation of regulatory writing, the career mainstay of the majority of medical writers. This year marks the 50th anniversary of the grant of a licence to sell the drug in the UK. In 1961, three years after its introduction, William McBride, an Australian doctor, wrote a letter to *The Lancet* reporting a link between babies born with deformities in his hospital and mothers who had taken thalidomide during their pregnancy to cure morning sickness. Thalidomide was withdrawn from the market later that year. An estimated 10,000 babies worldwide were born with deformities caused by thalidomide. It was abundantly clear that, to avoid future catastrophes of the same kind, tighter controls would be needed before a drug could be released onto the market. Legislation that was under consideration by the US Congress at the time gained urgency, and what came to be known as the Kefauver-Harris Drug Amendments Act was passed unanimously in 1962. This act considerably tightened provisions relating to marketing drugs and testing them in clinical trials, and it increased the amount of documentation that needed to be written and submitted to the FDA.

However, there is another side to thalidomide. There are reports that it is an effective treatment for various disorders, including leprosy, multiple myeloma, HIV/AIDS and ulcers. The manufacturers have provided the medication free for such conditions, but even so the World Health Organization advises that it should not be used because the risks are too high. Despite attempts to impose strict precautions against the use of the drug by pregnant women and to persuade men to use condoms because thalidomide is present in semen, three children are known to have been born with thalidomide-related deformities in Brazil over the last three years and apparently there have been other such cases in Mexico, India and Africa. On the other hand, people have died because they have not been able to obtain the drug [1].

This is paralleled by the more recent cases of the analgesics Vioxx and Co Proxamol, which in post-marketing research had been shown to entail a small but detectable risk of heart failure and death. Many chronic pain patients were distressed about the withdrawal of these drugs from the market, and the view was often heard that the risk was acceptable against the alternative of perpetual, severe pain.

Another perspective when considering drug development is to contrast our concerns about drugs today with the situation in England before drugs were developed. Take the time of Shakespeare's birth in 1564, for example. The population was diminishing dramatically; it had fallen by 6% in the previous decade. This was the result of numerous premature deaths, of which the plague was only one cause among many, which included tuberculosis, leprosy, measles, rickets, scurvy, smallpox, cholera, dysentery and a mass of fevers that have now slipped from our vocabulary, such as the 'English sweat', which could hit people in the morning and kill them by the evening of the same day. Today, immunity has been developed to many of these diseases. Effective treatments have been evolved using drugs to replace such mediaeval practices as bleeding with leeches. Today we face the problem of an ageing population and a diminishing workforce—at least these are the concerns in Western society because we tend to forget that there are still places in the world where people continue to battle with mediaeval diseases. Meanwhile pharmaceutical companies are seeking to develop treatments for a new generation of Western disorders such as Alzheimer's disease. And developing cures, once seen as a humanitarian enterprise, is now controlled by commercial whims.

Time, place and circumstances change perspectives. A number of articles in this issue show how current changes are altering the perspectives of regulatory writers. Art Gertel and Nancy J Stark trace the laten increase in the regulation of devices. In the process, more work has been created for regulatory writers, perhaps adding to the headaches that Linda Donnini describes in her article on adverse events—but tips are also given for curing the headaches. The obligation for the pharmaceutical industry to provide 'adverse reaction' reports was, in fact, brought in with the 1962 amendments mentioned above. Then there are the new provisions for registration of clinical trial results enacted by the Food and Drug Administration Amendments Act 2007, which will come into force in September this year. Kathy Thomas and Claudia Tesch give a detailed account in their article of what this will mean for regulatory writers. Examples of how things can be seen from different sides are to be found in Adam

Perspectives

Jacobs' article in Journal Watch in which he outlines the extremely polarised views held by opponents and proponents of ghost-writing. The subject has come to the fore again with the publication of a study by Ross et al., which is the centre point of Adam's article. I also had the opportunity to see a different side to decision-making in manuscript publication, that of the editors at the *bmj*, and have reported my experiences.

But this issue of *TWS* does not only take a perspective on continuing developments in regulatory writing and different viewpoints relating to these developments; it also features two articles that show how views about the most widely used language of science—English—can change depending on your background and location. Joy Burrough describes how her attitude towards English changed when, after spending many years as an author's editor in Holland, she returned to the UK, her native English-speaking country. Kathy Nelson describes a similar experience, but in her case the return migration was from Austria to the USA.

Finally, an article by Richard Clark looks at PowerPoint, often seen as the equivalent of a wonder drug in communication. Could there be another view—that it in fact hinders communication?

Elise Langdon-Neuner
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Reference:
1. Murphy C. Thalidomide: a curse or blessing? BBC News. Available at: http://news.bbc.co.uk/2/hi/health/7326588.stm

Call for Applicants for EMWA Professional Development Committee

A vacancy has arise on the EMWA Professional Development Committee (EPDC). I would like to invite applications from EMWA members for this position.

As an EPDC member, you will be involved in all aspects of developing and maintaining the EMWA Professional Development Programme (EPDP), ensuring quality of the workshops in the programme and supporting the development of new workshops through mentoring of new workshop leaders. By serving on the EPDC you can help shape the future of this vital programme at the heart of EMWA's activities. Furthermore, as in the past, future candidates for the post of EMWA Education Officer will be drawn from the EPDC members.

If you would like to apply for this position, or would like to know more about it, please contact me at stephen.delooze@accovion.com, or any EPDC member (details on the EMWA website) who will be happy to provide further details.

Stephen de Looze
Education Officer

Perils of the slash

Study objective: To show superiority in terms of overall survival time in subjects receiving chemotherapy A/chemotherapy B plus MabX compared with subjects receiving chemotherapy A/chemotherapy B alone in the first-line treatment of Stage IIIb NSCLC.

It would have been so easy for the author here to have written:

To show superiority in subjects receiving MabX combined with chemotherapy A and chemotherapy B compared with subjects receiving chemotherapy A and chemotherapy B alone in ...

It would then have been clear that subjects were to receive EITHER MabX plus chemotherapy A AND B OR chemotherapy A AND B and not MabX plus chemotherapy A OR B OR chemotherapy A OR B.

See how complicated the slash can make things?

Alistair Reeves
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Call for articles for the September issue of *TWS* Guest editor: Alistair Reeves

The Sword of Damocles in the shape of time with a very sharp point hangs close to the head of every writer, editor and manager in our business—whether freelance or employed. The theme of the September 2008 issue of *TWS* is 'Who manages your time?' The focus will be on time management of medical writing from the point of view of writers and managers.

This is a perennial discussion point at conferences ('How many days do you allot for a clinical study report?' or 'Whatever I do, I always seem to end up working at the weekend'), so I expect that many of you have something to say on this topic. Any contribution relevant to time management—however small or large—will be welcome, and should reach me by 4 August 2008.

Alistair Reeves
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Message from the President

by Julia Forjanic Klapproth

Who are we and where are we going? Where do we want to go? How can we make sure that our organisation continues to grow and develop in ways that meet the needs of our broad membership? These are all questions that have been occupying EMWA's Executive Committee (EC) for some time now. And after having spent the past 2 years behind the scenes streamlining the administrative side of running EMWA, we are now poised to focus our time and energy on tackling these broader questions. The time that all of us dedicate to EMWA can now be spent developing concrete, long-term strategies for continued growth and development of our association.

We have taken the first major step in hiring an international Head Office service provider offering a wealth of resources. This means that as we identify potential new programmes—such as further extracurricular activities, sponsorship plans or scholarship schemes—we will have dedicated teams at Head Office at our disposal to help us put them in place. Members, who provide support to EMWA on a voluntary basis, alongside full-time professions (not to mention family and other obligations!), understandably have limited amounts of time to give to EMWA. This precious resource will be of much greater value to EMWA if our dedicated members act more as "think tanks" for events and programmes that would best contribute to our professional development and promote the public view of medical writing: teams at Head Office will then coordinate and implement these ideas.

The next step will be to develop a 5-year plan for EMWA, focusing our time on exploring or strengthening many areas of our activities. Over the next year, the EC will list and prioritize initiatives, and develop a business plan to make them happen. For example, we all have an interest in raising the awareness and perception of medical writers as professionals who bring expertise and add value to our clients' or colleagues' endeavours. As members of an esteemed organisation, we all benefit from increased recognition in our professional domains. One way of increasing visibility would be to have teams of members at hand to address topics of concern to medical writers arising in the media and industry, and in regulatory or communications arenas. The goal is of course to further strengthen EMWA as a respected authority and the voice of the medical writing community in Europe. If you have other ideas, please let us know; with your help we can identify and explore other important ways to make EMWA an organisation that works for us all.

The next two conferences are already set, and planning is underway. This year, our autumn conference will be held in London from 20-22 November and will offer a diverse programme of workshops to be added to your EMWA Professional Development Programme (EPDP) accreditation. The spring conference in 2009 will be held in Ljubljana from 26-30 May, and will have a theme of regulatory writing. I am still looking for members working in this area who would be willing to share their ideas and expertise to make the theme events of the Ljubljana conference as memorable as those of the Barcelona conference. If you are considering getting involved, you do not need to worry that this will mean a huge workload. What EMWA really needs are your ideas. If you give me suggestions, for example for speakers or topics for discussion, I will work with Head Office to make the suggestions happen. Of course, if you are good friends with an EMEA or FDA reviewer and can convince him or her to come and talk at the conference, even better! But no commitment from your side would be necessary other than to participate on three or four telephone conferences over the next few months, and brainstorm with other writers to help us put together our "dream conference". So please let me know if you are willing to get involved.

One last point before I sign off. The feedback from the Barcelona conference has been resoundingly positive and I really felt that the programme had a fantastic selection of workshops and seminars for everyone—new and experienced writers across the medical writing spectrum. Thank you to everyone who helped to make this conference something special.

Julia Forjanic Klapproth
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MET members: Thank you and *TWS* subscriptions

EMWA would like to thank the MET members who contributed to the great success of the translation session at the EMWA conference in Barcelona.

Also a reminder that MET members are entitled to a subscription to *TWS* at the reduced rate of 30 euro per annum. Please contact EMWA head office (see inside cover) for further details.

What's news at EMWA?

The EMWA 26th Conference, Barcelona 2008

Scientific and medical translation

The special focus of EMWA's 26th Conference held in Barcelona was scientific and medical translation. Translators among members of EMWA, the Mediterranean Editors and Translators (MET), and the Spanish Medical Writers Association (AeRTeM) contributed to the great success of the translation session at the conference in Barcelona. The following are a sample of reports on the theme.

Tools of the Modern Translator's Trade: Laura Russell

No discussion on modern-day translation would be complete without at least a brief look at some of the software tools available to the modern translator. In her seminar on computer-aided translation (CAT), Laura Russell, University of Mainz, presented the general functions of the most common translation memory (TM) programs available.

Contrary to widespread belief, a TM has nothing to do with machine translation. Rather, it is a database storing translations previously done by human translators. Thus, the concept of TMs is based on the premise that sentences used in previous translations can be 'recycled.' The TM consists of text segments in a source language and their translations into one or more target languages. These segments can be sentences, phrases, or other predefined parts of text.

When a new text is translated, the program splits the source text into segments, looks for matches between source and target language segments among translated pairs stored in the TM, and offers matching pairs as translation suggestions. The translator can now accept the suggestion, modify it, or replace it with a new translation. The modified or new translation will again be stored in the database.

One major advantage of a TM is that it can significantly speed up the translation process. Also, it guarantees the terminological and stylistic consistency of translations. In general, the more technical a text, the longer a text, and the more often it is updated, the more useful a TM. In the world of medical writing, an example of a text genre lending itself to being translated using a TM is the Summary of Product Characteristics or the Package Leaflet. Both documents may have to be translated into up to 24 European languages within a period of just a few days—the ideal application for a TM.

Useful as TMs may be, there are a few constraints, and the seminar was interspersed with interesting discussions of the advantages and disadvantages of TMs in different translation settings. For example, TMs offer only few, if any, benefits when translating texts of a more creative or artistic nature, such as prose or fiction.

Even though TMs are of greatest interest to translators or translation managers—in other words, to those who sell translations—a basic knowledge of what CAT tools can offer and in what situations they are of greatest benefit is also essential for anyone buying translations, enabling informed decisions to be made when selecting or cooperating with a translation service provider.

Gabi Berghammer
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Linguistic validation of questionnaires used in health outcomes: Paz Gómez-Polledo

Linguistic validation is a complex process which is designed to ensure robust data in international clinical trials. The goal is to confirm that all patients respond to the same questions, no matter what language they speak; only then can reliable data be compared on a multi-national basis. Patient-reported outcome questionnaires are translated into the language of the target country and then 'back translated' by a different language professional to confirm that the content of the translation matches the master document. The original text and the back translation are reviewed by local and central project teams and modified as needed. The process is then repeated at least once and sometimes more times: the revised document is 'forward translated' into the foreign language again and back translated for purposes of comparison and review. Each phase of the process has to be carried out by language professionals with specific qualifications.

Paz Gómez-Polledo explained the procedure of linguistic validation in detail and cited examples of the textual ambiguities which come to light when texts are forward and back translated. These passages have to be resolved in all of the documentation in all languages. Patient-friendly idiomatic language can be misconstrued; Gómez-Polledo discussed one case in which a query about patients' activities 'around the house' was rendered literally in the sense of 'in circles outside the house.' However, even more straightforward turns of phrase can be unclear (e.g., is 'at night' supposed to mean 'in the evening' or 'while sleeping'?). Texts may also need to be localized to make them more culturally appropriate; when comparing relative levels of exertion in a COPD trial, for example, asking patients in Spain if they have difficulty breathing while shovelling snow does not yield useful data. The interesting presentation and discussion provided greater insights into a very specialised branch of the translation industry.

Laura Russell
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>>> What's news at EMWA?

Corpus-guided translation and editing: Mary Ellen Kerans

Mary Ellen Kerans' short workshop on 'corpus-guided translation and editing' taught us how writers without a linguistic background can learn from linguists. Mary Ellen gave an enthusiastic and convincing presentation on practical applications of corpus linguistics for medical writers. 'Corpus-guided translation and editing' basically means putting together a body of carefully selected (electronic) texts and analyzing it with computer tools to answer specific questions on language usage. Taking this approach, medical writers who want to produce (or edit) a text in a certain medical subspecialty that is new to them will collect reliable 'model' texts from the given subspecialty into a 'corpus' and analyse it to obtain information, e.g. on the frequency of a term in a certain subspecialty or on typical word combinations such as compounds. This type of linguistic information proves tremendously helpful for non-native-speaking writers of English, who are often insecure about 'just the right term' their target audience expects to hear. The analysis can also assist English native-speaking editors in making competent editing decisions when working in a subspecialty that is new to them. But what is the advantage of corpus analysis over a simple Google search? In the corpus-based approach, the search is performed on reliable, 'good models' of subspecialty texts; therefore the information from the analysis can be trusted. Even though unreliable search results from a Google search can be discarded, statistics, e.g. on the frequency of a term or word combination, will be unreliable. While the corpus approach does involve upfront effort for selecting and generating a good text body, it appears to be a promising method for medical writers. The scope of the 90-minute workshop was too short to fully cover this fascinating subject. I would be very interested in a more comprehensive workshop with hands-on training on the tools and methods.

Susanne Geercken
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Welcome lecture

Mercè Piqueras, who is a native of Barcelona and author of the book *Walks around the scientific world of Barcelona*, gave the welcome lecture. She described how Barcelona universities had developed and gave tips for finding signs of the city's scientific past in the street signs and buildings of Barcelona. A particularly interesting story was that of Maria Elena Maseras. She was the first woman to enrol at the School of Medicine, University of Barcelona. She enrolled for the academic year 1872-1873. There were no rules prohibiting female students because no one had ever thought women might want to study. However, her professors refused to examine her and it was not until 1882 that she was able to obtain her degree. Two other women who had enrolled in the meantime were also awarded degrees in 1882 but following their success a royal decree was proclaimed prohibiting universities from accepting female students. It was not until 1910 that women secured full legal rights to study at universities although several scores of women are reported to have taken university courses during the period of the ban.

Education

EMWA conferences are a prime training venue for medical writers. Participants at the Barcelona conference were offered a choice of 48 workshops—more than ever before—from the 68 titles in the EMWA's Professional Development Training Programme (EPDP). Eleven of the 48 workshops were newly introduced and under assessment for the Barcelona conference on such diverse topics as Systematic Reviews, The CTD Clinical Summary, Beyond Simple Editing, and Writing PowerPoint Slide Kits. The Barcelona EPDP programme included 27 foundation workshops, 19 advanced workshops and 2 'soft skills' workshops. Foundation workshops can take a maximum of 32 participants and advanced workshops up to 20 participants. Seventeen workshops (6 foundation, 11 advanced) reached this capacity at the Barcelona conference. Those participants who were unable to secure a place on their workshops of choice are assured that opportunities will be available at future EMWA conferences. At the AGM, Stephen de Looze, EMWA's Education Officer, announced that since the last AGM, 26 members completed the requirements for a foundation certificate during the 24th EMWA conference in Vienna, and a further 13 members during the 25th EMWA conference in Basel. Furthermore, there are now 8 advanced certificate holders (the advanced programme was launched at the 20th EMWA conference in Malta, 2005).

Presentation

Julia Forjanic Klapproth and Geoff Hall

If you weren't at the AGM this year, well, you should have been ...

The thought of attending an AGM is not usually considered to be the highlight of any conference meeting, but even more so when held in a location as enticing as Barcelona….

However, to use the proverbial 'there are always exceptions' and this AGM was one of them. The hour-long meeting was organised, informative, succinct and interactive.

Julia Forjanic Klapproth, our President, opened the meeting, welcoming attendees and introducing the panel of committee members. Refreshingly, the often-usual laborious style of reading and presenting lengthy reports, was substituted with a short presentation of key activities and main points from each of the EC members.

These reports were followed by an open forum for discussion and interaction. Questions from the floor ranged from the development of Internet-based workshop modules, the impact of meeting locations on cost for attendees (although all agreed our Spring meeting 2009 in Slovenia was an excellent choice!), maintaining commitment from pharmaceutical companies to allow employee attendance, and so on… For those less comfortable with expressing their views publicly, suggestions and comments offline were welcomed.

Julia thanked the EC for their commitment, time, and hard work; and applauded the excellent organisation and running of the meeting by Nancy Barkan and her team. Finally Julia reminded us all to consider election to the EC, because a number of positions on the EC would be up for election again next year. The meeting was then closed.

So next time, when the thought of another 10 minutes in bed or that sightseeing jaunt is more appealing, spend that hour with your fellow EMWA colleagues and friends instead, and join in and participate.

After all, without the rigours and efforts of the Committee, we wouldn't have an EMWA meeting to attend.

So, see you at the AGM next year?

Rosalie Rose
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Keynote lecture: Scholarly publishing in peripheral countries and scientific multilingualism[1]

Françoise Salager-Meyer, from the Multidisciplinary and Multilingual Research Group on Scientific Discourse Analysis at the University of the Andes, Merida, Venezuela, gave a fascinating lecture exploring the main problems faced by peripheral scientists writing in non-English languages, particularly those in developing countries. She gave a clear, well structured presentation of the key issues hindering these scientists from achieving the same status and recognition as scientists from developed countries. These issues include world power structures, the social organisation of peripheral countries, and the question of collaborative research. The discursive (i.e, language related) and non-discursive problems faced by peripheral researchers were nicely illuminated. Ultimately, she proposed that peripheral scientists should try to work together and develop communities that can promote and aid each other to become fully integrated members of the worldwide network of science and to promote scientific multilingualism. A worthy goal that we should all try to be a part of.

Note: For further reading on Françoise's topic see Salager-Meyer F. Scientific publishing in developing countries: Challengers for the future. *Journal of English for Academic Purposes* 2008 in press

Plenary lecture 1: Translation: An exciting job and a delicate art

Llorenç Serrahima started the plenary lecture series the first morning with an entertaining and thought provoking discussion from the translator's perspective on who a translator is and where the hurdles lie in the life of a translator. It is clear that there is a large cultural component to translating from one language to another, but often the difficulties stem quite simply from poorly written texts. His plea to keep the language concise and to avoid adjectival phrases is something that applies to all of us, whether writing or translating.

Plenary lecture 2: Evolution of the translator in the pharmaceutical environment

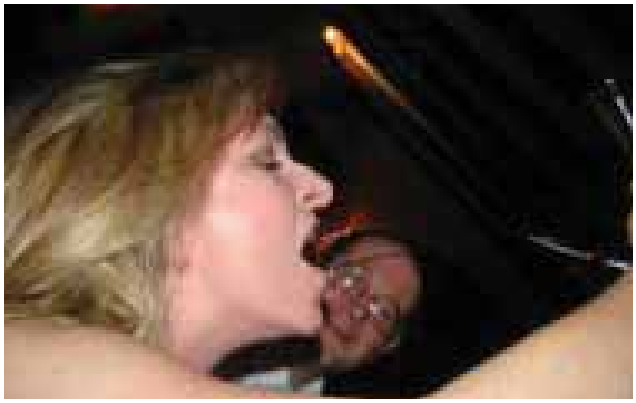
Catherine Bougette's plenary lecture on Friday morning looked at the development of translators within pharmaceutical companies. Beginning with the role of the translator before Microsoft dominated the work environment and moving up to today, this was an insightful tracing of how technology and globalization (with the spread of English as the daily language) has dramatically changed the need for translators in this industry. Coming from a time where everything used to be written on paper in a local language, which demanded the need for translation at many levels, we have moved into an environment where things are written directly into an electronic medium (which simplifies dissemination) and often directly in English (which saves the need to have it translated from the local language into English for regulatory or administrative purposes). Of course translators are still in demand, but the role they play within a pharmaceutical company has shrunk considerably.

1. The reports of the keynote and plenary lectures were written by Julia Forjanic Klapproth. There is no report on the Saturday plenary lecture because Julia was unable to attend it.

>>> What's news at EMWA?

Banquet

The conference banquet was held in the Can Travi Nou, a 'masia' outside Barcelona city centre. A masia is a typical farmhouse for the region from the 16th and 17th century. At that time animals were housed on the ground floor and the farmer and his family lived on the first floor, benefiting from the warmth coming up from the animals below. Traditional Catalan food was served at the banquet polished off with a fortified wine which is customarily drunk direct from a decanter with a thin spout. The idea is that you pour the liquor in a steady stream from the decanter directly into your mouth, head thrown back. A few brave guests had a go at this. Christine Cyrus, who won a free banquet ticket in the *TWS* carnival competition (see page 61) commented, "I was very delighted to be the winner and spent a very funny evening in the Can Travi Nou with delicious food and wine but fortunately I was careful with the perron."



Drinking from the perron

Banquet

Social events

After conference days filled with earnest learning this year's social events provided relaxation and a lot of fun. Wendy Kingdom declared that the Paella Challenge was the most fantastic social event ever. Under expert instruction participants first cooked paella in teams and then sat down at tables running the length of the room to enjoy the fruits of their labours. Other events were a walking tour, biking tour, and aquarium visit.

Cycle tour

Paella challenge

Lunchtime discussions

EMWA's tradition of setting aside one lunchtime during the conference for discussion was continued at the Barcelona conference. Participants interested in any of the topics listed can sign up for a table where this topic will be discussed. Each table has a discussion leader. There was some lively discussion in Barcelona as can be seen from the following reports. One table discussion, not included below, centred on ghostwriting. Journal watch on page 99 reports on the topic of this discussion and concludes with a mention of the exchanges at this table.

<u>Conference reporting</u>
<u>Discussion leaders: Geoff Hall and Lisa Chamberlain James</u>

Conference reporting, perhaps more than any other topic, lends itself to discussion very well. Anyone who has done this kind of work has a library of anecdotes and experiences, because no two projects are ever the same.

This conference's lunchtime discussion proved the point beautifully. Gathered around our table were people who had spent their whole careers reporting on conferences, side by side with people who had only covered one or two—and some who liked the idea but were a little daunted by the whole process.

We shared ideas and experiences on a range of topics, from 'how to handle a client with unreasonable demands' to 'how to infiltrate the Press Room and get them 'on side'. There was a very interesting debate about the advantages and dis-

advantages of specialising in one particular field or therapy area, compared with being a 'jack of all trades' and covering conferences on all areas…. the consensus being that each writer must decide what they are most comfortable with.

As usual, lunchtime was too short to cover everything, but even the most experienced present learnt a few tips and heard about situations they had never encountered before. Not least, the discussion highlighted the variety and challenges that this kind of writing can bring.

Lisa Chamberlain James
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Ethics in clinical trials
Discussion leader: Art Gertel

The round table discussions and networking at lunchtime during the EMWA Spring conferences are always a must, not to be missed. Funny enough, most of the people who joined the table to discuss ethics in clinical trials weren't aware of the round table debates. They didn't know they would be taking part in a hot topic discussion!

I was so thrilled to be there. For me, this was one of the conference highlights. Helen Baldwin started by bringing up themes like ghostwriting (pointing out EMWA and CONSORT guidelines), transparency in publishing trial results (and sites like http://clinicaltrials.gov/ and http://www.clinicaltrialresults.org/) and the role and responsibility of medical writers.

Art Gertel presented 'insider's facts' related to the medical journal editorials accusing Merck and Schering-Plough (and their medical writer co-conspirators) of withholding damaging data in journal publications on Vioxx and Vytorin studies. The Seroxtat court cases (US x UK) were also mentioned. Personal experiences were related of how journalists retain the power to present information in a biased manner, and how conflict-of-interest may enter into public perception.

Unfortunately, time was over and we had to break. I just hope the same subject will be covered in the next Spring conference—I'll be swift to guarantee my place at the table!

Andrea Palluch
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EMWA bookgroup
Discussion leaders: Alison McIntosh and Wendy Kingdom

For our first "EMWA reading group" we had suggested two quite different types of book, and each was given a dedicated lunch table.

The Surgeon of Crowthorne: A Tale of Murder, Madness and the Oxford English Dictionary by Simon Winchester.
Most of the people who joined the networking table had not read the book but did want to learn about it and hopefully go on to read it. Three of us had read and enjoyed it, all for very different reasons: one because of an interest in dictionaries, one because they had lived in Crowthorne and one because it sounded intriguing and different. We all felt that it was an interesting book dealing with both the illness of the man and also how dictionaries were first compiled without the aid of a computer. I took my copy of the book to the meeting and it is now wending around Europe as three people at the table exchanged addresses to receive it in turn. Happy reading!

The Constant Gardener by John Le Carré.
Some of the people who joined this table had read the book; others had seen the film. John Le Carré tells a good story and, despite the impression he gives that all pharmaceutical companies are corrupt, the book is an enjoyable read. The focus of our discussions was not on the story or the writing but on the issues it raised. In particular, we discussed the ethics of conducting clinical trials in third world countries where the people are poor and unlikely to afford the drugs once they are marketed and unable to give truly informed consent when they are desperate for treatment. We also discussed the bad publicity that the pharmaceutical industry typically gets and how easy it is for one rogue company to damage the reputation of all others. Le Carré, it was noted does, however, describe the pressures from the investors at the company in question. This prompted the discussion to move on to what leads to immoral or unethical scientific behaviour and how this contributes to the generally negative public view of science, and what can be done about it. Unsurprisingly, we didn't come up with solutions to any of these problems, but it was interesting and entertaining to share and hear the views of everyone to these difficult issues.

Most of the people on the table were happy for the book group to remain a feature of the networking lunches. If we can gain enough momentum it might become a social feature in its own right. Our next book will be *Lucky Man: A Memoir by Michael J. Fox* at the spring conference in 2009.

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TWS editorial meeting

Among the many exciting events—for me at least—at the Barcelona conference was *TWS*'s first editorial meeting. This provided some lively discussion and great suggestions for future articles and topics for the journal. One idea I was keen to promote was that more issues should be guest edited to offer variety to readers and an opportunity for EMWA members to become involved practically with the journal. Guest editors set the theme for their issue, solicit and process 4 or more articles around the theme, and write an editorial. I remain responsible for the rest of the issue content and also liaise on the cover with the guest editor. The September issue will be on the topic of time management guest edited by Alistair Reeves (see page 54 for a call for articles) and the March 2009 issue will feature regulatory writing guest edited by Sam Hamilton.

Editorial meeting will certainly be a regular event at future EMWA conferences and will be open to anyone who wishes to attend—no invitation or registration necessary.

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Congratulations to the three winners...

... of the photographic competition at EMWA's 26th Conference in Barcelona: Karin Knapp, Shinji Ichii and Art Gertel. Each winner will receive an Amazon gift voucher in the sum of 50 euros.

Winner of the most artistic section: **Karin Knapp**, Monheim am Rhein, Germany with the photo entitled '***Palau de la Generalitat***'

Winner of the spirit of EMWA section: **Shinji Ichii**, Tokyo, Japan with the photo entitled '***Conference banquet at the restaurant Can Travi Nou***'

Winner of the funniest photo section: **Art Gertel**, Flemington, USA with the photo entitled '***Punctuation or Anatomy? You Decide!***'

Announcement of the winner of the Carnival Competition

Congratulations to **Christine Cyrus** who won *TWS*'s carnival competition [2007, volume 16 (4) pages 179-80]. Christine received a free ticket to the banquet at EMWA's conference in Barcelona. Matching *TWS* authors to their pets proved a difficult task for contestants! The correct answers are given below:

1	ALEXANDER POPE	Ursula Schoenberg	**B**
2	BLUE	Richard Clark	**A**
3	BONO	Karen Shashok	**N**
4	CLOUD	Adam Jacobs	**I**
5	GASPAR	Barry Drees	**F**
6	GINGER AND SPORTY	Alison McIntosh	**G**
7	JACQUES	Nancy Milligan	**E**
8	MARLON	Diana Epstein	**C**
9	NUTTE	Kari Skinningsrud	**J**
10	BAGHIRA	Joeyn Flauaus	**O**
11	PIMMS	Elise Langdon-Neuner	**K**
12	PLATY	Sam Hamilton	**L**
13	SIR HENRY	Julia Forjanic Klapproth	**H**
14	NO PETS	Alistair Reeves	**M**
15	ZOE	Wendy Kingdom	**D**

Breast currency

I was recently checking an English translation by a French homeopath who believed he had discovered a natural solution for post-menopausal symptoms. As a woman in my mid-forties, I was interested in his product as I thought it could be useful a few years down the line. However I was rather put off by his statement that the product induced a reduction in "mammalian dollars"! I could only assume he was going to charge a fortune for his miracle cure, and that he was even thinking of selling it to extraterrestrials too (who would pay in alien dollars). However, I was reassured to read in the French version of his article that the product actually reduced "douleurs mammaires" – i.e. "breast pain". So maybe I can afford it after all!

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Improving the safety of translators and interpreters in war zones: The FIT ID Card

In the past few years, the translation and interpreting profession has unexpectedly proved to be life-threatening in conflict areas. Local translators and interpreters in Afghanistan and Iraq are seen as traitors that commando groups hunt down and execute. Translators and interpreters accompanying journalists, foreign business representatives, peacekeepers and alliance forces are often killed in kidnap situations because they are not considered 'valuable'; a high ransom cannot be extracted in exchange for their freedom, nor does their release generate 'added value' or 'goodwill' in the media. The 260-odd named translators and interpreters known to have lost their lives in Iraq and Afghanistan in 2006 alone is an illustration.

The Council of the International Federation of Translators (FIT) followed the situation in 2002–2005 with increasing alarm, and actively sought means for improving the safety of translators and interpreters, however slightly. The outcome was the FIT ID card, the international translators' card launched at the XVII FIT World Congress held in Tampere, Finland, in August 2005.

The FIT ID card is a personal card, complete with a photo of the cardholder, granted by FIT. Its purpose is to prove that the bearer is a professional translator, interpreter or terminologist belonging to a member association of FIT, regardless of where the person works. The card is granted for two years and costs US $25 (€20). The FIT ID card needs to be renewed every two years, for a nominal fee of US $10 (€8). A sponsorship scheme is being considered so that the cost of the FIT ID card would not be an obstacle preventing anyone who truly needs a card from obtaining one; some FIT member associations are willing to sponsor the costs of such cards. So far, in three short years, about 700 FIT ID cards have been sold.

The International Federation of Journalists (IFJ) has been contacted to explore cooperation modes and recognition for the FIT ID card. The IFJ is a natural cooperation partner, as in many situations—including work in dangerous areas and combat zones—representatives of the press cannot do their work without translators and interpreters. The IFJ is willing to recognise the FIT ID card, e.g. by adding a suitable mention of this to the FIT ID card. The details remain to be worked out. Recognition of this type is important because it would raise the level of local assistants, putting them on equal footing with other team members, such as media personnel. It would also enable translators and interpreters in danger to turn to member associations of the IFJ for assistance.

As with any new venture, the FIT ID card is still little known and has yet to find its proper niche in the professional community. More information about the FIT ID card is available on the FIT website at www.fit-ift.org.

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A Translator's account

The Translator: A Tribesman's Memoir of Darfur by Daoud Hari describes the dangers faced by translators in war zones. Daoud Hari, a tribesman with a gift for languages, worked in Darfur as a translator for six teams of Western journalists and for the UN genocide investigators. He accompanied Paul Salopek the National Geographic journalist who was kidnapped, beaten and almost died in Darfur in 2006. Hari himself took incredible risks and miraculously escaped death more than once. A reviewer on Amazon says "Readers would be making a grave mistake if they turned away from this powerful and unforgettable memoir. This book is more than a recounting of genocide. It is a fierce story of heroism and survival—it also a loving lament to a culture and people on the brink of extinction." As for how one culture can affect another Hari notes that as a consequence of the Iraq War, "Torture was the popular new thing because Guantanamo and Abu Ghraib were everywhere in the news at that time, and crazy men like this were now getting permission to be crazy."

See also http://www.timesonline.co.uk/tol/news/world/africa/article3822617.ece

The Sudanese army have killed an estimated 200,000 to 400,000 people and more than 2.5 million have been displaced by the conflict. But a UN report concludes that this is not genocide (http://edition.cnn.com/2005/WORLD/africa/01/31/sudan.report/).

The return of the native: A British perspective

by Joy Burrough

Keeping up with new usages

Borneo, 1972: that was where and when the implications of living outside mainstream English dawned on me. Back then, expats like me kept up our English by talking to each other in an English peppered with 'bazaar Malay', listening to the crackling BBC World Service and reading. My husband and I subscribed to the *Guardian Weekly*, and it was on its flimsy pages that I noticed that the word 'charismatic' had become a mode word to describe politicians. I looked it up in the dictionary, but the definition 'having a gift of God' didn't seem to make sense. 'The recency illusion' is what linguist Arnold Zwicky of Stanford University calls the false assumption that what you've noticed recently is indeed recent [1], but my discovery of the new connotation of 'charismatic' turns out not to have been an illusion: my *Shorter Oxford English Dictionary* notes that 'charismatic' acquired the meaning of 'having the gift of being able to influence people' in the mid-20th century. It's just that it took time for the new meaning to be used sufficiently frequently for me to notice it and add it to my vocabulary. If I had been living in an anglophone country, perhaps I would have absorbed the new meaning sooner.

Even today it is difficult to maintain 'English-native-speaker standards' when you're in an English-language backwater

From 1973—with the exception of three years in Australia, where I learnt to be a copyeditor—I was to spend the next three decades in the Netherlands, editing and translating for Dutch scientists. As a result of my experience with 'charismatic' I had put out linguistic antennae to identify apparently new (or, at least, new to me) English usages. Those that I noticed during my time in that English-language backwater included 'trades unions' and 'drugs dealers' (instead of 'trade unions' and drug dealers'—it's remained a mystery why banana republics didn't go bananas), 'there you go' (instead of 'here you are'), 'Hopefully,' (meaning 'it is to be hoped') and 'So,' being used to start sentences, and 'oversight' in the connotation of 'supervision'. Whether these are examples of recency illusions, I cannot say, but I do know that I have had to consciously incorporate them and other mainstream English changes into my speaking and writing. Other coinages ('at this point in time' and 'at the end of the day', for example) I noted but rejected, because I dislike verbosity: often they've proved to be transitory, so I feel vindicated.

Mother-tongue attrition

To keep up English-language expertise while you're living in an English-language backwater, not only do you have to monitor mainstream English, you also have to resist absorbing aspects of the language and writing culture of the non-anglophone country in which you live and work. The technical term for the erosion of competence in your native language is 'mother-tongue attrition'. Before the advent of cable TV and the Internet, it was difficult for backwater English-language professionals to avoid this attrition. Not surprisingly, therefore, after some years in the Netherlands I began to go Dutch linguistically. If you too use a second language daily while continuing to read, correct and edit the English of non-native speakers, you'll recognise the problem. Perhaps your authors are assertive, querying your textual changes and sometimes reinstating their idiolect, thereby undermining your confidence in your editorial judgement. No wonder that despite the easier access to colloquial and current English provided by the Internet and cable and satellite TV, even today it is difficult to maintain 'English-native-speaker standards' when you're in an English-language backwater. No wonder that it's tempting to bemoan the degeneration of the English language caused by seemingly uncontrollable spontaneous coinages and careless usage by native speakers, on the one hand, and the proliferation of non-native forms of English full of learner errors and mother-tongue transfers, on the other. No wonder that backwater editors become defensive editors.

Editors of texts are abnormal readers…We don't read these texts for pleasure, or for information, but to identify shortcomings.

In December 2005 we moved back to the UK: to a village in Oxfordshire that has featured in the TV detective series *Midsomer Murders*. My editing and translating for Dutch scientists and academics has continued. But, plunged back into mainstream English, I have had to readjust. Only now do I realise how much my backwater English experience had shaped my approach to editing and my competence in English. In the past 30 years I had regularly spent short periods in an anglophone country—usually the UK—returning to the Netherlands feeling that my English-language skills had improved, though without eliminating certain Dutchisms (turns of phrase, literal translations, the odd Dutch word) from my conversational English. But Dutch had become

more embedded in my subconscious than I realised; in my first year back in the UK I was often lost for words in English, and even now, I occasionally have to suppress Dutch and Dutchisms (especially when I'm tired). Meanwhile, though, my English has become more assured and I have lost the siege mentality I had in the Netherlands. I now realise that in the Netherlands I often felt beleaguered: a native speaker, bunkered down in alien territory in the midst of highly opinionated non-native speakers. I was linguistically on the defensive. Now, as a British native speaker of English, living in Britain, I'm more relaxed—not in the sense of having lower standards of acceptability, but more in terms of understanding my reaction to the non-native English I am confronted with in my work.

Editors as abnormal readers

I can best explain the shift in my perspective on editing Dutch-authored texts as a shift in my perspective on English—particularly, international English. Now I'm back in the UK, I am more aware that editors of texts are abnormal readers and that editors of non-native English texts are more abnormal still. We don't read these texts for pleasure, or for information, but to identify shortcomings. Give us a draft text and we will improve it! But the danger is we will become over-zealous, as I learnt at an editing workshop many years ago: I got carried away and used my red pen liberally on a manuscript (this tells you how long ago it was), only to discover that I had been amending an excerpt from a book by Somerset Maugham—a punctilious writer, trained as a medical doctor, who spent hours honing his prose. Nowadays his style seems old-fashioned, so I could argue that I was trying to make him sound more late twentieth century. But actually, I was trying to impose on him *my* ideas of readability and good style and I was doing so from my native-speaker bunker.

Language professionals… should be sympathetic to the non-native-driven trend towards a simpler, less idiomatic English.

But surely, when we edit non-native English authors, we have to assume that there will be much to amend? Not only are such authors likely to have a more limited vocabulary and less practice in writing in English than their native-speaking peers, they will also unintentionally make linguistic and stylistic transfers from their native tongue into English. Plenty for us to look for, correct, or improve. And yet…we shouldn't forget that not only are we editors abnormal in that we actively seek out things to improve in texts; we also tend to be conservative rather than trend-setting. We have Standards and we aspire to produce Proper English.

Accepting change and empowering authors

A recent (29 March 2008) article in *New Scientist* on 'English as she will be spoken' [2] has reminded me what we European English-language professionals—mainstream or backwater—are up against. Two main groups drive change in English: the native speakers and the people who speak English as a second language. As the latter hugely outnumber the former, we can expect them to affect English significantly—though probably not in our lifetime. (And in any case, many of the changes will be to speech rather than to the written word.) Meanwhile, English native speakers are also changing English. We language professionals need to keep abreast of the changes. Whether we adopt them straightaway is another matter: having read an article about how 'into' is ousting 'in' in idiomatic British English, I have not been surprised by the in-train announcements of 'We are arriving into Reading'. I would not accept that usage in a science article—at least, not yet. But even conservative editors must go with the flow eventually, which is why, after years of resistance, I no longer correct 'data is', though I myself would still always write 'data are'. Living and working in an anglophone environment has made me more comfortable about letting the current of English sweep me along: on mainland Europe I think I tended to overestimate the significance of accepting new usage, because I was afraid that by so doing, I'd lose my integrity as a native speaker of English. From the—admittedly limited—contact I've had with other language professionals in the UK, I know that my decades of living and working in a non-anglophone country have both enriched and eroded my knowledge of English. I think I now have the best of both worlds: I am surrounded by people who write and speak current English unselfconsciously, but I can draw on my experience in the Netherlands to empathise with Dutch scientists who must consciously try to write current English.

It seems to me that language professionals should be sympathetic to the non-native-driven trend towards a simpler, less idiomatic English, as this surely chimes with our desire to allow our authors to communicate effectively in the global arena. Given this desire, we still have to remove linguistic impediments to successful communication (the confusing influences from the non-English mother tongue). However, we could more often refrain from 'correcting' unambiguous, non-standard English or English that is not in the expected register; instead, we could empower the author to make the final decision, by explaining our 'native speaker' reaction to the original and suggesting an alternative. Instead of being language police, we would become language consultants. The backwater would not be cut off from the mainstream.

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The return of the native: An American perspective

By Kathryn Nelson Emily

Not-so-standard English

Like Joy, I am a native speaker of English who returned home after spending 30 years in a non-anglophone country. I had spent most of my career in Vienna, Austria, writing, editing, and translating for German-speaking scientists, and returned to take a job at Mayo Clinic in Jacksonville, Florida (one of two offshoots of the famed original Mayo Clinic in Rochester, Minnesota). For me, 'returning home' was a relative concept. I was indeed returning to my home country, but after growing up amidst the Scandinavian-American traditions of the American Midwest and then spending 30 years in Central Europe, moving to the American Southeast was like going to a third, quite different country. Jacksonville, which calls itself the city 'where Florida begins,' is a city in transition. Linguistically and otherwise, it's a hodgepodge of cultures transposed onto a deeply traditional southern city. The growth of its economy, the presence of a large Navy port, and the influx of escapees from the harsh winters of the northern and midwestern states have made Jacksonville a fascinating mix of American subcultures and accents. Not only does it represent a microcosm of America, but it also has become an international melting pot. According to the 2000 United States Census, 72 different languages are spoken in metropolitan Jacksonville, and more recent data show that children representing 125 countries of origin and 88 languages are enrolled in the public school system's English for Speakers of Other Languages program [1]. Working at Mayo Clinic Jacksonville with doctors from all over the world, I was right in the middle of the language mix.

> ***Sometimes non-native English authors pay more attention to the mechanics of writing…***

At first I was so happy to hear English spoken at all that I didn't pay attention to the differences in accents and dialects that surrounded me. But then I began to appreciate the many varieties of English I heard. Most prominent in everyday life, of course, was the colorful and creative language of the American South. At home, I asked one of my new neighbors how he was. He answered, "Ahm jes' fine—fine as frog's hair split four ways. If things get any bettah, Ah may have to har [hire] someone to help me enjoy it." That summer there was a drought and everyone was hoping for rain. "It's so dry, the trees are bribin' the dogs," they said. Coming home from my first day of work, I told another neighbor how relieved I was that things had gone well. "That's good," she replied. "This mornin' you looked as nervous as a long-tailed cat in a roomfull of rockin' chairs."

'Native' and 'non-native' editing

At work, my services as a manuscript editor were available to the staff of approximately 300 physicians at Mayo Clinic Jacksonville. This service was part of Mayo's Section of Scientific Publications, probably the world's oldest academic editorial department [2]. The Mayo brothers, whose ground-breaking development of the concept of a private group practice resulted in the well-known Mayo Clinic in Rochester, Minnesota, realized early on the importance of well-written scientific communications. In 1907, they hired Maud Mellish-Wilson to organize and develop a library, and to do editorial work in connection with the preparation of scientific publications [3]. Today, a number of large medical research facilities in the United States maintain editorial departments to ensure the high quality of publications that are the source of their reputations [2].

Since returning to the United States, I have worked with both native- and non-native English speaking authors, first at Mayo and now as a freelance editor. Initially, I assumed it would be much easier and faster to edit manuscripts by native-English authors. I was wrong. Both native and non-native English authors can have trouble choosing the appropriate words and organizing their thoughts. Both often leap from one idea to another without providing an adequate transition. Both often leave out important details because they assume readers will be versed in the field and will know what is meant. Native-English authors may be more knowledgeable about the language, but they can also be more careless; sometimes non-native English authors pay more attention to the mechanics of writing, simply because they are aware of their own inadequacies.

> ***Global communication would profit if we could help native-English authors become more understandable to non-native English readers…***

Internet and SMS influences

I know that many of the native-English authors' mistakes result from the fact that they are busy clinicians who don't have the time or the peace and quiet necessary for good writing. But I do find myself worrying about what seems to

be a growing lack of concern for traditional standards of written English. The need for speed and efficiency in communication caused by the rise of the Internet (chat rooms, email, and instant messaging) and Short Message Service [SMS] technologies (text messaging via cell phone) are causing dramatic changes in language [4].

Text messaging has produced a new form of English adapted to the need for immediacy and terseness. Text messages rarely use punctuation and vowels are often eliminated (as in 'JstCllMe' for 'Just call me!'). Words or parts of words are replaced with symbols, numbers, or letters that create the same sound (See you later = CUL8R). Abbreviations are also used (for example, 'IMNSHO' for 'in my not so humble opinion'). Teenagers seem to learn the rules easily, but they are complex enough that many parents were grateful when one cell phone service provider posted a tutorial for parents on its website [5]. So far, the only incursion of this type of cryptic language into a scientific manuscript that I have noticed was @ for 'at,' but I am wondering if it will be only a matter of time before I see more.

English conforming to American and British standards still brings prestige…

We must maintain a delicate balance between respecting the author's voice and imposing our own ideas of readability and style.

A world of many 'Englishes'

As Joy points out, changes in English are driven not only by native speakers, but perhaps even more by non-native speakers. David Crystal estimates that there may be as many as two billion English speakers today [6]. It is fascinating to contemplate the concept that there are now many 'Englishes' [7] with varying degrees of evolution of their own standards. The idea that 'proper' English is the sole provenance of native speakers (the so-called 'inner circle') and that everyone else must strive to emulate them seems no longer to be valid. We appear to be headed toward a 'a tri-English world, one in which you could speak a local English-based dialect at home, a national variety at work or school, and [a simplified] international Standard English to talk to foreigners…'[8].

Respecting and teaching

On the one hand, I agree that editors need to be sympathetic to the changes brought about by this trend when they lead toward a simpler, less idiomatic English. Indeed, global communication would profit if we could help native-English authors become more understandable to non-native English readers, for example by avoiding esoteric vocabulary, idiosyncratic forms and structures, and cultural references that are not universal [9]. Quicker acceptance of new word forms, phrases, and structures entering the body of global English may help rather than hinder our efforts to increase comprehension.

On the other hand, we should remember that we are also teachers. Even if other forms of English are perfectly valid, English conforming to American and British standards still brings prestige, and learning to conform to those standards can open career doors for our authors [10]. How will they learn if we accept non-standard forms without instructing them? Thus, we must maintain a delicate balance between respecting the author's voice and imposing our own ideas of readability and style. I agree with Joy that the key to success lies in our ability to explain the differences and thus empower the author to make the final decision.

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EMWA member receives Serbia's highest award

Congratulations to Sofija Micic, an EMWA EPDC member and *TWS* author[1] from Belgrade, Serbia, who received The City of Belgrade Award on 18 April 2008. The award is made for the highest achievements in 7 areas including art, science, medicine and education. Sofija, who has a doctorate in linguistics, received the award in the area of education for a medical dictionary (English-Serbian/Serbian-English) that she compiled. Serbia's new democratic regime introduced the award—the most prestigious in the country—6 years ago.

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Adverse events: More than a mild headache for the regulatory writer

by Linda Donnini

A large clinical study can produce an overwhelming volume of adverse event (AE) data. Picking out the important findings can be a difficult task for the medical writer—most of us are not medically qualified and resort to medical dictionaries to tell dysgeusia from dysphonia, or cholesterolaemia from cholelithiasis. International Conference on Harmonisation (ICH) topic E3 [1] gives guidance on presenting AEs in a clinical study report but is mainly concerned with the summary tables attached at the end of the report. What to include within the body of the report is left largely to the discretion of the writer and reviewers. As for the discussion section, the ICH guidance—to not simply repeat the description of results—is often ignored if the writer is not sure what else to say about the data. Some points to consider in deciding what to present, and how to interpret it, can make the writing process much easier.

Common adverse events

The only in-text AE table stipulated in ICH E3 for a clinical study report is a summary of common AEs. So how do you define common? ICH suggests including AEs occurring in at least 1% of treated subjects but this frequency cut-off point is arbitrary and may not be appropriate for the size of your study population. If N≤100, then one subject equals ≥1% and your table would include every AE rather than only the most common. Use your judgement to choose a cut-off that allows you to include all important information without compromising readability.

If your table includes an 'overall' column for all groups combined, make sure you apply the cut-off to each treatment group—or to the group that received study treatment rather than placebo. If you apply it only to the overall column, you may miss AEs which are frequent in the treated group but absent in the control group (such as headache in Table 1). It is important that the cut-off, and how it was applied, are clearly identified in the table title or footnote.

Table 1: Common adverse events reported in at least 10% of subjects in either treatment group

	Placebo (N=50) n (%)	Study treatment (N=50) n (%)	Overall (N=100) n (%)
Rhinitis	4 (8%)	6 (12%)	10 (10%)
Headache	0	9 (18%)	9 (9%)

Applying the 10% cut-off only to the overall column would exclude headache.

The investigator's description of each AE, as entered on the case report form, will have been coded using a standard dictionary so that similar events can be counted together. Currently the most commonly used dictionary is the Medical Dictionary for Regulatory Activities (MedDRA); each event is given an appropriate description—the preferred term—and is grouped according to the body system or organ it affected—the system organ class. Some writers include system organ class in their common AE table while others prefer to present AEs by system organ class in a separate in-text table.

Looking at AEs by system organ class can help to reveal patterns in the data; for example, the majority of AEs may be nervous system disorders. This could be due to a particularly high incidence of headache or it could reflect a range of less common AEs that all affect the nervous system. It is important to remember that the MedDRA dictionary contains such a large number of preferred terms that the same symptoms can be coded differently depending on how the investigator described them (e.g., somnolence, sleepiness and drowsiness); the frequency of the symptoms is thereby diluted, making it less likely that they appear as common AEs. On the other hand, a system organ class will not necessarily contain all like events; in MedDRA, the preferred term 'liver function test abnormal' falls under the system organ class of investigations whereas 'liver function abnormal' is in the system organ class of hepatobiliary disorders. It is important to review the types of AEs with a critical eye and not just focus on their numbers.

Treatment group differences

Most medical writers are comfortable with summarising the most common AEs in each treatment group but they often omit what is the most important step for controlled studies—checking for differences between the treatment groups. A consistent difference across studies between the study treatment and control groups forms persuasive evidence that an AE may be treatment-related. The problem for the writer lies in deciding what constitutes a difference as there are no set rules. One solution is to set your own criteria, and summarise in the text all AEs that meet these criteria. For example, if the incidence of an AE in the treated group is at least twice that in the control group, or at least 5% higher, this may be reported as a difference. This presents difficulties at low frequencies, however; 4% could be said to be similar to 2%, or twice as high. In this case, you could seek medical opinion as to whether the AE is clinically relevant in this subject population and so worthy of

comment in the report—a small increase in AEs of headache may be unimportant whereas an increase in pneumonia AEs may be a cause for concern. Whatever criteria you choose, make sure you are consistent in applying them not only to common AEs but also to other categories such as serious AEs (SAEs) or AEs leading to withdrawal. Too often, writers will be inconsistent, making a general statement that the incidence of each common AE is similar between the treatment groups, and then later drawing attention to a minor difference in the incidence of AEs leading to withdrawal.

The writer's job is made easier if statistical analyses have been performed to compare AE rates between the treatment groups. However, if comparisons have been conducted for each preferred term, bear in mind that you should expect some statistically significant differences simply because of the large number of tests.

Number of subjects or number of events

AEs are usually summarised by the number and percentage of subjects who have reported an event at least once. In this way, subjects are counted only once even if they had the same event multiple times. Sometimes the number of events is also summarised; this will show if subjects are repeatedly experiencing the same symptom and is useful in a long duration study or for events that are episodic, such as vomiting or diarrhoea. If the information is available, check for obvious differences between the treatment groups; a subject who experiences a single bout of diarrhoea after receiving study treatment may not be noteworthy whereas a subject who experiences repeated episodes of diarrhoea could indicate a safety concern.

Make clear whether you are talking about the number of subjects or number of events.

Make it very clear whether you are talking about the number of subjects or number of events; this is an area that often causes confusion.

Treatment-related adverse events

The ICH definition of an AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and *which does not necessarily have a causal relationship with this treatment*. Yet the purpose of collecting AE data is to identify any signs or symptoms potentially caused or worsened by the study treatment. You may, therefore, conclude that the presentation of treatment-related AEs is the most important safety aspect of a clinical study report; in reality, it is important to be aware of the limitations of causality data.

Causality can be very difficult for the investigator to assess based only on the information available at the time, such as knowledge of the subject's health, the temporal relationship of the event to when the treatment was administered and also on which AEs are expected according to the Investigator's Brochure. The investigator will not know which treatment the subject has received if the data are blinded. Their judgement is a best estimate and so medical writers often use wording such as 'the event was considered to be treatment-related' to reflect that this is just an opinion. Consequently, do not assume that an AE can be discounted if it is considered to be unrelated to the study treatment.

Compare the common treatment-related AEs with the common AEs you identified as being more frequent in the treated group than in the control group—are they the same? Also check how many events have a missing causality assessment—these are sometimes counted as treatment-related AEs when actually the investigator has not expressed an opinion.

Causality data help the sponsor to identify the safety profile of their treatment as it develops. By the time the data are submitted as part of an application for marketing approval, the reviewer may place less importance on the investigator's assessment of causality because knowledge will have moved on. The role of subject narratives, which are written for each SAE and other significant AEs, is to provide enough background and follow-up information so that the reader can reach their own opinion as to whether the AE was treatment-related.

Severe and serious adverse events

Not all AEs are a cause for concern; even healthy volunteers receiving placebo will report AEs. The most important AEs are those which indicate poor tolerability or a detrimental effect on health. The usual criteria that are applied are intensity and seriousness.

Intensity—mild, moderate or severe—is a subjective assessment based on the degree of discomfort or limitation experienced by the subject as a result of the AE. Seriousness, on the other hand, is based on well-defined criteria relating to the threat that the event poses to the subject's life or functioning. An AE is serious if it results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, consists of a congenital anomaly or birth defect, or is otherwise considered medically significant by the investigator. A severe event may not be serious (e.g., severe headache) and a serious event may not be severe (e.g., a mild myocardial infarction that results in admission to hospital).

A summary of the most common severe AEs can be obtained by applying a cut-off frequency to the incidence of severe events for each preferred term. All SAEs, particularly fatal SAEs, should be considered important, regardless of how common they are. Detailed information about SAEs will be included in subject narratives so a summary can be sufficient in the body of the report. ICH E3 allows for SAEs that were clearly unrelated to the study treatment to be omitted or described very briefly; this may apply if there are many SAEs due to disease progression, for example in a subject population with advanced cancer.

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>>> Adverse events: More than a mild headache for the regulatory writer

Adverse events leading to withdrawal

Severe or serious symptoms may cause an investigator to withdraw a subject from treatment but mild symptoms may be enough to make a subject withdraw consent. The side effects that a subject is prepared to tolerate often depend on the amount of benefit they feel they gain from the treatment. A treatment can only be effective if subjects take it as prescribed; large numbers of withdrawals in the study treatment group could spell the end of the product's development. An imbalanced withdrawal rate between a treated and control treatment group could also affect the integrity of the study; withdrawals are rarely random—often the sickest subjects are more likely to withdraw—and so the groups will no longer be comparable.

Look out for discrepancies between the percentage of subjects whose primary reason for withdrawal was an AE and the percentage of subjects who had AEs that led to withdrawal. These numbers do not always match. For example, a subject may not be willing to tolerate the rash they have developed and they tell the investigator they no longer want to continue in the study. On the AE case report form, the investigator may tick that the AE led to withdrawal. However, on the separate case report form documenting reason for withdrawal, the investigator may tick the primary reason as withdrawn consent. Subjects lost to follow-up may also have had AEs that were part of their decision to drop out of the study. The medical writer should explain in the report the reasons for any discrepancies between the two tables, if possible.

Also remember to discuss any subjects with an AE that led to a dose reduction or temporary discontinuation of treatment, if this was permitted in the protocol. An AE that resolves after dose reduction, but then recurs if the dose is escalated again, could be treatment-related.

What to write in the discussion

Identify the unexpected

While the discussion has to contain some of the data already presented in the body of the clinical study report, try not to simply restate the results. ICH guidance recommends highlighting 'any new or unexpected findings' so first you have to determine what AEs were expected.

Were the common AEs in your study expected in that subject population? Healthy volunteers confined to the ward of a research unit for days often report headaches and fatigue, and nasopharyngitis can quickly spread within the group. Patients, on the other hand, can be expected to have symptoms that reflect their underlying disease; even though their illness was present at baseline, symptoms that worsen or change during the course of the study will be included as AEs. Events that would be uncommon in your subject population are more likely candidates for an effect of the study treatment.

If your study is controlled and you identified any AEs that were more frequent in the study treatment group than the control group, consider whether these AEs were expected. Were they identified in the Investigator's Brochure or the protocol as possible effects of the study treatment? Was a similar treatment difference seen in previous studies? Equally importantly, did the Investigator's Brochure highlight any safety concerns that you did not observe in your study?

You are not expected to provide an expert medical opinion; get input from the medic or the safety specialist who reviews your clinical study report. Don't be afraid to suggest discussion points in your draft report, or draw attention to any AEs you think may be worthy of note. They can always ask you to amend the text but, more often than not, they will appreciate your input. They are medical experts rather than writing experts and may not be familiar with ICH requirements.

The effect of study design

If your study did not have a control group, you may wish to compare the AE rates in your study with previous studies. Here, the effect of study design can be particularly important.

Not all studies employ the same methods for collecting AE data. Most commonly, subjects are asked an open question such as 'How are you feeling?' This puts the onus on the subject to recall any signs and symptoms, and to decide whether to mention them. Other studies prompt subjects about specific symptoms using scripted questionnaires, or diaries that subjects complete at home. Not surprisingly, the prompted collection methods generally lead to a higher rate of AE reporting. Study duration affects the incidence of AEs; most subjects will experience AEs if you monitor them for long enough. Frequent study visits give subjects more opportunity to report symptoms and less time between visits to forget them. Geographical location should also be considered; some cultures are less likely to report AEs and so the AE frequency may appear lower than in studies conducted in other countries.

Signs and symptoms observed by the investigator can be recorded as AEs, including abnormal readings for vital signs, laboratory parameters or other safety assessments that the investigator considers to be clinically relevant. The higher the number of safety assessments performed, the greater the likelihood of abnormal results being detected and reported as AEs.

A poor report may come back to haunt you

Remember that, ultimately, your clinical study report and the AE data it contains may be compiled into a Marketing Authorisation Application—and that task may fall to you. So make your future work easier by using consistent styles of data presentation across clinical study reports for the same study treatment, and by making the important findings clear. One day you may be thankful you made the effort.

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Reference:
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Clinical trial disclosure—focusing on results

By Kathy B. Thomas and Claudia Tesch

Introduction

Clinical trial disclosure has reached a peak of activities over the last year and more promises to come during the next year. The activities around this topic deal with the prospective *registration* of *new* clinical studies and the retrospective disclosure of *results* for *completed* studies.

The original purpose of *clinical trial disclosure*, some 10 years ago, was to register clinical trials with serious and life-threatening diseases and conditions in a public domain (Internet) so as to provide an opportunity for patients and their physicians to locate a clinical study with new treatment options for their condition (FDAMA Section 113 of 1997) [1]. The original purpose was expanded in 2004 by the International Committee of Medical Journal Editors (ICMJE), who in an effort to curb the 'positive results publication bias', announced an unprecedented editorial publication policy that made public registration of clinical studies (not just those with serious and life-threatening diseases and conditions) at or before the start of patient enrolment a prerequisite for future publication of results in a growing number of peer-reviewed journals. The ICMJE policy became effective in September 2005 [2-4]. Additional impetus to *clinical trial disclosure* came from the pharmaceutical and medical trade associations [5], the general public and professional media [6-9], healthcare professionals, legislators worldwide, and healthcare consumers [10]. The latest activity occurred in September 2007, when the US congress updated the previous federal law dealing with *clinical trial disclosure* [1] and enacted a new law (Food and Drug Administration Amendments Act of 2007—FDAAA 801), which mandates the registration of *new* clinical studies and disclosure of results for *completed* studies [11].

In our contribution on *clinical trial disclosure* to *TWS* in June 2007, we covered the following topics: ·Background and chronological development, ·Stakeholders—their claims and recommendations, ·Implications of registry databases for *new* clinical studies, and ·Implications of results databases for disclosure of *completed* clinical studies [12]. Here, we summarise selected points of interest and milestones of the last 12 months and indicate some of the announced future directions of *clinical trial disclosure*. The focus here will be on *clinical trial disclosure* with regard to the newly enacted federal law FDAAA 801. We also indicate developments on this topic in other countries, although a complete overview of the international situation is not possible at this stage, as many countries are still in the process of either establishing a national registry or investigating processes to align with other established registries. During this evolving phase, those who require information on national requirements regarding *clinical trial disclosure* need to seek instructions and guidance with the appropriate national health and regulatory authorities.

Prospective registration of new clinical studies

In the last 12 months, the registration of *new* clinical studies has been generally accepted and implemented by the pharmaceutical industry, universities, government affiliations, and other organisations involved in studies with human subjects. This can be deduced from the steady number of new user accounts and records for *new* clinical studies in the various clinical study registers [10], the largest of which are ClinicalTrials.gov (run by the National Library of Medicine of the US NIH; www.clinicaltrials.gov) and the ISRCTN (International Standard Randomised Controlled Trial Number) Register (administered by Current Controlled Trials Ltd; http://isrctn.org/) [8,13,14]. The registers provide a unique study identifier, which may be required as proof of study registration in a public domain for ethics committees, regulatory authorities, conference presentations, manuscript submissions to peer-reviewed journals, or when applying for research grants.

Ideally, new study information should only be entered into *one* register to avoid duplication and potential confusion. However, this is not always feasible because in some countries the national law or guidelines require national registration of clinical studies, often in the national language (e.g. Japan, Taiwan). Consequently, companies that perform international clinical studies will likely be obliged to register the study in the respective national clinical study register and additionally in an international register. The WHO International Clinical Trials Registry Platform (ICTRP) provides a search portal to locate trials from many primary registries worldwide (http://www.who.int/ictrp/en/). A similar service for ongoing and completed studies is available through the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (http://www.ifpma.org/clinicaltrials).

FDA Amendments Act (FDAAA 801)

On 27 September 2007, the US Congress passed and enacted a federal law dealing with *clinical trial disclosure*—

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>>> Clinical trial disclosure—focusing on results

'FDAAA 801'[11]. The new law expands on the previous law (FDAMA Law, Section 113, 1997) [1] and covers topics of prospective registration of *new* clinical studies as well as retrospective results disclosure for *completed* studies.

The new law FDAAA 801:

- mandates prospective registration on ClinicalTrials.gov of *all new* controlled clinical investigations (other than Phase I) of drugs, biologics, and devices subject to regulations by the FDA;
- applies to research for *any* condition, regardless of sponsor type (industry, government, or academic) or location of conduct—if the products concerned need approval by the FDA;
- expands on the required mandatory information fields, being consistent with those of the ICMJE and the WHO [3,15];
- requires that *results* of *completed* clinical studies for FDA-approved or cleared medical drugs and devices be electronically available in a public register (linked to a registry entry as well as to any Medline citations of published results);
- specifies enforcement measures for non-compliance;
- is effective for *new* or *ongoing* studies from December 2007 (90 days after enactment) and for *completed* studies of approved medical products and devices from September 2008 (12 months after enactment).

Registry of new studies

Under the new law, the responsibility to register a *new* study lies with the sponsor or the principal investigator designated to conduct the study and having sufficient data rights. New clinical study must be registered within 21 days after the first patient is enrolled, updates of the registry information must occur at least every 12 months, and recruitment status should be updated within 30 days of any change. December 2007 was the due date to start registering *new* studies or updating all required information fields for *ongoing studies*.

After submitting information for drugs, biologics, and *approved* or *cleared* medical devices to the administrator (of ClinicalTrials.gov), the entries are usually publicly available (posted) on the Internet within 30 days. It is noteworthy, that unlike with therapeutic drugs and biologics, in the case of *new* clinical studies with medical devices *not* previously *cleared or approved* by the FDA, information submitted will be posted on the Internet only *after approval/clearance* by the FDA.

The basic elements for *registry* of *new* studies include:

- descriptive information (title, study design, primary/secondary outcome measures);
- recruitment information (eligibility, recruitment status);
- location and contact information (site-specific);
- administrative information (protocol number, IND/IDE, ethics committee vote).

Not all of the requested information is visible to the public (e.g. a copy of at least one ethics committee approval must be provided but the details are not made public). The entries may be updated; version control is in place. The linguistic style of entries should be checked with communication experts to assure that there is no risk of patients or the lay public being misled.

Results disclosure of completed studies

The new law requires that results of *completed* clinical studies for FDA-approved or cleared medical products be electronically linked to the registry entry in the NIH register (www.clinicaltrials.gov) as well as to any Medline citations of published results. Results disclosure in other databases is not accepted (e.g. databases supported by the pharmaceutical industry or professional associations such the Pharmaceutical Research and Manufacturers of America, PhRMA). In addition, certain agreements between the sponsor and non-employees, such as restrictions on the principal investigator to discuss or publish results after study completion, need to be declared.

The basic elements for *results* of completed studies include:

- demographic and baseline characteristics;
- number of dropouts (flow-chart);
- primary and secondary outcomes;
- point of contact;
- certain agreements (between the sponsor and the principal investigator).

Two models have been proposed for the presentation of the results: a structured narrative style and a tabular form, the tabular form being favoured. Results tables should be similar to those given in research articles; data can be edited or changed as necessary (with public tracking of changes). The challenge now is to determine the technical aspects for data entry that would suit all study types. The deadline for results disclosure is 12 months after study completion; the definition for study completion being '*last patient, last visit*'. Delayed disclosure of results (up to two years) is possible in exceptional cases, e.g. when national security interests are affected or if the sponsor can show that initial approval or a new indication or use for the drug or device is currently being sought. The due date to start posting results for *completed* studies for FDA-approved drugs or devices is 27 September 2008.

Enforcement measures for non-compliance

The new law specifies enforcement measures for non-compliance. Those who fail to comply will be fined $10,000 for each infringement with no upper limit and in addition will be named in the non-compliance list posted on the ClinicalTrials.gov Internet site.

Future action points

The new law specifies further action points proposed to come into effect in March 2009. In addition to study registration and/or results disclosure, the sponsor will be required to collect and provide information on adverse

events of tested drugs and devices. This should include a table with *serious adverse events* (by system organ class, number and frequency, and study group) and a table with *frequent adverse events* (non-serious anticipated and unanticipated events occurring in >5% of patients within any study groups, by system organ class, number and frequency, and study group).

ICMJE

Registry of new studies

The ICMJE's position on the prospective registration of *new* clinical studies has remained unchanged since their last editorial in June 2007 [4]. The ICMJE, joined by other journal editors [16], require that in order to qualify for future publication "*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*" be registered in a non-profit register *before* enrolment of the first study subject. This requirement includes preliminary studies, e.g. Phase I, whereas purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration to qualify for future publication. However, registration of observational studies is required in some countries by national industry associations (e.g. Germany [17]). The latest ICMJE policy comes into effect for studies that start enrolment on or after 1 July 2008; studies that began before that date must be registered prior to editorial review [4]. This policy is being adopted by a growing number of journals, many of which are included in the list available on the ICMJE homepage http://www.ICMJE.org or by checking the 'Instruction for authors' in the journal of interest (http://mulford.meduohio.edu/instr/).

Results disclosure of completed studies

The international and legislative pressure to disclose results of completed studies in a timely manner has led to a potential conflict of interest regarding publication of clinical studies in peer-reviewed journals. The question has been raised as to whether editors would still want to publish previously disclosed data. For the present, the ICMJE has stated that results posted in the same clinical trials register in which the initial registration resides will *not* be considered as prior publication (prepublication) provided the results were only presented in the form of a brief (less than 500 words) structured abstract or table [4], and further solutions are being sought [18]. The next meeting of the ICMJE is planned for middle of June 2008 and the main topic of discussion is likely to be the alignment of the ICMJE requirements with the new US federal law on *clinical trial disclosure*—with focus on the study results disclosure and the various national requirements. An editorial on this meeting is eagerly awaited by all affected.

The WHO—international requirements—other than those included in the FDAAA law

The WHO proposals regarding *clinical trial disclosure* go even beyond the new US FDAAA 801 law. The WHO calls for *all* interventional studies (including early-phase studies such as Phase I) to be registered and information on results made public. Furthermore, the WHO promotes information on *new* clinical studies to be registered in national primary registers, thereby facing the dilemma of the language used for communication and reporting. The information is avail-

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Watch out for fake hamsters and eggs

A news items on the BBC reported that pet hamsters are banned in Vietnam. Their popularity as pets had been soaring partly due to 2008 being the Chinese Year of the Rat. The Ministry of Agriculture sees these imports from China and Thailand as a disease risk. The report goes on to say "The animals are just one of many imports that escape adequate scrutiny or epidemiological control in Vietnam. A recent survey alarmingly showed that most anti-malaria drugs—in Vietnam and other countries of the region—were fakes traced back to China". Does this mean there is a danger that the hamsters might be fakes too? This is not such a stupid question because the report further states "And reports abound of other counterfeit or dangerous items sold for human consumption—including rather startling internet rumours of a trade in fake chicken's eggs."

http://news.bbc.co.uk/2/hi/asia-pacific/7283299.stm

Indentify your punctuation mark and vocabulary improvement

A blog where you can do the sort of 'tests' typical for teeny and women's magazines, e.g. 'Is he more than a friend?' is the sort of nonsense that is of no interest to us level-headed medical writers. But there is a blog that offers one test medical writers should ignore at their peril. What's more the answer and explanation I got on trying the test was remarkably accurate. Try for yourself at http://www.blogthings.com/whatpunctuationmarkareyouquiz

For something more addictive you can test your vocabulary for a good cause. The site owners state that they donate 20 grains of rice to the UN World Food Program every time you answer correctly. For 'Free Rice' go to http://www.freerice.com/index.php

Elise Langdon-Neuner
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>>> Clinical trial disclosure—focusing on results

able through the WHO's International Clinical Trial Registry Platforms Search Portal (http://www.who.int/trialsearch) [15,19,20].

The WHO has just announced their first round of consultation processes aimed to promote reporting of clinical study results. A discussion paper on the topic has just been published in the WHO bulletin. Those interested in contributing to the discussion survey can do so, by 27 June 2008, at http://www.who.int/ictrp/results/en/.

Current requirements—worldwide

Currently, registration of *new* clinical studies is mandatory in the following countries: Argentina, Croatia, Israel, Italy, South Africa, Taiwan, and the USA. National guidance on voluntary registration exists in Australia, China, Germany, India, Japan, the Netherlands, New Zealand, Spain, and the United Kingdom. Proposed national laws are being discussed in several countries, including France. For other countries, no relevant reliable information was available to us at the time of writing.

With regard to results disclosure for completed studies, except for the USA (FDAAA 801), no other country in the world has a clear law mandating this aspect of *clinical trial disclosure*. Nevertheless, even within the United States, state law may take precedence over federal law as is the case in Maine—at least until the FDAAA 801 law is fully implemented in 2010 [12,21].

Final comments

The global situation with regard to *clinical trial disclosure* is changing and developing at a fast pace. This is sometimes at the expense of clarity and coordinated efforts of the stakeholders. The next 12 months will be the testing ground for results disclosure of completed clinical studies performed with approved products. Stakeholders such as the ICMJE, EMEA, WHO, and professional industry associations will have to align to reach an effective and agreeable solution. For those actively involved in preparing and disseminating medical and scientific information, as medical writers, this is an opportunity to make professional contributions to this cause.

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Affiliations/Competing interests

Kathy B. Thomas is an independent medical and scientific writer working on various projects from her office in Meersburg on Lake Constance, Germany. Claudia Tesch is an employee of Nycomed Deutschland GmbH, located in Konstanz, Germany. Both are well versed in coordinating entries for registers (new clinical trials and results of completed trials) applicable to *clinical trial disclosure*. Both have presented the topic and actively participate in professional international working groups dealing with this topic.

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The world of medical devices—serving two masters

by Art Gertel and Nancy J Stark

Many of us who have worked in the Medical Writing profession and have been associated with the Pharmaceutical Industry, cut our teeth in the world of DRUGS.

The research, development, and registration of other medical interventions, such as vaccines and devices, were always considered to be 'lightweight' in comparison to drugs. Devices, in particular, seemed to us to require much less diligent research, certainly less monitoring, and only simplistic evaluations of therapeutic safety and efficacy.

In the past five years, however, there has been a change in the way that regulators in the United States have addressed the requirements for the development of devices.

This may, in part, be due to an increasing interest in the development of drug-device combinations to enhance the delivery of already approved medications; the advent of more sophisticated diagnostic tools (eg, assays for the early detection of disease); development and design of more biocompatible materials, allowing the implantation of indwelling devices; and, of course, the ever-present spectre of product liability and associated litigation.

In the USA, devices are usually handled under the authority of the Center for Devices and Radiological Health (CDRH). A notable exception to this is devices that involve blood collection or analysis. These are the purview of the Center for Biologic Evaluation and Review (CBER).

What is a 'device'?

The term 'device' is defined as instruments, implements, machines, and other things that are intended for use in diagnosing diseases or other conditions and in treating disease in humans. Also, items that are intended to affect the structure or function of the body of humans or other animals are considered devices. Essentially, devices do not depend on being metabolized or on chemical action to achieve their primary intended effects.

Medical devices initially were subjected to regulation in the USA, based on the Federal Food, Drug and Cosmetic Act (FD&C Act) in 1938. However, until 1976, there were no requirements that devices be reviewed or approved before they were distributed commercially. Device regulation was defined by the FDA&C Act's misbranding and adulteration provisions, and device regulation was "after the fact" because the Agency had no authority to keep unsafe products from entering commerce. Finally, in 1976, Medical Device Amendments gave the FDA authority to require premarket review.

The key feature of the 1976 Amendments was a classification scheme that placed all devices into one of three classes (Class I, Class II, or Class III). Although Congress intended that Class III devices be subject to the highest level of regulation, which requires product-by-product approvals prior to marketing, and that Class II devices comply with FDA-issued performance standards—resulting in what would amount to a generic premarket approval process. However, this level of oversight never materialized! FDA did not issue any performance standards for Class II devices, and did not require manufactures to submit premarket approval applications (PMAs) for the vast majority of Class III devices that were on the market prior to the 1976 Amendments.

Class I: Those for which "general controls" reasonably assure safety and effectiveness. If there is insufficient information to demonstrate that general controls are adequate, must meet the following criteria:

- It is not purported to be life-supporting or life-sustaining;
- It is not intended for a use that is of substantial importance in preventing impairment of health; and
- It does not present a potential unreasonable risk of illness or injury.

Class II: Those for which Class I controls are inadequate and there is evidence that "special controls" reasonably assure safe and effective use.

Class III: Those for which there is insufficient information to show that either Class I or Class II controls can provide reasonable assurance of safety or effectiveness.

As a result, Congress was placed in the position of either forcing the FDA to comply with the original intent of the 1976 Amendments, or altering the law's approach. Congress chose the latter path, and passed the Safe Medical Devices Act of 1990 (SMDA). Instead of relying

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>>> The World of Medical Devices—Serving Two Masters

Table 1 Examples of differences:

TOPIC	ICH	Ref	ISO	Ref
QA/QC	sponsor responsible for implementing & maintaining QA/QC control systems w/SOPs to ensure compliance with protocol, GCP, other regs.	5.1.1-5.1.4	The sponsor "shall ensure … through a quality system" –without giving detail as to what that system should include	Part 1-8.1
Transfer of Obligations	sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor	5.2.1-5.2.3	only mentions CROs in passing, as an example of an additional party to be listed in the final report	Part 1 – C.13.c
DSMB	establishment of an independent data monitoring committee	5.5.2	Not addressed	
e-Data Handling		5.5.3	Not addressed	
Archiving	original copy of data should be archived before transformed during processing	5.5.4	Not addressed	
Data Ownership	sponsor may not be the 'owner' of the data	5.5.6	Not addressed	
Data Retention	2 years	5.5.8	Not addressed	
Transfer of Ownership of Data		5.5.10	Not addressed	
Financial Agreements	allows the protocol to substitute for agreement between sponsor & investigator; suggests a separate agreement on financial matters	5.9	requires unique, written agreement between sponsor & investigator; silent on financial matters.	
Good Mfg. Process	investigational product must be "manufactured in accordance with any applicable GMP"	5.13.1	literature summary, list of materials & components, intended clinical performance, summary of relevant pre-clinical data, summary of previous clinical experience, list of International Standards complied with, & results of the risk analysis—presented in Investigator's Brochure. These data are intended to support the safety and appropriateness of the investigational device and substitute for compliance with Good Manufacturing Practices [3] .	Parts 1-7.2
Access to Source Data	Sponsors should obtain agreement in writing for monitors, auditors, IRBs, & regulators to have direct access to source data/ other trial documents. Should verify that subjects have consented to such access.	5.15	only mentions 'direct access' indirectly	
SUSAR Reporting	sponsor should expedite reporting of all serious & unexpected adverse drug reactions (i.e., adverse device effects) to other investigators, other IRBs, and to regulators	5.16.2	requires sponsors to report all serious adverse device effects & all other SAEs to regulators, ethics committees, & safety monitoring committees and to other principle investigators **See Figure 1, below**	Parts 1-8.2h, i
Central Monitoring	when conducted in conjunction with procedures such as investigator training and meetings; allows for statistically controlled sampling for selecting data to be verified	5.18.3	Not addressed	
SOPs	sponsor's established written SOPs required	5.18.5	Not addressed	
Audits	devotes an entire section to defining purpose & frequency of audits, having SOPs for auditing, how to conduct audits, audit certificates, & that audit reports should not be requested by regulatory authorities	5.19.1-5.19.3	one sentence on auditing: "The clinical investigator(s) shall allow auditing of their clinical investigation procedures"	Part 1-6.12
Protocols	Basically, same as for ISO Exception: allows for description of 'stopping rules' or 'discontinuation criteria' for individual subjects, parts of trial, and entire trial	6.4.6	Basically, same as for ICH Not addressed	
Source Data	provides for data to be recorded directly on CRFs (i.e., no prior written or electronic record of data). These data are considered to be source data and shall be identified in the protocol	6.4.9	doesn't provide for this possibility, yet certain forms are commonly completed by contemporaneous interview and are both source document and CRF	
Early Discontinuation	specify in protocol the criteria for discharging subjects from a trial early; ie, for noncompliance	6.5.3	Not addressed	
Investigator's Brochure	purpose of an IB is to provide investigators with information to facilitate compliance with the protocol; contents are pharmaceutically oriented, eg, "highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic, & clinical information available"	7.1 7.2	ISO asks for a more device-oriented content: a literature summary, list of materials & components, intended clinical performance, summary of relevant pre-clinical data, summary of previous clinical experience, list of International standards complied with, & results of the risk analysis	Part 1-7.2
Essential Documents	comprehensive list of documents that should be kept during conduct of a clinical trial, and designation of who should keep them	8	Not addressed	

on premarket approval or performance standards as the premarket means of protecting the public, Congress accepted the FDA's reliance on premarket notification as the primary safety and effectiveness screen for devices. Specifically, Congress took the FDA's guidance on 510(k)—which requires persons who intend to market devices to notify the FDA at least 90 days before introducing a device into interstate commerce—and, essentially, turned it into law, with some additions (which apply to Class II and Class III devices):

- currently marketed medical devices may be used as predicates;
- premarket notification must include a summary of safety and effectiveness that describes substantial equivalence between the newer and predicate devices;
- conduct reasonable searches of all known or available information regarding the new and predicate devices;
- certify to FDA that an appropriate search was completed and submit a summary of all adverse safety and effectiveness data for both the new and predicate devices.

The FDA Modernization Act of 1997:

FDAMA changed many Agency practices, including the elimination from premarket review of those devices that did not really require FDA review before marketing.

FDAMA imposed numerous deadlines for CDRH to make significant changes to its programs, issue regulations, and produce guidance documents. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) imposed even tougher performance goals on CDRH in exchange for payments from industry to supplement review costs. More recently, FDA has increased the rigour to which devices are subjected. They seem to be moving toward standards that more closely reflect those required for drug and biologic applications. This resulted in the 'rude awakening' among some device developers that times have changed. Sometimes, there were no Standard Operating Procedures (SOPs), no organized system for conducting animal safety tests or conducting clinical studies in humans. The companies most affected were start-ups and European manufacturers attempting to enter the US market.

While drug development and approval processes have referenced the (ICH), the processes for devices are caught between two worlds: that of ICH, and that of ISO.

Import/Export:

The international movement of devices is an area of growing interest for manufacturers and regulatory authorities in various countries. Under the FD&C Act and in conjunction with the Department of Treasury (US Customs Service), FDA controls the movement of devices to and from the USA.

Current status:

While drug development and approval processes have referenced the International Conference on Harmonisation (ICH), the processes for devices are caught between two worlds: that of ICH, and that of International Organisation for Standardisation (ISO). Companies with experience in the ICH context must assess applicability of these standards to the world of devices. This is not always self-evident, since ISO and ICH do not agree on some requirements and, often, ISO is silent on issues that are emphasized in ICH, as shown in Table 1, above.

ICH-GCPs: Applicable to devices?

The *ISO 14155 standards for the Clinical Investigation of Medical Devices* were written for the purpose of clinically investigating devices [1]. Now 10 years old, the ICH Good Clinical Practices (ICH-GCP, E6) were written for the purpose of clinically investigating pharmaceuticals [2].

This may present a dilemma for those who are preparing to register devices, as the original purpose of these guidances had different foci. For device manufacturers who decide to conduct their first-in-man trials in Europe, the question of which document to follow can be difficult one. Following ISO 14155 is easier, and will bring the device to market in Europe faster, but the data may be of limited value in the USA. The converse is true with respect to following the ICH-GCPs.

Figure 1. The Venn diagram describes the reporting requirements of sponsors in medical device clinical trials, as required by ISO 14155. 2003

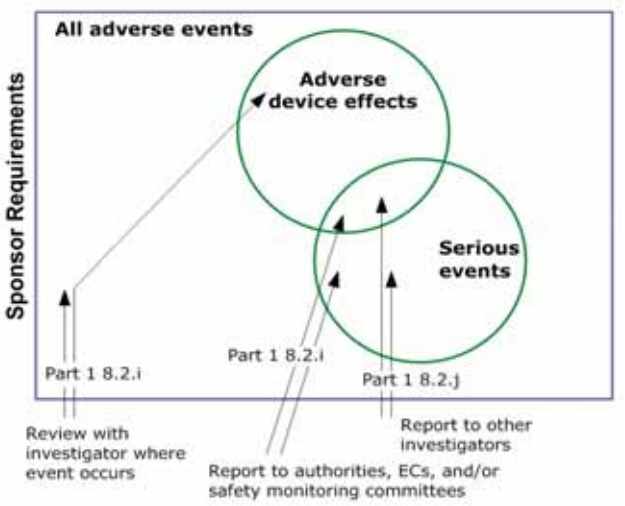

Figure 2. Responses of 26 medical device manufacturers re: adverse event collection procedures

AEs Collected:	US Sites	EU Sites	ROW Sites
Only Device AEs	3	3	2
All AEs	10	11	3
Mixed AEs	5	7	3

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>>> The World of Medical Devices—Serving Two Masters

Responsible and rational adverse event reporting is a continuing problem for all device sponsors. Most sponsors, regulators, investigators, and IRBs agree that ISO is too restrictive and the US Part 812 is too confusing. An informal survey of device manufacturers in October 2006 showed that most sponsors collect ALL adverse events regardless of whether or not the event is device-related [4].

Recommendations:

Don't follow either ICH or ISO. Instead, write your own standard operating procedures for international trials, using ISO as a base and adding ICH components as necessary. If you do this methodically, you'll have procedures that meet FDA requirements, but don't place unjustified burdens on unsuspecting European investigators.

Conduct your first-in-human and pivotal clinical trials in Europe or other developing nations, where it is usually easier to get clinical trials started. Choose countries with investigators trained in western medicine, ample subjects for participation, and an interest in implementing FDA-accepted trials.

Write a clinical quality system for yourself, methodically basing it on the ICH-GCPs compared to ISO 14155 and ISO compared to ICH, and incorporate checkpoints for host country regulations. Become familiar with the International Ethical Guidelines for Biomedical Research Involving Human Subjects [5]. Be absolutely ethical in the conduct of the trials.

Watch this space:

A new ISO Draft International Standard (DIS), is expected to be issued by mid-2008: ISO-DIS *14155—Clinical Investigations in Humans of Medical Devices—Good Clinical Practices*.

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3. 21 CFR Part 812 takes a similar approach, asking for a Report of Prior Investigations and a statement as to the extent of compliance with good manufacturing practices.
4. The following survey question: "Of the medical device or device-combination clinical trials you conducted in 2006, did you collect only device related adverse events, all adverse events, or a mix of adverse events according to a plan your company developed?" was emailed to 100 companies outside of the United States and 200 companies within the States. The table is based upon 26 responses received within the first 5 days.
5. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland
See http://www.cioms.ch/guidelines_nov_2002_blurb.htm

Not only can you too author a science paper but you can calculate p values too

There are easy solutions for the busy author to bloat his/her CV without even employing the services of a medical writer.

The following is quoted from the website http://www.inklingmagazine.com/inkycircus/detail/you-too-can-author-a-computer-science-paper/ and runs under the title: You too can author a computer science paper!

"I've been hearing a lot of grief from my scientist friends about having to write research papers or submit or edit them, etc.

Here's a silver bullet—if you're in computer science that is. SCIgen randomly generates an entire computer science research paper (complete with graphs and figures) at the click of a button. All you have to do is fill in the five author fields.

For example, the trio behind inky circus came up with a paper titled On the Visualization of Hierarchical Databases.

Here's the abstract. Can I just say, who knew we had it in us?

In recent years, much research has been devoted to the visualization of XML; however, few have deployed the investigation of spreadsheets. Given the current status of classical archetypes, end-users daringly desire the refinement of the partition table. We construct a heuristic for autonomous information, which we call Emu. Such a claim is usually an extensive mission but fell in line with our expectations.

As you can see the results are pretty spiffy—which explains how three randomly generated papers made their way to the World Multiconference on Systemics, Cybernetics and Informatics in Orlando in 2005."

The site also has a 13-minute film clip about the hoax.

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And you too can test a p-value under the null hypothesis without seeing any data by going to http://www.meduniwien.ac.at/medstat/misc/pwert.html

Some thoughts on writing slide presentations: Avoiding 'death by PowerPoint'

by Richard Clark

Power (point) snoozes

How often have you felt bored, even a bit sleepy, within minutes of listening (and watching) a slide presentation? A true story from my old research institute involved a rather elderly, balding Nobel-prize winner who nodded off during a slide presentation soon after the lights were darkened. This was in the last days of 'real' slides, when you could put slides in a projector carousel the wrong way around, and mechanical failures sometimes occurred. On this occasion the carousel jammed and slides were ejected up and out, like empty shells from a machine gun. One slide looped high through the air and landed with some force on the slumbering Nobel-prize winner's bald pate. Being rudely awakened and somewhat startled, he jumped into the air, providing much amusement and a welcome diversion from the presentation.

PowerPoint is evil. Power corrupts. PowerPoint corrupts absolutely.

None of us—not even Nobel laureates—are immune to slide presentation boredom. So what are the problems that cause such boredom and how can they be overcome? Are slides, and PowerPoint in particular, a good means of communication? There are a variety of views. Ronald LaPorte believes that PowerPoint has become the *prima lingua* of scientific communication and that traditional peer-reviewed journals are becoming obsolete [1]. In response, others have stated that PowerPoint slides rarely stand alone and they need written or oral supplementation [2]. Others go further. As we shall see later, John Sweller (who propounded a theory which helps to explain slide presentation boredom) thinks that the use of PowerPoint presentations has been a distaster [3]. Edward Tufte, who is well known for innovative approaches to presenting technical evidence, states that "PowerPoint is evil. Power corrupts. PowerPoint corrupts absolutely"[4]. We will come back to Tufte's opinions too, but for the moment we should first try to evaluate why slide presentations can be so soporific.

The main problems with slides

The advice you are likely to hear on how to produce slides is "keep it simple or you will lose your audience's attention" or maybe "use plenty of bullet points" or even "keep graphs and tables simple." In my view, *trying to keep things simple causes most problems with slide sets at the moment*. This is not a good strategy for a medical or scientific meeting as it is condescending towards the audience at they become bored with a lack of content and simple statements unsupported by data.

In an effort to inject something of interest into these bland 'death by bullet point' presentations some people like to add animations or cartoons, maybe a colourful background, or worst of all clipart. This variation is a second common problem facing writers of slide sets, and arises naturally from the 'keep it simple' scenario. I admit to a personal bias on this subject as I have very distressing memories of clipart from presentations given by an editorial manager. She tried to make the presentations more interesting with humorous clipart stick men, but it failed to relieve the tedium of the latest Excel costing model spread sheet, or other exciting administrative procedures. A shorter presentation without the clipart would have been better to get it over with as quickly as possible.

A third scenario, which is more recognisable to most people, is presenting too much information. This situation is made worse by the low inherent resolution of projected slides or acetates (i.e. you can't read the things if the text is too small and cramped). An example of this problem was at a meeting I was writing-up for a newsletter. Here, a Greek clinician presented a scientific paper using acetate sheets which were facsimiles of his published manuscript. Even though the room and the audience were small the text was not readable. Even if the acetates had been readable there wasn't enough time to read it all. Worse still, the speaker was unintelligible owing to a thick Greek accent, and though the meeting was recorded I could not understand him even when listening to the recording a second or third time. Luckily it was sufficient to read the published paper when writing-up the meeting!

Imagine a world with no pronouns or punctuation, where any complex thought must be broken into seven-word chunks with colourful blobs between them. This is the reality of a PowerPoint presentation, repeated about 30 million times a day [6].

In the following sections I'll focus on why the keep it simple approach is the main obstacle to good slide presentations, and how to deal with this problem without falling into the trap described in the third scenario (i.e. avoiding both oversimplification *and* data overload).

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>>> Some thoughts on writing slide presentations...

Dick and Jane have fun

PowerPoint guidelines will often recommend something like a 6 times 6 rule (no more than six lines of text and no more than six words per line) to keep slides simple. In fact, EMWA also recommends this approach for workshop leaders preparing slides: "limit text to approximately seven words per line, and five or six lines per slide; keep graphs and charts simple" [5]. It's a bit disappointing when you consider that this is the writing style used to teach young children to read (Figure 1).

Figure 1. Children's literature provides a good example of how to write slides according to PowerPoint 'keep it simple' guidelines (from an unknown 'Dick and Jill' book, traditionally used to teach children to read in the USA).

When this simplistic approach is combined with various desperate attempts to enliven the presentation the results are instantly soporific. Another good way to induce sleep in your audience is to place a bullet point in front of each line of simple text, and animate the slides so that each line is revealed as the presenter clicks a button and simultaneously reads the line out aloud. Perhaps animate is an unfortunate and inappropriate word to use here, as this approach will soon result in audience lifelessness. The cognitive load theory provides a plausible explanation as to why reading and hearing the same text simultaneously has this effect, as has been mentioned in a previous issue of *TWS* [3]. It is far more effective to use visual evidence in the form of a picture, table, figure, graph or chart and discuss or describe what is shown on the slide.

Not only is this simplistic, bullet-pointed method dull, but this format can be misleading. The use of bullets and worse still, strange and complex bullet-point hierarchies (bullets with 'sub-bullets' and often 'sub-sub-bullets'), creates an impression of false causal relations in the minds of the few audience members who are still awake. Often, bullet points seem to have been used randomly, and it is as if someone has carelessly shot each slide of text with a machine gun. As a result, text can be sliced into small, arbitrary and misleading fragments. Thus, bullet points are frequently a poor substitute for the proper use of *language*, and should be used sparingly—or at least thoughtfully.

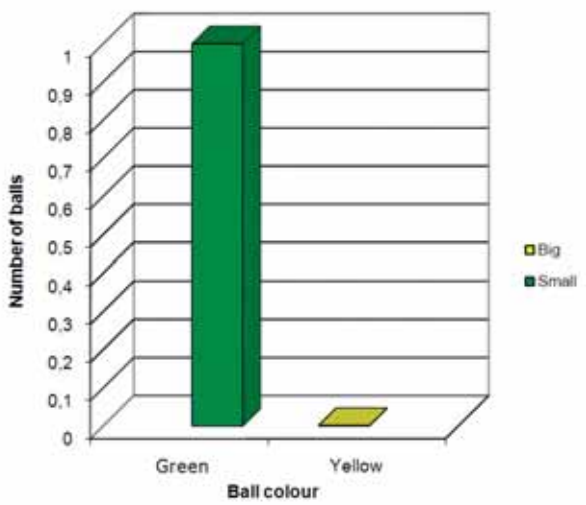
Salami tactics

The simple approach is not limited to text. It also extends to figures and tables. All the same points apply about not condescending to offer a snippet of information that you think is important to the audience. An example is a slide showing a bar chart with one or two bars, or a table with three or four data cells. A succession of slides, each showing a tiny gobbet of data, is revealed to the audience with an increasingly hypnotic effect (I like to call this phenomenon 'salami tactics'), whilst any story, narration, or context, is lost completely (Figure 2).

As for a picture, if it isn't worth a thousand words, the hell with it.

It is often said that a picture conveys a thousand words. Maybe we should update this saying with regards to slide presentations (and particularly PowerPoint which tends to steer the slide writer towards simple, and yet strangely difficult to read, three dimensional charts and graphs)? The artist Ad Reinhardt is, perhaps more appropriate, stating "As for a picture, if it isn't worth a thousand words, the hell with it."

Figure 2. A typical '3-D' bar chart of the type often used in presentations and generated automatically by Microsoft Excel 'chart wizard'. Note the pointless 3-D effect and that this chart contains little information.



Unfortunately bullet points have become so ingrained in slide presentations (mainly because of the dreadful PowerPoint default style) that is difficult to get away from them. Bullet points are no more than little black circles in front of phrases that are supposed to summarise something. Remember, *using bullet points is not compulsory*—you can even use full sentences if you want! Again, bullet-point phrases slice the content of each slide into thinner and thinner fragments. Is this good? Sometimes yes; sometimes no. Sometimes it is very liberating to write in normal English and it can be far clearer. Compare the following well-known speech by Winston Churchill given on 4 June 1940, after the evacuation of British forces from Dunkirk, with a

Figure 3. **Winston Churchill's 'we will fight them on the beaches' speech as a PowerPoint presentation using the PowerPoint default bullet-point style and typical use of unnecessary clipart.**

slide set made using the PowerPoint autocontent wizard, selecting the 'recommend a strategy' option from among the presentation types (Figure 3).

"We shall not flag or fail. We shall go on to the end. We shall fight in France, we shall fight on the seas and oceans, we shall fight with growing confidence and growing strength in the air. We shall defend our island, whatever the cost may be. We shall fight on the beaches, we shall fight on the landing-grounds, we shall fight in the fields and in the streets, we shall fight in the hills. We shall never surrender!" [7].

Some solutions?

This is the difficult part, and there is no simple answer. On the one hand, being too simplistic will lead to audience boredom and lack of meaningful communication of data or results. Clearly, this approach is particularly unsuitable for scientific presentations. The audience needs to be treated like intelligent adults and shown *evidence*—which is often complex—rather than the presenter's semi-justified opinions. The audience may then be interested, questioning and involved, and ultimately more convinced if the evidence is presented effectively and they can understand it for themselves. The reverse of this is when too much detail is included so that the audience cannot follow the presentation.

The solution is to think a bit when making slides. It is so easy to fall into the bad habits outlined. It is, however, not always easy to think of novel ways to present data without losing detail or becoming too difficult to follow, but it is possible. For example, Leonardo da Vinci and Galileo were expert at integrating figures and text on a page to aid explanation, in what is now almost a lost art. Many other examples can be found in the writings of Edward Tufte, who is no friend to PowerPoint [4,8,9].

Tufte rightly argues that slides are a low-resolution format, and therefore not particularly suitable for conveying much useful information. Furthermore, slides are frequently cluttered with all sorts of design elements, unnecessary pictures and bullet points, all taking-up a surprising amount of the little space that is available. After all, if the rate of information transfer in slide presentations is 'approaching zero', as Tufte writes, then what is the point of having these meetings at all? We could use handouts which contain the detailed information required. (Think about how much readable information is contained in a scientific paper, for example: this is a high-resolution method.) Thus, we return to LaPorte's belief that as scientific papers have been in existence for about 300 years it is time for a change, and that peer-review articles may soon be replaced by PowerPoint [1]. In response I would add that if something has been in use for 300 years it has probably survived because it is still doing something useful and different from any other formats of communication, rather than being due for replacement.

> ***The audience needs to be treated like intelligent adults and shown evidence—which is often complex—rather than the presenter's semi-justified opinions.***

> > >

>>> Some thoughts on writing slide presentations...

One final 'nuclear' solution that should be mentioned is not to use slides at all in your presentation. This format is usually more suitable to a speech rather than a scientific talk though, as the audience will be unable to view any proof you may have (unless you give a handout such as published paper(s) on the subject). However, this approach can result in a very interesting talk as the audience's attention is focussed on the speaker rather than slides. A skilful and very knowledgeable speaker may be able to work this situation to their benefit, but most would consider jotting down some key points on cards in case they get stuck even if they do not usually need to use them.

Those of us who want or need to use slides should remember that no quantity of clipart, cartoons, bullet points, weird 3-D charts, strange slide layouts and colours can make a presentation interesting for long. Let's cut out the cheesy clipart, and ditch the default styles of bullets and charts favoured by slide presentation software. This is the first and most important step. After this, each presentation does warrant the cliché 'a case-by-case basis'. In each instance thought will be needed rather than inputting data to templates. This approach should *give priority to scientific evidence* (otherwise there is no point having a presentation as there needs to be something substantial to communicate). Next, communicate this evidence effectively but without over simplification. By following these steps we can produce an interesting and informative presentation because the audience are given information and evidence that they may be interested in and which could be useful. This means the audience might stay awake.

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Call for contributions: The lost art of science writing

I am gathering examples of the style in which science used to be reported for a future feature in *TWS*. All contributions, for publication as boxes (up to 1000 words), are welcome.

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Three words or one?

For the moment, let's disregard anything else you may want to do to this sentence to improve it (see my 'possible edit' below), and just consider *as well as*. Is it ever necessary to use it when writing in our field? Speaking is quite a different matter.

Safety pharmacology studies complying to GLP requirements were performed for <drug> and investigated effects on the central nervous system, respiratory and gastrointestinal systems, skin and subcutaneous systems as well as the cardiovascular system.

By the time they got to *subcutaneous systems* in this sentence, the author thought 'We've had enough *ands* here, let's put in an *as well as* to avoid repeating *and* and make it more interesting'. This is not necessary and makes this cumbersome sentence even worse. It is acceptable to repeat *and* as many times as you want in our type of writing as long as all the elements in a list are appropriately separated by commas (or semi-colons, if you like—I don't). One solution for the above might be (possible edit):

GCP-compliant safety pharmacology studies investigated the effects of <drug> on the central nervous, respiratory, gastrointestinal, skin and subcutaneous, and cardiovascular systems.

Note the comma before the last *and* because of the *and* between 'skin and subcutaneous'. If 'skin and subcutaneous' were not there, the comma before the last *and* is optional.

Some authors think that using *as well as* means that the verb in a sentence does not need to be in the plural:

Pursuant to article 67 (6) AMG, the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) as well as the competent federal authority (Paul Ehrlich Institute) was informed immediately.

This is not the case. You still need to use the plural, so you may as well use *and*.

Maybe the best reason is that *and* is always shorter than *as well as*!

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Book reviews in the medical scholarly literature Part I: A brief historical incursion

by Françoise Salager-Meyer

It is commonplace to say that today's researchers and scientists who wish to keep up to date with new and relevant information in their field of enquiry face a truly daunting task. Indeed, from the ever increasing amount of research being published, they must discriminate between what is worth reading and what is not. But we often tend to forget that the concept of 'critical appraisal' of science is not new at all. Indeed, attempts to respond to the needs of busy people for relevant research information already existed more than three centuries ago when the output of books, and thus new knowledge, increased dramatically.

In this respect, the medical world was marked by two particularly important events in the late 17th century. It was, on the one hand, the publication in 1679 of the first medical journal, *Nouvelles découvertes sur toutes les parties de la médecine*, edited by Nicolas de Blégny, then director of the *Académie des Nouvelles Découvertes* where medical news were discussed and free medical assistance was provided for indigenous patients.

The second event was the publication five years later, in 1684, of the first English medical journal: *Medicina Curiosa*. Although two earlier publications, the *Philosophical Transactions of the Royal Society of London* (the first English scientific journal published in 1665 and, according to some scholars, the first world scientific journal) and the *Weekly Memorials* (the first English abstracting journal)[1] contained some medical information, *Medicina Curiosa* was the first periodical entirely devoted to medicine.

Two other journals, the aim of which was to chronicle and summarize the explosion of learning in the sciences, also made their appearance at that time on the scene of scholarship: *Analytical Review* and *The Monthly Epitome*. Later, in the mid-18th century, the German periodical *Commentarii de Rebus in Scientia Naturali et Medicina Gestis* was published in Leipzig [4]. It contained abstracts of scientific and medical books and was to serve as a model for the first English-language journal of abstracts of books relevant to busy clinicians, *Medical and Philosophical Commentaries* which was launched in Edinburgh in 1773.[2] The journal became sufficiently well regarded to justify translation into languages other than English [5].

In the Introduction of its first issue, its editor, Andrew Duncan, wrote something which will strike any physician and/or medical researcher today as extremely familiar:

> *"No one, who wishes to practice medicine, either with safety to others, or credit to himself, will incline to remain ignorant of any discovery which time or attention has brought to light. But it is well known that the greatest part of those who are engaged in the actual prosecution of this art, have neither leisure nor opportunity for very extensive reading."* [6]

And Duncan goes on to explain how the journal will help physicians to learn about new discoveries without having to consult a great variety of books, thus helping them to improve their practice. In fact, of the 4 sections of the journal, the first one, entitled *"An account of the best new books in medicine"*, was to be a principal feature of the journal.

With respect to the content of the book reviews (hereafter abbreviated as BR) published in the first issues of *Medical and Philosophical Commentaries*, it merely consisted in impartial comments where book reviewers were not giving any personal opinion with regard to the content of the book. As a matter of fact, the editor of the journal urged booK reviewers to avoid, as much as possible, either applauding or condemning any author, because, as he put it, the chief aim of that section was "*to give such a view of books as may enable every reader to judge for himself.*" [6]. Incidentally, this rhetorical feature seems to be a distinctive feature of early scientific BRs (i.e., not only medical BRs) because Hyland [7] made the exact same remark regarding scientific BRs in general which only "*served to summarize and chronicle uncritically the explosion of learning in the sciences.*"

But the simple recording of published scholarship in BRs was quickly abandoned in the second decade of publication of the *Medical and Philosophical Commentaries* in favor of a more critical appraisal of the books reviewed. Book reviewers were then encouraged not to confine themselves >>>

1 Indeed, according to some scholars [1], [2], [3], it is in January 1665 when Denis de Sallo published the first issue of the Journal des Sçavans (The Scholars' Journal), that is, two months prior the publication of the first issue of the Transactions by Henry Oldenburgh.

2 In 1796, Medical Commentaries became the Annals of Medicine, and in 1805, the new periodical was renamed The Edinburgh Medical and Surgical Journal. In 1855, the words "and surgical" were dropped and the journal lasted for another 100 years [5].

>>> Book reviews in the medical scholarly literature

to a mere analysis of new books but to "*candidly offer their opinions of the book contents*" which should be expressed "*with that respect which is due to merit and that diffidence which the nature of the subject demands.*" [6].

It is thus at the end of the 18th century when BRs underwent what is called a 'rhetorical shift'. Book reviews, however, only became a regular feature of most medical journals in the 1930's. *Annals of Clinical Medicine*, for example, published BR since its first issue in 1924, as did its successor, *Annals of Internal Medicine*, which was first published in 1927.

Book reviews, then, have contributed to the improvement of medical and/or scientific research in general and have played an earlier role in the construction of scientific knowledge than the research article itself, a scholarly genre which emerged in the closing years of the 19th century and to which so much attention has been dedicated within the English for Specific Purposes (ESP) movement in the past three decades or so ([9] and [10]).

Because of the importance of criticism in the advancement of science and the refinement of paradigms, I will, in the second part of this paper, provide examples of critical remarks that illustrate the diachronic variation of the rhetorical strategies used to convey criticisms in book reviews published in English-medium journals in the mid-20th century (1940-1960) and in the closing two years of the 20th century (1999-2000).

One of the pragmatic markers of mid-20th BR, for instance, was the emotional, devastating, merciless, even downgrading tone with which critical comments to books were then formulated. This is why criticisms at that time were much more face-threatening to the book author than those found in BRs published in the closing years of the past century which, although also still very direct and straightforward, are conveyed in a much less emotional, more dispassionate and matter-of-fact tone. What is more, today's book reviewers tend to accommodate the criticisms uttered in the body of the reviews with a final positive evaluation. This was certainly not the case in "early" BRs.

In Part II I will also give examples that will show how the targets of criticism have changed over time, and how early book reviewers voiced their criticisms to a much wider range of content-related (i.e. conceptual) and external/non-textual aspects than today's reviewers do.

All this, I hope, will illustrate how the two time periods examined present features that mark a breaking point or disruption in scientific thought.

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Corrected incorrects are not always correct

I have just wasted about a day, while attempting a sample size calculation, wondering why my numbers just don't look right. I've been using a formula in a published paper, and was alert enough to discover that there was a published erratum for the paper, which was just as well as the formula I needed for my calculation was wrong in the original publication. But despite using the corrected version, the numbers still didn't seem right. It took me a long time to figure out that the corrected version was also incorrect. The moral of this story is that you should never assume that something is correct just because it's in a peer-reviewed paper, even if it's already been corrected.

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Medical writing educational materials

The International Medical Communications Center at Tokyo Medical University have put all their educational materials onto a free-access website. Just register with your e-mail (so they can distinguish their students from other users) and put in a password of your choice: www.emp-tmu.net

This was made possible by a grant from the Japanese Ministry of Education and the generosity of many of the clinicians with whom they developed materials and also *The New England Journal of Medicine* who allowed them to upload materials with their copyright.

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Hangings at the *bmj*: What editors discuss when deciding to accept or reject research papers

by Elise Langdon-Neuner

Editors at the *bmj (British Medical Journal)* gather every Thursday to meet as a hanging committee. An invitation to sit in on such a meeting is too good to be missed. But we are not talking here of gallows, word games, or even Nebraska Football, but rather decisions on the fate of manuscripts that have passed through the journal's external review process. The *bmj* itself likens the meetings to those held at art galleries to select paintings to be hung in the gallery.

I was very grateful for the opportunity to attend one of these meetings, also known as manuscript meetings. I wanted to know what editors at such a prestigious journal with a high rejection rate (see Box below) discuss when making publication decisions. What are and what are not important factors in influencing their decisions to accept or reject manuscripts for publication? Expectations of something formal and stuffy were quickly dispelled. Nevertheless coffee and biscuits, and the casual and convivial atmosphere, belied the unwavering focus and impressive professionalism that marked the meeting's seamless progress.

First I should explain how things work at the *bmj*. All original research manuscripts received by the *bmj* on one day are reviewed by the handling editor on duty for that day. About 12 research manuscripts are received a day. As the abstract is the first point of reference and an average of 7 minutes or even less is spent on the initial scan of each manuscript and covering letter, authors are well advised to heed the *bmj*'s advice on their webpage to 'ensure that the abstract is as complete, accurate, and clear as possible'. Special attention is paid to the aims and methods parts of the structured abstracts; the results are considered less important, i.e., it matters less if these are positive or negative. If the abstract is of interest, the editor next looks at the methods section of the manuscript before deciding whether to reject the paper or pass it on to the screening editor on duty for that day. The screening editor decides whether the manuscript should be sent out for external review. If it is decided that the manuscript is worthy of external review, the screening editor sends it back to the handling editor who is responsible for selecting reviewers and conducting the process through to the final decision. The handling editor presents the paper and the reviewers' comments at the manuscript meeting. Between six and eight editors attend the meetings. At the meeting I was at, one external editor joined by telephone from the US. Sometimes there are more. A statistician, who like the rest of the participants has read all the papers to be discussed, is also in attendance and takes a very active part.

Naturally the discussions at the meetings are strictly confidential. The following report of the meeting I attended is a composite of the dialogue to demonstrate the type of points that were raised but does not relate the discussion of any particular paper.

The first manuscript was a survey, which the handling editor presented as a 'novel and titillating study'. It was not ideal, but it was the best that was available on the topic. The editors thought the paper was possibly worth publishing—but was the sample representative? In any event the discussion needed to be shortened because it pretended to be more than it was and the study limitations should be explained. In discussion of subsequent papers, the statistician warned on two occasions that studies were underpowered. One of these papers had an uncommon design and was thought to be better for a specialist journal, although had it been a definitive study it might have been of interest to the *bmj*'s specialist readers. In another study, the follow-up was not long enough. Here the editors resolved to send a message to the authors that they would be interested to see the study again with a longer follow-up in a couple of years' time. There was a risk of losing the paper in the meantime, of course.

One resubmission and one appeal numbered amongst the manuscripts discussed. Appeals are encouraged by the *bmj*. On the resubmission the editors felt that the authors had done a good job in giving very detailed responses to the reviewers' comments and supplying supplementary files. They had redone some of the analyses but the paper could have been written better. The editors decided to ask for a revision. The appeal paper had originally been rejected because of concerns about the power of the study, and the authors had not presented 95% CIs for the main result. It had been thought that the non-significant *p* value could have arisen from high variance rather than a small effect.

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Rate of rejection

The *bmj* received around 7000 manuscripts in 2007. Approximately 3300 of these were research papers, of which 147 were accepted for publication (acceptance rate 4.45%). About 60% of the research papers received were rejected within 2 weeks of receipt (often on the day of submission) without being sent out for external review.

>>> Hangings at the *bmj*...

By the time a manuscript reaches the manuscript meeting there is a strong will among the editors towards acceptance, but at this meeting a large study that tackled a poignant disease was rejected. Although the study had been carefully conducted and was well reported, there was a question about its clinical usefulness. The results were unsurprising and did not really produce new knowledge. Another problem was that it had been database-driven rather than hypothesis-generated. Moreover, the reviewers had raised issues that were intrinsic to the study and therefore could not be addressed by making changes to the manuscript.

Then there was a trial that had not been blinded, but probably this would have been impossible anyway. Many patients had previously had the therapy, so they were not newly diagnosed patients, but this did not come over very clearly. Such a limitation should be reflected in the abstract and the title. The authors had some ties with manufacturers, but there wasn't thought to be any spin. Another paper reported on a field in which there are strongly opposing views and lots of conflicts of interest. One researcher had declined to review the paper because he did not think he could give an open review[1] without damaging his relations with the authors. Conflict-of-interest statements had been provided, but the editors thought this was a case where the paper should include a statement explaining which company made each of the drugs mentioned.

Some time was spent discussing a study that raised an important research question but the study also had quite a few problems. The method of randomisation had not been described and the power calculation was hard to disentangle. Only secondary outcomes were presented in the abstract, tables and figures. Buried somewhere in the text was the fact that the primary outcome had been non-significant. Usually articles are not sent out for review before the authors have submitted a CONSORT statement and the protocol and clinical trials registry numbers, but somehow this paper had slipped through the net and these were missing. The greater than 50% reduction in XXXX associated with the study medication could be regarded with some scepticism, and the editors wondered if this could really be sustained in the long term. They decided to ask for the missing documents and offer revision to resolve these problems. If the paper was eventually published it was agreed that one of the editors should write a commentary on the statistical aspects of the paper to be published with the paper. Often when research articles are accepted they are published accompanied by an editorial.

The final paper for discussion posed a nice question and was intrinsically interesting. Little data had been published on the topic and a publication would be read and cited. One editor commented that it was something where you wanted the results to be true. The author had phoned before submission to ask if the *bmj* would be interest in the paper, which was an unusual one for the journal. The paper was discussed as a possible candidate for the Christmas issue, which includes topics that are not normally covered in the *bmj*. The paper needed a lot of work before it could be accepted, for example: was the question in the survey asked in the right way? If the methods were explained better it might be acceptable. The editors had the will to get a decent paper out of it, but decided that they should send it out for review again for another opinion.

Finally, what were the editors at this meeting looking for?

- sound science and statistics (the outcome of a clinical trial could be positive or negative)
- new information
- papers that would be read and cited
- papers that were well written—although if other criteria are met the *bmj* will work with authors to produce a good paper (that said, well-written papers always make a good impression).

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Language revisers/translators/editors: is there anyone out there?

We—Christine Møller in Copenhagen and Monika Schoell in Regensburg— have for many years been revising and editing manuscripts for Danish and German scientists. This led us, independently of each other, to compile lectures on typical errors of grammar and usage made by non-native English speakers. We focused not only on language problems but also on cultural differences, and then naturally progressed to structure and style.

There are many PhD students and researchers in Denmark and Germany who need help with writing manuscripts for publication.

We would like to contact other language revisers/translators/editors with an interest in the problems experienced by non-native English speakers. Any members of EMWA who would like to exchange information and ideas are urged to get in touch with us.

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1 The *bmj* have a policy of open review. The names of reviewers are included on the reviewers' comments sent to the authors.

What editors at *JAMA* discuss when deciding to accept or reject research papers

The tradition of confidentiality surrounding editors' decisions whether to accept or reject manuscripts means that little has been written about the factors that influence editors in these decisions. This concept of confidentiality has recently been strengthened by a US judge's ruling against Pfizer's motion to compel the *Journal of the American Medical Association* (*JAMA*) and the *Archives of Internal Medicine* to produce confidential editorial judgements and unpublished peer review comments [1].

An observational study of discussions at 12 manuscript meetings held at *JAMA* that was conducted by Kay Dickersin and colleagues has recently been published [2]. Their aim was to identify unrecognised aspects of editorial decision-making. In the study phrases spoken by editors were noted and the editors themselves completed a form listing their reasons for considering the manuscript for publication. The spoken and written phrases were classified into three main categories: science, journalism and writing.

Together with the *bmj*, *JAMA* numbers among the top 5 journals of general medicine. The editors are only able to accept a small portion of the manuscripts they receive (5-10%). The *JAMA* study findings were similar to the observations made at the *bmj* manuscript meeting described on pages 84-85. The editors' primary concern as shown by this study was the quality of science reported in the manuscript. The most frequent phrases related to science and included mention of the quality of the description of the design and methods, concern whether the conclusions matched the study strength, adequacy of references, adjustment for confounders and effect modifiers, concerns about the population or database and why it was chosen, potential for selection bias, comments about the power of the study, whether measures used were reliable, concerns about completeness of data, representativeness of broader patient population and comments about conflicts of interest (for more examples see Table 2 in [2]).

The next most important category of phrases 'journalism' depicted the editors' wish to maximise strategic advantage for the journal with interesting and important topics and findings, and included mention of 'cool new technology', 'unique work', 'few similar studies', 'potential readership interest', 'hot or timely topic' and of the prominence of the authors.

The last category in order of the frequency of phrases was 'writing'. These phrases referred to writing either directly, e.g. 'not clear', 'dense', 'needs a rewrite' or indirectly from reviewer comments, e.g. 'good revisions'.

Kay Dickersin and her colleagues concluded that their study provided insights into the editorial decision-making and concepts that needed to be explored further in future studies.

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What do editors at speciality journals look for in manuscripts?

Diabetologia is a prominent biomedical journal publishing articles on diabetes. The journal rejects 80% of the manuscripts it receives but the editor, Edwin Gale, assures authors that he is looking for reasons to accept rather than reasons to reject a manuscript. The problem is that good papers are few and far between. What the journal wants are manuscripts which tell a story and convey a message that can be written in two or three sentences. The message should be something that is new and something that is interesting. Gale's delightful short article on the journal's website is true to form: refreshing and interesting with two to three sentences of essential advice to potential authors on each section of the manuscript. Some important messages are:

- Write the abstract first
- Forget the 'cut and paste' facility in Word; it's the downfall of most methods sections
- Always ask for professional advice on the analysis (even go as far as to ask the statistician—if you find a good one—to marry you: analysis is that important)
- Keep the reference list short
- Use a good illustration to convey your central message; it will be used over and over again in review lectures while papers with no illustrations sink into oblivion

As for revising your paper, to quote Gale you should "pick up a marker pen and strike out the following:

- Adjectives
- "Soft" qualifiers (e.g. slightly more, somewhat less etc)
- Any word that can be lost without changing the meaning of a sentence
- Any sentence that can be lost without changing the meaning of a paragraph
- Any statement that does not form an essential part of the story
- Any inference that goes too far
- Any phrase that you consider particularly clever
- If your paper is not 25% shorter, go back and start again."

Source: http://www.diabetologia-journal.org/eicadvice.html

Darwin Award and moles

Of the many awards that are made each year perhaps the Darwin Awards are the most extreme. These awards are named in honour of Charles Darwin because they are granted to people who ensure the long-term survival of the human race by removing themselves from the gene pool in a sublimely idiotic fashion (http://en.wikipedia.org/wiki/Darwin_Awards). This means that to be a candidate for the award you need to be dead, unable to reproduce or indefinitely incarated in prison. Other prerequisites for the award are

- that the activities leading to the demise must not only be foolish but unique and sensational, e.g. smoking in bed and then going up in flames is not good enough.
- you must be the instrument of your own fate. It is not good enough to kill or incapacitate someone else
- You must be free from mental defect

Finally the event must be verified by reliable sources, e.g. a newspaper article (what could be more reliable?)

The awards date back to as long ago as 1985 and have been recorded through e-mails, discussion groups and various websites (see http://www.darwinawards.com/)

The 2007 award went to an alcoholic in Texas who imbibed more than 100 fluid ounces of sherry as an enema. After he had passed out the liquid continued to be absorbed through his rectal cavity and he was found dead the next morning with a blood alcohol level of 0.47%.

My favourite nomination, however, for 2007 was an East German who tried to get rid of moles in his garden. He hammered metal rods into the ground and then connected them to a high-voltage power line. The problem was that when he made the connection he was standing on the ground himself and was electrified. Before the police could enter the property to inspect his dead body they had to trip the main circuit.

In choosing this favourite I might have been influenced by the fact that on the very morning before I read about the awards I had caught a mole that had made an excursion through our front door into the house. Fortunately the cat was asleep at the time. I was about to take it into the garden when I remembered the children's book *Mole Moves House* by Elizabeth Buchanan. The story line is that Mr Carrington fails to appreciate mole's huge efforts to help dig the garden. His many and varied attempts to get rid of mole fail. Finally he gives up and decides to move house. However, seeing all the preparations, mole packs all his belongings on his bike and follows Mr Carrinton's removal van to his new house. After second thoughts I took the creature to the woods nearby where it quickly buried itself under the leaves.

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Vital signs

Dear TWS

Very interesting the *TWS* issue [2007. vol 16 (4)] devoted to titles in medical research papers written in English. A cross-cultural and diachronic study on that issue is almost a must now! I would simply like to draw *TWS* readers' attention to the following paper that deals with metaphors in medical research papers written in (today's) scientific lingua franca. It's written by an Italian discourse analyst. Here is the exact title and the Internet link:

Mungra P. Metaphors among titles in the medical literature. *Ibérica* 2007;14:99-121. Also available at http://www.aelfe.org/?s=revista

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Dear TWS,

Thank you for sending the pdf version of the March issue of *Write Stuff* to me by email. As I was reading it on my computer screen, it occurred to me that I don't actually need a paper copy anymore. Have you considered giving members of EMWA the option of choosing to receive just an electronic copy? I am not suggesting that the paper version should be abandoned completely but proposing that members are given the chance to 'opt out' of receiving the paper version. I imagine you could probably save quite a lot of paper.

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Plagiarism-detection software does not infringe copyright

Raquel Billiones mentioned in her article in the last issue of *TWS* [1] that Mount Saint Vincent University in Halifax, USA had banned the use of plagiarism detection software because students had raised objects to its use. These objections included that keeping term papers in a database used by such detection tools as Turnitin may be an infringement of the students' copyright. Some students in the USA have sued the company that runs Turnitin for breach of copyright. A federal judge has now ruled against the students in an important decision that could also have wider implications not only for biomedical journals who use plagiarism detection software but also for Google in its endeavour to scan and index books for research purposes. However, the students have indicated that they intend to appeal the decision.

1. Billiones R. Plagiarism prevention in educational institutions is extending to biomedical journals. *TWS*. 2007;17(1) 43.
2. Young JF. Federal Judge Rules That Plagiarism-Detection Tool Does Not Violate Students' Copyrights. *The Chronicle of Higher Education* 26 March 2008. Available to subscribers at http://chronicle.com/free/2008/03/2250n.htm

French catch English semi-colon disease

Biomedical papers written by French authors contain two times more long sentences than those written by all other nationalities—except German speakers [1]. This might be because they are catching the lazy disease of the English-speaking world in using their *point-virgule* less and less nowadays [2]. French linguists, however, do not give up on their errant countrymen so easily. There is currently a drive afoot in France to counteract this trend and promote the *point-virgule*, which to you and I—if we can remember it—is the semicolon. Sylvie Prioul, a French equivalent of Lynne Truss, has said: "People do not like it; writers are frightened of it; newspapers no longer use it. It's a bit sad". She argues that semicolons bring clarity to multi-clause sentences.

Jon Henley gives the British point of view and quotes comments for and against the semi-colon from well-known grammarians and authors in his recent article in *The Guardian* [3].

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3. Henley J. The end of the line? *The Guardian* 4 April 2008. Available at: http://www.guardian.co.uk/world/2008/apr/04/france.britishidentity

Plagiarism: The sins of our fathers

Plagiarism is not only causing eruptions in the biomedical authorship world. Polish priests, especially young ones panicking about Sunday mass on Saturday nights, have been nicking their sermons from the Internet. They risk fines or up to 3 years in prison if parishioners tip off the church authorities. A book has even been published, *To Plagiarise or not to Plagiarise*, which seeks to shame culprits and prompt them to confess their sin. 'Pastoral plagiarism' is also rife in Britain and America, where two evangelical pastors resigned in 2004 after confessing that they had plagiarised sermons.

Source: http://www.guardian.co.uk/world/2008/apr/26/poland.religion

A call for equitable access to science throughout the world

The 1st International PPRISEAL (Publishing and Presenting Research Internationally: Issues for Speakers of English as an Additional Language) Conference, held in 2007 at La Laguna University (Spain), has issued a statement, the Tenerife Statement, calling upon the international community to provide equitable access to published research and publication opportunities to academics working outside the established Western academic systems (non-centre locations). While accepting that much has been done, it lays down a list of further measures that need to be taken geared at scientists in non-centre locations. These include

- a review to overcome inequities in eligibility criteria for schemes such as HINARI (Health InterNetwork Access to Research Initiative)
- an acceleration of open access
- allowing manuscripts to be submitted in hard copy
- reduced conference registration fees
- lower subscription costs of scientific journals
- create regional editorial bodies in each region of the non-centre world (i.e. Latin America, Africa and Asia) to promote the refereed publication of research in languages that suit the needs of the region. These bodies should be funded by national governments and international research and development agencies, and fully supported by the nations of the region.

The full statement is available at:
http://webpages.ull.es/users/ppriseal/index.htm

Publishing clinical trials: Ethics and the pharmaceutical industry[1]

A Joint Symposium by the European Medical Writers Association and the Institute of Clinical Research

by Nancy Milligan and Andrew Smith

February 27th 2008 saw the first joint symposium held by the European Medical Writers Association (EMWA) and the Institute of Clinical Research (ICR). Nearly 100 members of the two professional organisations gathered in London to discuss the ethics and best practice of publishing clinical trials.

Publications: Purpose & process

Julia Donnelly, Julia Donnelly Solutions Ltd

Julia gave an overview of publications in clinical research, from conference posters to peer-reviewed journals. She began with some examples of bad publication practice: over-reporting of positive results (whether deliberately or inadvertently, as a result of over-enthusiasm), under-reporting (or not reporting at all), and ghostwriting.

She went on to consider posting of protocols and summary results on registry websites. Trial results are often published within weeks or months of the last patient's last visit, although such tight timelines can cause problems for medical writers. This early publication can encourage a peer-reviewed journal to also publish the study rapidly, but lacks any interpretation or expert opinion, and may negatively affect the decision of a peer-reviewed journal to publish.

Julia discussed the criteria for authorship: conception or development of the study, acquisition or analysis of data, and involvement in preparing and approving the paper. Ideally, an author should meet all criteria.

In conclusion, Julia stated that publications are highly regarded overall, and that it is possible to develop ethical publications, but it is important to follow the guidelines.

Fraud in publications

Harvey Marcovitch, Chairman, Committee on Publication Ethics (COPE)

Harvey Marcovitch began by discussing several cases of fraud, including that of Jon Sudbo, who published 38 peer-reviewed papers and was awarded a $10m grant before admitting fraud in 2006.

He referred to principles of publication ethics and the Declaration of Helsinki, which are referred to in the International Committee of Journal Editors (ICMJE) guidelines, and summarised the cases discussed by COPE; falsification was mid-way through the list (behind duplicate publication). Competing interests are common: a quarter of researchers have received pharmaceutical funding, while 1 in 3 had a financial interest in their work. In 2001, only 54% declared this interest. There appears to be a correlation between positive 'spin' on results with competing interest.

He went on to discuss 'missing' negative studies and the impact this can have on meta-analyses, and the ways in which fraud is detected. Even when detected, fraud is sometimes not reported for fear of recriminations from the fraudulent author. Signs to watch out for are studies that are unfeasibly large for the authors' resources, the data looking 'too good to be true' or counter-intuitive, or if the author puts undue pressure on the editor. Editors should be prepared to act on complaints about old publications, remembering that dishonest people are often dishonest more than once. Publishing declarations of concern, corrections and retractions are important measures for the future as well as for the scientific record.

There are many obstructions to investigating fraud: they are difficult and costly, and institutions can be in denial, whether due to their own conflicts of interest as employers, poor experience of conducting investigations and the increasingly international nature of research.

Authorship, guests & ghosts

Elise Langdon-Neuner, Director of Preclinical Documents & Scientific Communications, Baxter BioScience, Austria

Elise Langdon-Neuner spoke on guest- and ghost-authorship: a guest author is an author but shouldn't be, while a ghost author isn't an author but should be. Most guest authors are departmental heads, perhaps on the basis that having a 'big name' author can boost acceptance chances.

Elise next discussed why writing assistance is not acknowledged as authorship: ignorance, embarrassment and deceit. She called for all those involved in writing and approving content (including medical writers and publication managers) to be acknowledged. In looking for ghost authors, ICMJE guidelines state that editors should specifically ask for additional contributors not named by the authors.

Elise pointed out that very few journals have adopted the concept of contributorship, embodied in the ICMJE guidelines, to replace authorship. Of those that do ask for contributor statements, there is little if any vetting, and a study showed 70% unreliability between forms completed twice by the same authors.

Looking at why the ICMJE guidelines fail, Elise reported that many authors are not aware of, ignore or disagree with them. However, not even all journals use the guidelines: in one study only 29% of 234 journals' guidelines are based on them. Even one member of the ICMJE committee admits that the guidelines have serious flaws.

1 This report of the joint conference will also be published in the ICR members' journal, Clinical Research focus

Elise also discussed guidelines by the World Association of Medical Editors (WAME), which suggest that editors should alert the author's institution and share the information on the WAME list-server. However, again, not everyone is doing this; there is little incentive for publishers, pharmaceutical companies and the scientific community. The only people who are suffering are junior staff who are excluded from authorship, and the public who are receiving distorted information.

Ghostwriting: What's the problem?

David Healy, Professor of Psychiatry, Cardiff University

David Healy spoke on the drivers behind ghostwriting, including the potential for a pharmaceutical "blockbuster" to make or break a company and the increasing involvement of specialist medical writers alongside (or instead of) the independent investigators. He analysed the work of one medical writing firm, contrasting the impact factors and citation rates of their papers with other papers with the same named authors, and concluding that their involvement had had a significant influence.

He then considered the notion of 'disease mongering', and the influence of early papers in defining guidelines for future treatment, cementing the place of those treatments in the market. He suggested that this underpins companies' selection of authors and target journals.

David looked at studies on paroxetine (a selective serotonin reuptake inhibitor (SSRI), one of his areas of interest), in which many serious adverse events were not reported, and showed correspondence relating to the articles, demonstrating the conflicts of interest and their impact. He further discussed a meta-analysis of suicidal acts with SSRIs which was declined for publication and listed a number of journals where his own articles were declined for 'legal reasons' and fear of litigation.

He finished by stating that the altruism with which people have taken part in clinical trials since the 1950s has been undermined by the activities of pharmaceutical companies in restricting the publication of their results.

Panel discussion

Closing the morning session, the speakers took part in a panel discussion. The first two questioners asked why protocols are not routinely sent with article submissions and why submitted papers are not routinely checked against their registry entries. In both cases Harvey Marcovitch said that this was simply a matter of insufficient resources, but reviewers are now able to check.

The next questioner discussed ghostwriting, highlighting the difference between preparing the paper with clarity and following guidelines, and taking responsibility for the scientific decisions, analysis and interpretation in the paper. David Healy responded by saying that this wasn't so much the problem but that the raw data should be made publicly available for verification. Delegates responded by suggesting that this should be extended to all studies, not just those sponsored by the pharmaceutical industry.

A delegate questioned the role of the regulatory authorities in determining whether the full data from a study had been made public. There was some disagreement on whether regulators analyse study data or just examine expert reports, and whether requested data is given, in full or in part. Another delegate suggested that protocol and result registries would aid this although David argued that the raw data should be published rather than summary reports. Harvey welcomed this development, but also expressed anxiety about the completeness of the data, particularly the reluctance of pharma companies to share commercially sensitive information during a competitive time window.

A journal editor's perspective of industry practices

Trish Groves, Deputy Editor, British Medical Journal (BMJ)

Trish Groves, deputy editor of the *BMJ*, gave her viewpoint as a journal editor. Trish discussed article placement in journals, suggesting that primary research articles *create* influence while secondary articles *spread* influence. She talked about the journal acting as a gatekeeper, having its own brand and commercial interests, and outlined the *BMJ* brand of aiming to help doctors make better decisions; providing truthful, clear, and engaging writing; and taking a tough stance on misconduct. She suggested that research misconduct is widespread, but it is hard to detect and stop. She also argued against the belief that journals are anti-pharma.

Trish went on to discuss transparency in reporting, mentioning a 2006 *BMJ* paper which suggested that industry-sponsored reviews were of lesser quality than Cochrane reviews, and how results were always in favour of the sponsored drug. However, a similar study in 2007 suggested that things had improved, but there was still a problem with the conclusions drawn from data. She suggested that there is some 'spin' in all research articles and that there is an argument that articles should end after the results section to leave readers to draw their own conclusions from the findings. The counterargument is that this would make articles difficult to read by not placing the results in context.

Her four simple points of advice for dealing with journals effectively were: get to know the journal and their brand, follow the editorial instructions and policies, ask the editor's advice before submission, and don't be afraid to tell the truth; her phrase was "Life is messy; show us your mess". She also outlined the *BMJ*'s requirements for papers on drug trials: transparency policy, request of the protocol, statements, registration, and compliance with guidelines.

The new Food and Drug Administration requirements on registration and disclosure of trial results were then talked about. For example, it is now a requirement to register the trial (on clinicaltrials.gov) and provide tables (both raw data and statistical tests) for outcome measures and information on adverse events grouped by organ system. In addition, results must be posted within a year.

Trish concluded by discussing transparency in secondary (review and educational) research articles. At the *BMJ* they ask: have you been asked to write this (referring to

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commissioning), have you been paid to write this, did a professional writer work on this? She assured that even if the answer to any of these questions is yes, the article will still be considered for publication. It seems that it is the transparency that is the key.

Publication policies: Why every company needs one

Liz Wager, Publications Consultant, Sideview

Liz Wager's presentation focused on publication policies stating that every company should have one and keep it up to date. Liz started by looking back to the 'dark ages' when drug companies used to have a free rein with study data and frequently used ghostwriters, but this meant that the scientific record was distorted and consequently patients suffered. Now things have changed, journal editors ask more difficult questions and companies can be sued for non-publication of results. She also made the point that editors can now publish damning reports if companies misbehave.

Liz went on to distinguish between professional medical writers and ghostwriters and talked about the EMWA guidelines, which state that the use of professional writers should be acknowledged.

She then examined the risks of not having a publication policy, these were: authorship disputes, delayed publications or rejections, poorly informed and inconsistent publication decisions, and negative publicity. Conversely, the benefits of having one include: it is an efficient way of working which survives despite staff changes, it facilitates internal and external communication, and it strengthens relationships with authors and editors. The importance of devising this policy early enough and integrating it with the protocol and study negotiations was also highlighted. She suggested the process of developing a policy is also useful, and that it should become part of a company's brand and identity (i.e. being ethical can be a selling point).

Liz went on to discuss various elements that should be included in a publication policy. For drug companies, she suggested: investigator contracts, access to data, authorship policy, commitment to publish all trials, and the right to comment and/or delay trial registration. For agencies, she suggested: policy for acknowledgements, process (e.g. good publication practice [GPP]) and quality (e.g. CONsolidated Standards Of Reporting Trials [CONSORT]) standards, avoiding redundant publication and plagiarism. She closed her presentation by running through the guidelines available, including the Declaration of Helsinki (which is committed to publishing negative findings), ICMJE, EMWA, and GPP.

The view from 'big pharma'

Valerie Siddall, Global Director of Publications, AstraZeneca

Valerie Siddall closed the day by giving the perspective of a pharmaceutical company. Valerie started by suggesting that publication policy is about reputation, so everyone in this industry should really care about it. She argued that single events are behind headlines, and that single events can affect reputations that may have been built up over many years. She went on to suggest that publication policies should be clear, current, well-communicated, widely understood, and followed.

Throughout her presentation, Valerie gave her 'top tips'. One of these was "if you have a publication policy, share it" with internal staff and external providers (for example, investigators, contract research organisations, collaboration groups, authors, communications agencies/writers, licensing partners). Valerie talked about giving careful thought to communication and training in the publication policy, she suggested important factors were: sponsorship at the most senior level, having a passionate owner, targeting to your audience, and making it relevant, interesting, and fun.

She then discussed factors important in the effectiveness of a policy (coverage, clarity, consistency, level, differentiation versus other pharma companies) and how staff and agencies must follow the policy (compliance, use of internal audit group).

She concluded her presentation by suggesting that policies are tested by getting the opinions of investigators and authors, and reiterated the importance of keeping the policy current by using regular review cycles.

Panel discussion with Q&A

Some interesting points were raised in the panel discussion at the end of the afternoon, based primarily on the topic of publishing research results. One delegate thought that it was worrying and impractical for pharmaceutical companies to have to publish all results, and that there would be an information overload if all data were available in this way. They went on to suggest that it would then be difficult to distinguish what was relevant and what wasn't. Members of the panel suggested that it is most important to publish trials related to marketed products; in other words that it is ethical for companies to publish all data for a product that is being sold. During the discussion, it was also suggested that systematic reviews could be used to prevent information overload and remove bias from results. It was also pointed out that programmes such as CDISC could be used to make raw data available. The final discussions centred on whether there is an ethical obligation to publish and whether medical writers have a responsibility to be ethical.

Conclusion

In conclusion, this proved to be a very interesting, lively, and sometimes controversial day symposium, which was enhanced by the interesting variety of speakers who all had their own differing viewpoints on the current role of ethics in publishing clinical trials. Here's hoping that similar, equally successful symposia will be organised jointly by the ICR and EMWA in the future.

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Four letter words and others (3)

by Alistair Reeves

I start this time with a word you might not expect to see here: *some*. I recently edited a set of 130 narratives from different authors in oncology patients, and *some*, as an adjective, was often used not incorrectly, but inappropriately for the written context of our work. This is followed by a few words about *upon*, much more about *either*, and finally I explore the use of that innocent-looking word, *nor*. All have one thing in common: not surprisingly, they are used more loosely in spoken than in written English, which means that care is due when using them in written texts.

Some

Three examples from narratives:

He had reported some headache in the 4 weeks before the study treatment was started.

According to the patient, she had had some pain in the leg before she was admitted to the emergency room.

She had had some diarrhoea after starting drug X and took OTC loperamide without consulting her doctor.

"What is wrong with these?" you ask. Nothing is 'wrong' with them; but you can literally *hear* the patient speaking here, and this illustrates very well that *some* used as an adjective in this way is a constant feature of spoken English, but that when you write it, the meaning is imprecise. The general feeling when speaking is that *some* used in this way means that the symptom was not severe, occurred infrequently or was transient. But what does *some* really mean in these examples? A few episodes of headache, or just slight continuous headache? Intermittent pain, or just a dull ache, or a few episodes of shooting pain? Continuous diarrhoea for 2 days or isolated episodes over an extended period? Often when writing narratives, you don't know. Had the word *some* plus the symptom been enclosed in inverted commas in these examples, it would have been clear that the patient (or investigator, i.e. CIOMS form) was being quoted and signals to the reader that *'We have only this information and cannot supply anything more precise'*.

Quote from a patient leaflet: *You may have some blurred vision for a short period after you start taking drug X.*

What is this supposed to tell the patient? The culprit here is not only *some*: what is a *short* period? Several hours, several days? The intention is obvious: not to alarm the patient by suggesting with *some* that blurred vision may occur, and that it most likely will be mild and transient. Whatever the case, the statement should be more precise, e.g.: *You may have mild blurred vision in the first few days after you start taking drug X.*

Either

Either is a real all-rounder: it can be an adjective, a conjunction, a pronoun, or an adverb. When using *either* as an **adjective**, take care that it cannot be misunderstood as a conjunction:

The antiproliferative effect of the combination was compared to that of either monotherapy on two breast carcinoma cell lines (EMT-6, 4T1) in a concentration range of 1 nM to10 µM for DRUG A and 10 nM to 100 µM for DRUG B.

This sentence is complicated by the fact that the effects of each drug as monotherapy were compared with those of the combination, but the effects of the individual drugs were not compared with each other. Maybe you were lucky and read *either* as an adjective and therefore didn't feel lost at the end of the sentence. If you read it as a conjunction, expecting an alternative introduced by *or* after the clause following *either*, then you will have been lost at the end of the sentence and had to backtrack. It is our business to know when we might make readers backtrack, and avoid it where we can. With the same word order, this could have been avoided here by saying *each* or *the individual drugs* instead of *either*.

You might also consider changing the word order: *The antiproliferative effect of the combination on two breast carcinoma cell lines (EMT-6, 4T1) in a concentration range of 1 nM to10 µM for DRUG A and 10 nM to 100 µM for DRUG B was compared to that of either monotherapy*.

With this word order, it is much less likely that *either* would be read as a conjunction, but, for me, the 'basic' subject (*The antiproliferative effect*) is too far away from the verb (*was compared*). The actual 'compound' subject in this sentence is enormous. It stretches from *The antiproliferative effect* to *DRUG B* because the information on the cell lines and the concentration range are positioned before the verb. So the problem with *either* may have been solved, but the sentence itself has not been improved. I am still not keen on *either* because what is really meant is *both*, so would probably prefer *both individual treatments*. I am not yet at the stage where I feel comfortable with monotherapy in the plural.

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>>> Four letter words and others

In the following example, *either* is used as a **conjunction** together with its frequent conjunction partner *or*, indicating a choice between alternatives: *The Territory Managers will return the specified items to CPG, or to Head Office, with the appropriate forms, clearly marked either for reworking or destruction*.

Purists would say here that you should say *for either reworking or destruction*, or, if you want to have *either* before *for*, then *for* has to be repeated before destruction. This is because they consider that the entire phrase *for reworking or destruction* is governed by the *either* as a single element and claim that a further possibility is required, otherwise the sentence is incomplete: ... *clearly marked either for reworking or destruction, or for filing in the central archive*. For me, the original sentence would only be misunderstood or held to be incomplete by a bad-willed reader, and I don't waste time correcting this sort of very marginally incorrect positioning of *either* as a conjunction, unless I think it will lead to confusion, which not often the case.

A further example of this is: *After treatment of the animals either with DRUG A or DRUG B as described above, they received 5–bromo-2-deoxyuridine (BrdU) after the last treatment to label mitotic endothelial cells*.

Again, some might insist on ... *of the animals with either DRUG A or DRUG B*. At the risk of sounding to lax, I no longer do.

An interesting conjunctional use of *either* in the sense of 'not any more than the other' is positioning it at the end of a sentence as a linking word: *Clearance of DRUG X was rapid and there was no evidence of accumulation in plasma; although clearance of the vehicle was much slower, there was no evidence for accumulation in plasma either*.

This is the sort of sentence you will *hear* every day. I stress the word 'hear', because this is a good example of a correct formulation that you would not normally write in scientific texts because it sounds too 'spoken'. In conversation, you might say *We didn't find any impurities in the sample*, and your conversation partner might answer *No, we didn't find any either* (or *Neither* or *nor did we*, of course). What is the solution if you want to express the same idea in writing so it doesn't sound spoken? Here are two possibilities, but there are certainly more.

... although clearance of the vehicle was much slower, there was also no evidence for accumulation in plasma, or *Clearance of DRUG X was rapid and there was no evidence of accumulation in plasma, nor was there evidence for accumulation of the vehicle, although it was cleared much more slowly.*

Example of *either* used as a **pronoun**: *Clean the slides thoroughly with fresh water or alcohol; either is suitable*. When used as an **adverb**, there is clear overlap with its conjunctional use: *Either reuse the slides after thorough cleaning with alcohol or discard them.*

Upon

I have yet to find an instance where the preposition *upon*, frequently used when speaking, cannot satisfactorily be replaced with *on* when writing in our context. *Upon* does not sound 'better' than *on*. It is acceptable if it forms part of a collocation, e.g. 'to put upon' (I don't want to put upon you, but …[=I don't want to cause you unnecessary effort, but…]), 'Once upon a time …', 'The holiday season is almost upon us', but in almost all cases such collocations are used only when speaking or in non-scientific writing.

Nor

Nor is a conjunction and is therefore a linking word. I was recently asked whether *nor* is dropping out of common use in English. My questioner had noticed that when 'native speakers' used *neither* they 'usually' followed it 'these days' with *or*. I have noticed this too, but would not say that it is 'usual', and it happens mainly when people are speaking. *Either…or…, neither… nor…* was what we learned at school, and this still holds true for writing. Here is an example from a text I edited:

Neither Method 1 or Method 2 was chosen; we selected Method 3 because ...

This should clearly be: *Neither Method 1* ***nor*** *Method 2 was chosen; we selected Method 3 because* …. And I make no exceptions to this when editing.

Nor without *neither* is a useful linking word, as in the examples for *either* above and the following:

... and there was no evidence of accumulation in plasma, nor was there evidence for accumulation of the vehicle.

The physician admitted that he had failed to measure the blood pressure according to protocol, nor had he documented the ejection fraction correctly.

Note: When *nor* is used in the above way, the subject and verb are ***always*** inverted (a rarity: a 100% rule in English).

Caution with *nor*: it can sound poetic or formal because of the subject-verb inversion and because it can help in presenting an idea in a compact phrase, a device often used in literature. Its perhaps most illustrious use in English is in the *Rime of the Ancient Mariner* by Samuel Taylor Coleridge:

> *Water, water, every where,*
> *And all the boards did shrink;*
> *Water, water, every where,*
> *Nor any drop to drink.*

(often misquoted as: *But* or *And not a drop to drink*)

The necessary inversion of the verb and subject after *nor* without *neither* is not a common device in English (the most frequent use is in conditional phrases such as *'Had we selected the nonparametric model, we would have …*, *Were we to opt for a twice-daily regimen, we might…*). This can lead to text sounding a little too 'literary': *A marked increase in AUC was not seen, nor was expected*.

Four letter words and others

This compact formulation is acceptable and grammatically correct, but some authors prefer to avoid this type of formulation in scientific texts. e.g.: *A marked increase in AUC was not seen, and (this) was not expected*, or *A marked increase in AUC was not expected and was not seen*, or the very compact *A marked increase in AUC was neither expected nor seen*.

The number of the verb after *nor* coupled with *neither* depends on the number of the subject nearer to the verb:

A) Neither the study physician nor the study nurses were present
B) Neither the study nurses nor the study physician was present.

If both nouns are singular, the verb is in the singular; if both nouns are plural, the verb is in the plural:

C) Neither the study nurse nor the study physician was present
D) Neither the study nurses nor the study physicians were present.

I must add, however, that when speaking, many people (including me, as I am unfortunately not consistent here) spontaneously use 'were' for examples B and C, because the feeling is that the subject of the verb is a plural idea.

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How to shorten text—we owe it to our readers

A little thought can relieve the reader of a great deal of stress. Consider the following:

Observation of neurobehavioural variables, automated motor activity (CNS) and assessment of the respiratory function were performed in male rats at <NameX> doses of 0.5 mg, 1.0 mg and 2.0 mg/kg b.w. lipid-complexed <drug>. The CNS variables were measured 5 min, 6 hrs and 24 hrs post-dosing, whereas the respiratory measurements were done 5 min, 15 min, 30 min, 60 min and 150 min post-dosing.

No effects were observed in any of the neurobehavioural variables measured after the treatment with <NameX> at any of the dose levels and time points tested. Likewise no effects of <NameX> treatment, neither as a main treatment effect nor as an interaction with the time were observed demonstrating that the breathing activity, the tidal volume and the ventilatory flow were not affected at any of the dose levels and time points tested.

The first reaction is to make the following changes (amongst others):

- Delete the unnecessary abbreviation 'CNS' in the first sentence (It had been used before in the text to denote 'neurobehavioural variables' and 'automated motor activity').
- Use 'h' instead of 'hrs' as the abbreviation for 'hours' ('hrs' is not the scientific abbreviation, and units are never used in the plural).
- Remove inappropriate definite articles, e.g. before 'respiratory function' in the first paragraph and 'time' in the second paragraph (controversial).
- Substitute 'after dosing' for 'post-dosing' (jargon).
- Change 'neither' and 'nor' to 'either' and 'or' in the second paragraph (double negative because it says 'no effects' earlier in the sentence).

Then you start to think: ***but what are these two paragraphs actually telling me***? They are telling me: 'We did this and saw nothing'. Obviously the text cannot be reduced to this, but it can be reduced by two-thirds and retain the same message:

Neurobehavioural variables, automated motor activity and respiratory function were assessed in male rats at <NameX> doses of 0.5, 1.0 and 2.0 mg/kg b.w. lipid-complexed <drug>. CNS variables were measured 5 min, and 6 and 24 h after dosing, and respiratory function 5, 15, 30, 60 and 150 min after dosing. No effects were observed.

The first paragraph is simplified by:

- Removing the active linking voice by putting the action in the sentence into a verb, in this case: 'were assessed' instead of 'Observation of … and assessment of … were performed', and choosing a new subject, in this case, the variables that were determined.
- Taking out the repetition of units.
- Taking out the confusing conjunction 'whereas': this is too strong a linking word for this situation. 'Whereas' implies a degree of unexpectedness or 'unusualness', or that something special has to be taken into consideration. This is not the case here: all the author wanted was to list the measuring times for different sets of variables, and the times for each happen to be different, which is not surprising. This is achieved by simple 'and'.

And, as you see, the second paragraph can be reduced from 72 words to 4, because the message you want to leave with the reader is: *No effects were observed*.

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Definitely not Shanks' pony

by Alistair Reeves

The proverbial Shanks had the unfortunate problem, as I do, that his name ended in an *s*[1] (it is the same with a *z* or an *s* that sounds like a *z*)—so what do you do to indicate the possessive? Marcel Milcent of Rio de Janeiro, Brazil, noticed in a past issue of *TWS* [1] that Karen Shashok referred to *Hames' book* in her book review, and asked whether it should have been *Hames's*.

What you do to form the possessive in such cases depends on many factors:

- A rule you learned sometime but which you often see and hear contravened, so you are unsure.
- How you feel.
- Whether the sibilant ending is preceded by a vowel, whether the vowel is voiced, and whether the vowel is long or not.
- Whether the sibilant ending is followed by a vowel.
- Whether you are speaking or writing.

Most of these influences are exerted subconsciously which makes this a complex business. But then language and the business of language are never simple. This is also the sort of thing that overzealous editors just love to 'correct', so people are sensitized to its controversial nature. We never want it to look as if we 'don't know the rules'. One of the rare occasions when you can actually 'hear' and 'feel' the apostrophe is when one of these editors snootily crushes you into red-facedness by tut-tutting and crossing out with great relish the *'s* you put after Jones when you wrote 'Jones's book' (or the reverse). But what is wrong with Jones's book? And shouldn't the editor be concentrating on more important things?

The cast-iron rule enforced when I was at school in England in the 1960s was: if the name ends in *s*, you add just an apostrophe and say the name as if it did not have an apostrophe (i.e. not rhyming with *sez* or *zez* at the end). So Jeeves' book—and not Jeeves's (*Jeevezez*) book—was correct. Why then did I hear people saying: I hate Tom Jones's (*Jonesez*) songs? Why, whenever my grandmother missed a bus, did she sigh and say: Well, it looks like Shanks's (*Shanksez*) pony again![2] (I never dared correct her!) And why did I read about *King Midas*' (not *Midasez*) daughter in my book of Greek myths, and Laertes' (not *Laertesez*) father in *Hamlet*? I first assumed that this was something to do with living in the North of England (and the funny way we speak 'up North'), but seeing St. James's Park (*Jamesez*) on the tube when visiting London told me that this couldn't be the case.

Every style guide contains rules and recommendations for this, and you can find any rule or recommendation you want in books and on the Internet. I have tried all of them—and I still can't decide.

I quote only the Chicago Manual of Style [2]. First it says that the ***general rule*** is to add *'s* to monosyllabic names, and goes on to say: *How to form the possessive of polysyllabic personal names ending with the sound of s or z probably occasions more dissension among writers and editors than any other orthographic matter open to disagreement.* This definitely also applies to monosyllabic names, and is one area where the exception does not prove the rule. This sort of statement usually means in plain text: *We are dealing here with a lost cause where no-one will ever agree; we should see to it that we are consistent within our own use and patiently allow ourselves to be 'corrected' occasionally by pedants. But do not waste your time 'correcting' others: it's not worth it!*

They do, however, follow the above with advice worth following because at least it gives you something to go on: *If it* (the polysyllabic name) *ends with a z sound, treat it like a plural (e.g. Dickens', Hopkins', Williams'); if it ends with an s sound, treat it like a singular (Harris's, Thomas's, Callas's)*. If you think about it, this follows the way we speak. I think we are much more likely to say I like *Hopkinz* books than *Hopkinzez* books, for example.

So, according to the Chicago Manual of Style, Karen Shashok should have written Hames's (monosyllabic, apply ***general*** rule), even though Hames' looks fine to me, and, I think, to many others; had she been writing about a book by Dickens, Karen should have written Dickens'. The Chicago Manual of Style and many other sources wisely

1 Good Writing Practice (GWP?) would be to enclose all the references to 's' and 'z' and 'sez' and 'zez' sounds and all the examples here in inverted commas, but I think you'll agree that this would have made this text just about unreadable. So I have made them all italic instead.

2 'To take Shanks's pony' (as far as I am aware, always spoken as Shanksez) means to go on foot. I always imagined a poor Mr Shanks who could not afford horses or coaches and had to walk everywhere who immortalized this saying. I had never thought of this before, but now I have looked it up and learned that the 'shanks' here are actually the legs (as in 'lamb shank'), so all it actually means is that you have to 'use your own legs'.

Definitely not Shanks' pony

shrink away from suggesting how you might pronounce these written formulations. Even though Dickens' might be appropriate when written, I can well imagine just *Dickenzez* novels when spoken.

I hesitate to talk about rules, but I will stick my neck out and say that the ***general pattern*** seems to be:

- Monosyllabic names (James, Reeves, Lars, Katz): add just the apostrophe and say the name as it is said without an apostrophe, or add *'s* and say the name with *sez* or *zez* on the end, whichever is appropriate and whichever you prefer.
- Polysyllabic names (Anders, Summers, Peters, Dolores): add just the apostrophe and say *sez* or *zez* at the end if you want, but this is unusual (e.g. "Let's go to *Anderz* office" and not "Let's go to *Andersez* office"), unless the *s* is preceded by a long or stressed vowel (e.g. Laertes' [*Laerteez*] sword and not *Laerteezez* sword, but Delius's [*Deliusez*] music and not just Delius' music).
- People with names ending in –ce, -ze or –se make life easy for us, and they gain an extra syllable in the possessive: Mace's (*Macez*) conclusions, Furze's (*Furzez*) hypothesis, Chase's (*Chasez*) film.

Now I know why my grandmother talked about Shanks's (*Shanksez*) pony (monosyllabic, so she added the *'s* at the end and transposed this to a spoken *sez* at the end—although I expect she never thought about it).

I do not, however, follow one recommendation of the Chicago Manual of Style to do with possessives and names:

When a proper name is in italic type, its possessive ending is preferably set in roman:

Example: *Boris Godunov*'s impact on the audience.

Why make our business any more complicated than it is?

Whatever: this all sounds like yet another good reason to get rid of the apostrophe in English. Try to be consistent with this one (but I bet you won't be!).

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Bleeding nuisance

A quirk of English is that patients can suffer from *bleeding*, *nosebleeding*, *major bleeding* or *secondary bleeding*, but not *bleedings*, *nosebleedings*, *major bleedings* or *secondary bleedings*, or, in fact, any *bleedings* at all. Like *information* and *advice*, *bleeding* is used only as an abstract noun, is therefore uncountable, and cannot be used with the indefinite article (*a*, *an*) or in the plural. *Bleeding can usually be stopped rapidly by applying pressure to the wound* is correct use; *The supplementary items on the AE form must be completed for AEs that involve bleedings* is not.

The pressure of usage sometimes turns abstract nouns into mixed nouns and makes them both countable and uncountable; *medication* is an example of one such noun. But this has not yet happened with bleeding. *Bleed* is countable and the correct term to use: *The patient suffered three nosebleeds in the 24 hours after intake of study medication*; or *The gastrointestinal bleeds occurred in the duodenum*.

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Be particular about *particularly*

Qualitative statements are never easy to write, and a commonly used word in such formulations is *particularly*. It is often used indiscriminately in conversation, but I think you have to be particular about how you use *particularly* when writing—and think about what it really means. For me, it is not appropriate here:

Drug X substance is a quantified extract from green tea leaves of the species Camellia sinensis, containing mainly tea polyphenols, including a family of related flavonoids, particularly catechins.

I suspected that what the author actually wanted to say here was *consisting mainly of catechins* or *of which the majority are catechins*, but after speaking to her, it emerged that she meant *almost all of which are catechins*. This meaning is not captured by *particularly* in the original sentence. 'But I copied it from a paper published by a native speaker …' was her response. No comment.

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In the Bookstores...

Nice book, useful guide

Silvia M. Rogers. Mastering Scientific and Medical Writing. A Self-help Guide. Heidelberg: Springer, 2007. ISBN 978-3-540-34507-7 (Paperback). Euro 26.70 GBP approx. 21.06. 147 pages.

The weight of experience in an objective work. This was the shortest (and most faithful) definition I could find for this book from Silvia M. Rogers. The author brought her knowledge in the field and her teaching skills together, and fused them into an easy-reading, straightforward piece. She had the obvious advantage of lecturing on scientific writing, thus having the opportunity to identify the issues students feel more difficulty on, but this does not diminish her accomplishment.

The book is composed of eight chapters followed by six appendices and 12 exercises. The first chapter gives us orientation about good versus poor scientific writing, setting some goals to be addressed further on. The part on "The Plain Language Movement" is a good reminder of the efforts towards high quality, less bureaucratic scientific writing. "The BASO Pyramid of Scientific Writing" part is an example of the didactical armamentarium the author uses in her classes. A section about myths and misconceptions pays attention to the errors that remain due to tradition and confusions between different languages.

The next two chapters focus on orthography, punctuation and grammar, with regard to the characteristics of scientific texts. The simplicity with which the text runs and the objectiveness of what is conveyed made me enjoy this usually dull part of any book or manual. Perhaps, as a non-English speaker I tend to value this part more than others do (as they have grown "inside"). A saying in the back cover states: "Although the book addresses certain issues more troublesome to scientific communicators of a non-English language origin, the guide will be of equal benefit to those whose first language is English." I cannot tell as an outsider, but I believe this will be proven true. Anyway, it is useful piece of information, and the book can be used as a guide as well, so when in doubt, one can take a peek.

The following chapter addresses style. It is incredible how sometimes one knows exactly what to do, and yet one gets tempted by bad habits to go in the opposite direction, as if making infinite sentences, full of prepositions and modifiers, and overusing of the passive voice would provide the text with the nobleness worthy of the related scientific work. Silvia Rogers gives us (I include myself in the tempted souls) a polite, wake-up "punch in the stomach" by remembering that the readers are the main goal, and what annoys them hampers the dissemination of information, just what the text author does not want. We Brazilians (I am not French, despite the name) use the passive voice extensively in any formal document; avoiding it in Portuguese feels almost disrespectful. Some habits are harder to brake than others.

The concern about discrimination in scientific writing is the scope of one chapter. The author shows "usual" phrases and citations that carry sex, race or age derogation and may offend the reader, and how to avoid them. Another chapter focuses on quoting published material—an everlasting matter. A glance at the pros and cons of reference manager tools is given.

The appendices and the exercises are to be considered more than complementary. The former make the book a guide to look up when in need, ranging from punctuation and general rules to awkward phrases to avoid, and lists of academic degrees and honors. The appendix 10.5, "A Light-hearted View of Scientific Jargon", gives the book a touch of humor. The exercises are of extreme help to reinforce the ideas of their respective chapters and strengthen knowledge.

My advice to the readers would be: read it all once, including the appendices; do not skip the exercises; keep the book with you when you are writing to clarify any doubt; when you finish the manuscript, run a checklist on it with the book's rules and tips and make sure you followed them. It is a thin book you can take everywhere. It is a complete guide you should read always.

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Spot the difference

1) *All pivotal toxicological studies were designed and conducted in full compliance with current GLP regulations.*
2) *All pivotal toxicology studies were GLP-compliant.*

There isn't one. 40% of the original sentence says exactly the same!

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Keywords for *Mastering Scientific and Medical Writing. A Self-help Guide*

- Medical writing
- Non-English professionals
- Non-English students
- Scientific publications
- Scientific writing

Webscout:

Getting published

by Joeyn Flauaus

Writing a manuscript is quite a challenge. When you have almost finished writing your manuscript, you need to think about the next step which is to decide where to publish it. In an ideal world this would be the first step but in reality clients prefer to see the manuscript before they decide where to publish it. When adapting the manuscript to the specific journal style, consider your intended audience. Each journal has specific instructions for the submission of manuscripts for publication. The easiest way to access these instructions for authors is via the journal homepage. The instructions usually specify the length of a manuscript and, however difficult it may seem, you should avoid submitting a manuscript that is appreciably longer or shorter than specified. It is worth the effort to cut out every unnecessary word or phrase. Be precise and define the take-home message clearly!

I have put together a selection of articles, blogs and websites on publishing manuscripts and on Open Access Journal Publishing. These provide some useful tips and advice from the experts to help you to make your manuscript stand out.

Articles to help you preparing a manuscript for submission:

How to write a scientific paper--a rough guide to getting published:
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1511068

Ten Simple Rules for Getting Published:
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1274296

Blogs:

http://network.nature.com/blogs/user/mfenner

Gobbledygook: This is a blog on scientific publishing in the Internet age. General issues on how to write a good scientific manuscript are discussed. Hot topics like fraud in research are also covered.

http://network.nature.com/forums/askthenatureeditor/567

Join the discussion with the Nature *editors*: is language a factor that determines if you get published? Is a nicely written paper more likely to be considered for publication in the peer review process? Clearly, authors for whom English is not their first language face specific difficulties in writing a manuscript. It is a challenge to write precisely in a language that is not your first language. If you want to take part in the lively discussion on this important topic then visit the public forum "Ask the Nature Editor":

http://www.doaj.org/
Directory of Open Access Journals: this is a directory of free, full text, quality controlled scientific and scholarly journals. You can increase visibility via Open Access. The aim of Open Access Publishing is to ensure immediate online access to the full text of research articles. Readers or their institutions are not charged for access. Open Access journals perform peer review and make the approved contents available to all. Many traditional journals offer now an 'Open Access' or hybrid publishing option. In order to stay abreast with the new developments in the world of Open Access Publishing, I recommend the following blog:
http://www.earlham.edu/~peters/fos/fosblog.html

Once you have submitted your manuscript to the journal, the review process varies depending on the journal (e.g., whether the submission and review process is carried out online or not). Good luck with your manuscript!

If you find a page or a blog that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at: joeyn@web.de.

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A recipe for writing 'Materials and Methods'

Failure to include enough detail in the materials and methods section of a biomedical manuscript makes this section of the manuscript the one most often responsible for a journal rejecting a manuscript. An article published earlier this year in the medical writing tips section of *Chest* provides an excellent recipe for ensuring that writing your materials and methods section is a 'piece of cake'.

See: Foote M. Materials and methods: a recipe for success. *Chest* 2008;133(1):291-3. Available at: http://www.chestjournal.org/cgi/content/full/133/1/291

Journal watch:

Ghostwriting

by Adam Jacobs

Regular readers of *Journal Watch* will know that it's usually written by one of my highly trained team of medical writers, not by me. But since I'm such a generous boss, I'm giving my team the day off and writing this one myself. Well, actually, the articles I'm going to describe in this article have piqued my interest to such an extent that I can't resist writing it myself.

So what are these fascinating articles? The first is an article in *JAMA* published in April by Ross et al, which described an analysis of Merck's authorship practices, based on documents obtained during litigation against Merck [1]. I'm also going to discuss a couple of editorials that appeared in response to it: one in the same issue of *JAMA*, written by *JAMA* editors [2], and the other in *Nature Biotechnology* [3].

The stated objective of Ross et al's article was to 'describe the practice of guest authorship and ghostwriting related to rofecoxib'. A good place to start would be to define 'guest authorship' and 'ghostwriting'. As most EMWA members will know, a guest author is someone who is listed as an author on the paper but has not made sufficiently substantial contributions to the paper to deserve authorship status, and a ghostwriter is someone (usually a paid medical writer) who has written the paper and not been acknowledged for their work, either as an author (often inappropriate anyway for medical writers) or even through a mention in the acknowledgements section (which is always appropriate).

Ross et al do indeed start there, and their definition of guest authorship is sensible enough: 'the designation of an individual who does not meet authorship criteria as an author'. OK, that's not completely precise, as there is no universally agreed definition of authorship criteria (although the ICMJE criteria are widely accepted as the best definition we have), but that's the way the world is and there's not much that Ross et al can do about it. However, their definition of ghostwriting is more problematic: 'failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript'. The problem there is that professional medical writers frequently don't merit designation as an author, but rather a mention in an acknowledgements section. Ross et al's failure to appreciate that important point leads to many problems with the interpretation of their results.

Another limitation of their paper is that they don't actually present any numerical results relating to guest authorship and ghostwriting. We are told that the practices were 'frequent', but nowhere are we shown actual numbers or percentages. Much of the paper is given to examples of supposed guests and ghosts in individual papers, but we have no information on how representative those papers are. And some of the examples aren't very convincing. An external author appears to be assumed to be a guest if there is evidence that a Merck employee drafted the manuscript. That's applying an unusually broad definition of guest authorship. Only one person can draft a manuscript, so by that definition, every paper that's ever published with more than one author would have guest authors. Provided someone makes important intellectual contributions, there is no reason why that person can't qualify for authorship even without drafting the paper.

What constitutes an 'important intellectual contribution'? It's hard to say. There is no universally agreed definition. Ross et al maintain that if an author makes only 'minor edits' to a draft, that doesn't count. I'm not convinced. A medical writer who is not qualified to write about the subject, but is nonetheless good at her job, may write an excellent first draft that needs very little editing. No-one would want the author to make sweeping changes just for the sake of it, if in fact the draft is already pretty good. But it is nonetheless important for an expert to validate the work of the medical writer, even if few changes need to be made to a draft, and I would argue that that constitutes an important intellectual contribution. It is, of course, possible that the supposed guest authors had already made some contribution before the first draft was produced, as indeed is recommended in the EMWA guidelines [4].

As an aside, we can get some idea of what the authors of the paper consider to be important intellectual contributions from looking at their own output. One of the authors of the paper, Harlan Krumholz, was a named author on 70 papers indexed in Medline that were published in 2006 alone. That's more than one a week. On the assumption that Dr Krumholz has other things to do besides writing papers, I think we can assume that his 'important intellectual contributions' don't take very long.

Examples of ghostwriting are equally woolly. We are given evidence that a medical communications company was involved in writing some of the papers, and this is presented as automatic evidence of ghostwriting. According the definition of ghostwriting accepted by EMWA and other bodies such as the World Association of Medical Editors

(WAME), it would only be ghostwriting if the medical writers were absent from the acknowledgements section, but we are not told anything about whether the medical writers are acknowledged or not. One of my greatest annoyances with Ross et al's paper is that it presents professional medical writers as automatically a bad thing, and completely fails to recognise that, when properly acknowledged, they have a perfectly legitimate role.

The conclusions of the paper don't follow from the data. We are told that 'Merck used a systematic strategy to facilitate the publication of guest authored and ghost written literature'. That's quite a leap of faith from seeing that some papers might have had guest authors and ghostwriters to saying that there is a 'systematic strategy', for which no evidence whatsoever is presented. One might be tempted to speculate that if Ross et al had had the benefit of a professional medical writer to help with their paper, such logical fallacies could have been avoided. One sensible conclusion they do draw, however, is that medical writing assistance should be fully disclosed, although disappointingly, they present this as if it were their novel idea. This was, of course, an important part of the EMWA guidelines, published in 2005 [4], and also mentioned in the GPP guidelines in 2003 [5], and I'm pretty sure that the GPP authors weren't the first to think of it.

Perhaps none of this should be too surprising, coming from a group of authors involved in litigation against Merck (who, to their credit, are at least completely honest about that involvement). What is frustrating is that the tone of the article by Ross et al is mirrored by the accompanying editorial by DeAngelis and Fontanarosa [2]. There is again a presumption against Merck, with statements such as how Merck 'manipulated' publications, despite a complete lack of evidence that a single article was 'manipulated' in the sense of inappropriate influence of the content. The editorial also reiterates *JAMA*'s previously published and utterly bizarre policy that all industry-sponsored studies submitted to *JAMA* for publication must have been independently analysed by an academic statistician. It's not clear whether the academic statisticians are supposed to do this out of the goodness of their heart, or if they are not, how they are to maintain their independence while being paid by the pharma company. But more importantly, there is a worrying assumption by *JAMA* here that analyses by industry statisticians are somehow less trustworthy than those by academic statisticians. Anyone who appreciates the highly regulated environment in which industry statisticians have to work will find that assumption as astonishing as I do.

The editorial in *Nature Biotechnology* [3] takes a much more balanced approach. It makes some of the same points I have made above. It also points out that the data in Ross et al's paper come from documents collected a good few years in the past (the cut-off date for the documents examined was 2004), and a lot has changed since then. At the time of the earliest documents (1996), no-one thought much about ghostwriting. Things have changed greatly in the present decade, with the publication of GPP guidelines in 2003 [5] and the EMWA guidelines in 2005 [4], and a whole host of other commentaries as well. Perhaps if some of Merck's papers were ghostwritten, it is more to do with the fact that no-one had appreciated the need for transparency then, rather than any 'systematic strategy'.

The *Nature Biotechnology* article also highlights the important roles that journals have to play in ensuring all contributions to papers are properly acknowledged and transparent. The *JAMA* editorial makes much of how dreadful it is that medical writers' contributions go unacknowledged, but very few journals ask specific questions about the role of medical writers, and those who do so have only started to do so recently. I am currently involved in an international team of medical writers who have been preparing a checklist designed to help journal editors assess whether a medical writer has been involved in a paper, and, if so, whether that involvement was ethical and appropriate, and thus to ensure proper acknowledgements are given in the paper. We intend to publish this checklist soon (watch this space!), and hope that journal editors will take it up to help make ghostwriting become increasingly rare as medical writers are properly acknowledged for their role.

Now, given some of the flaws in their paper, it is tempting to dismiss the article by Ross et al as simply anti-industry rantings and thus something that we can happily ignore. In my opinion, this would be a mistake. Although it is certainly true that there is much unfounded industry-bashing in the article, there are also some genuine and important criticisms hidden among it. For example, there is at least one example of a paper that was apparently written in complete first draft form before the named author was identified. If true, that is something I certainly would not condone, and is a clear breach of the EMWA guidelines. If Merck did write papers in this way in the past, I very much hope they no longer do. And whether or not ghostwriting is as common as Ross et al would have us believe, there is no doubt that it still exists, so there is no room for us to be complacent.

So, despite the temptation to go on the defensive when faced with an article like the one by Ross et al, we should resist that temptation, and redouble our efforts to make sure that the manuscripts we produce are absolutely in accordance with best practice. This means not only that the role of the medical writer must be transparent, but that the named authors must play a genuine part in the development of the manuscript. Recently, and particularly while writing this article, I have been thinking about the way we prepare manuscripts at Dianthus Medical. While I am confident that we ensure named authors play their full part in developing manuscripts, I have nagging doubts about whether we could prove it if any of our clients were to find themselves in a similar position to Merck, with all their documents opened to public scrutiny. Our regulatory writing is

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thoroughly documented at every step of the way, to ensure compliance with Good Clinical Practice (GCP), but our documentation is less thorough in the unregulated process of manuscript development. One of my next tasks will be to review our SOPs to ensure that author involvement is always thoroughly documented. If you are involved in writing manuscripts, could I suggest that this could be a good time to look at your SOPs with a similar eye?

As a final thought, at the recent EMWA conference in Barcelona, I led a lunchtime discussion session devoted to the articles I have described here. I went into it expecting lively discussion, but it was rather sedate. With hindsight, I should have realised that lively discussion was not to be expected: there is nothing controversial in the ghostwriting and guest authorship debate. Almost everyone agrees that guest authors and ghostwriters are a bad thing. The challenge for all of us is to ensure that the unethical practices that still persist be rapidly consigned to the dustbin of history.

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Can things do anything but develop *over time*?

The passage of time from one state to a later state is inherent to the meaning of *develop*, so adding the adverbial phrase *over time* in this sentence adds nothing to the meaning of *develop*: *CRPV-induced papillomas in rabbits become strongly keratinised and develop a crusty appearance over time, which may have compromised drug delivery to the affected skin layers*. The author here actually wanted to bring in the idea of *slowly*, and my empirical observation is that this is usually the intent when *over time* is thoughtlessly tagged on to the verb *develop*. If this is what you want to say, you should say it, and better still: quantify it in some way if you can. In this case it was possible: ... *and develop a crusty appearance after about 10 days of treatment*.

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Ghost management: Beyond ghostwriting

"Ghost management of medical research and publishing: when pharmaceutical companies and their agents control or shape multiple steps in the research, analysis, writing, and publication of articles."

This definition was coined by an essay in *PloS Medicine*[1] which considers the extent to which the entire medical literature and research behind it is managed by the pharmaceutical industry for marketing purposes. The writing of the manuscript may not be the key point at which behind-the-scenes influence is exerted; study design, statistical analysis, or the choice of placement of manuscripts may be equally important. Compounding this some publication planning firms that service the industry are part of businesses run by publishers, e.g. Excerpta Medica which advertises that its "relationship with Elsevier allows…access to editors and editorial boards who provide professional advice and deep opinion leader networks." This is not uninteresting in view of the Committee of Publication Ethics' (COPE)—an editors' organisation that promotes publication ethics in peer-reviewed journals—recent announcement that it has entered into a partnership with Elsevier.[2]

The article points out that twice as much funding is provided by industry for clinical trials and related research than by not-for-profit organisations. 70% of industry funding is allocated to CROs and 30% to academic researchers. The CRO research is by its nature ghostly because CROs do not own or take public responsibility for the data and conditions relating to academic research funding such as absence of full access to data allow for ghost management.

The conclusion reached is that as articles in medical journals have real effects on physician prescribing behaviour ghost management exerts a huge force on the shape of scientific opinion on new drugs and does so in the service of marketing.

1 Sismondo S. Ghost Management: How much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry? *PLoS Med* 2007;4(9): e286. Available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040286

2 See http://www.publicationethics.org.uk.

How to save three words

It is never necessary to say *over a period of*.

Drug X was investigated in two groups of three female animals (0.1 mL or 1.0 mL 3 times daily) over a period of 9 days.

Just say *for 9 days* and you save your reader three unnecessary words—***every time***!

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Academic titles revisited

When I wrote a short piece [1] for the "Titles" issue last year, I never imagined I'd be writing a sequel to it. But recent developments in the German scientific community forced me to tackle the issue of academic titles again.

At least seven American scientists working in different institutes of the Max Planck Society in Germany have been charged with misusing the title 'Dr' as reported by the *Washington Post* [2]. Apparently, these scientists (and I'm sure many others before them) simply assumed having a PhD from an American institution grant them the same 'title' privileges as their German colleagues enjoy. An honest and excusable mistake, surely.

The criminal charges were based on a late 1930's law which stipulates that only people with a doctorate or medical degree granted by German universities are allowed to use 'Dr' as an honorary title. The law has since been revised to include degrees from European universities outside Germany.

The incident has caused embarrassment to the Max Planck Society as well to the German central office for foreign education in Berlin. Some of these scientists have been long-term residents of Germany and occupy leading positions in the country's research institutes. Recommendations have been made to drop the charges and change the law to include American institutions. However, the amendment, according to the *Post*, will only apply to "people with degrees from about 200 U.S. universities accredited by the Carnegie Foundation for the Advancement of Teaching. Anyone with a PhD from Canada, Japan or the rest of the non-European world would still be excluded" [2]. I don't completely agree with this statement. Anybody who wishes to use his or her foreign degree in Germany can request a state education ministry to evaluate whether that degree is valid under the German system.

When I moved to Germany in 1998, the first thing I did was to check whether my PhD degree from Belgium was 'ankerkannt' or recognised by the German educational system as equivalent to a German PhD. I had the luck that recognition of degrees granted by educational institutions within the EU was had already been in place since February1995, according to a document sent to me by the Hessisches Ministerium für Wissenschaft and Kunst (Ministry of Science and Arts of the state of Hessen). Even universities in non-EU countries like Switzerland, Norway, Iceland, the Vatican, and Hungary (a non-EU member then) were already included in the list of recognised institutions at that time. To make a long story short, I was allowed to use the 'Dr' title without a certificate to prove my degree's worthiness.

A friend's MSc in Microbiology earned at the University of the Philippines was deemed to be only equivalent to 'Vordiplom'—basically the first 2 to 3 years in the German university education—by the Hessen ministry. This disqualified her from enrolling in a PhD programme in Germany. My German husband's PhD degree in computer science at the University of Auckland in New Zealand, however, passed the rigorous process of recognition in his home state of Saarland. He was issued an official certificate by the state granting him the right to use the title 'Dr. rer. nat./Univ. Auckland'.

What I've done here was summarise the experiences of three different people who went through this validation process. I think this issue is highly relevant to many German-based EMWA members who earned their degrees outside the European Union. A disgruntled colleague or displeased client can use this law to cause a lot of trouble. The process is long, costly, and may not give you the results you want. But in the end, you have your ass covered, if I may use this crude term.

Although I personally think the Germans' preoccupation with titles is rather exaggerated, I can understand why they are wary of foreign degrees. The threat of falsified credentials is even more pronounced now than it was 70 years ago. We all know that online degrees are instantly available to anybody willing to pay for them.

One American scientist admitted to the *Post* that he was aware "there is a legal way for foreign PhDs and MDs to register for permission to use the appellation, but he has never bothered" [2]. *The German American Law Journal* described the case of a "graduate of English institutions and renowned translator of legal documents who practices in Germany refused to deal with the formalities and fees required for recognition of her titles in Germany and suffered the consequences" [3].

My request for validation of my degree was a pre-emptive move on my part. Coming from a developing country, I was always used to have my documents and credentials scrutinised, even questioned in the developed world, from my visa to my driver's licence.

I think that the order of the day is for people to practice humility. Germans should stop touting their titles around like crowns and foreigners coming to Germany, regardless of their status back home, shouldn't assume too much but should bother, deal with and show a little bit of respect to their host country's laws and traditions.

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Out on our own: From freelancers for freelancers

We were very pleased to have such a good turnout at the Freelance Business Forum in Barcelona this year (although we did miss a few familiar faces!). Read Alison McIntosh's report on our very full agenda (thanks very much, Alison!). It is a shame we have to squeeze this event in after workshops and before evening leisure, but it is the best way to maximise attendance.

This issue also sees the continuation of Stefan Lang's series on setting up as a freelance writer in Germany, where he looks at general terms and conditions of business, insurance, finding clients, and invoicing. Debbie Jordan, a freelance member for many years and known to many of you for her workshops and contributions to *TWS*, has answered our 'Ten questions' this time. Contrary to previous contributors, she gives a resounding 'No' to the question of whether she would ever consider working for a company (again) as a fulltime employee. We can understand why!

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Finding my feet as a freelance writer

by Stefan Lang

Towards the end of my last contribution about my first steps into freelance medical writing, I discussed taxes, laws and legal structures. I will start this article with some more and no less exciting issues, such as insurance and general terms and conditions. Later on, I will report on how I acquired my first clients.

Liability, general terms and conditions, and insurances

Is liability a concern? Is it true that the longer you work as a freelance medical writer, the more you expose yourself to potential liability? Some companies now expect freelancers to have professional liability insurance. Sometimes a liability clause in the client's contract requires the writer to indemnify the client's company for any judgment, damage cost, and expense. Until now, I have not been faced with such a clause, and nobody has asked me to take out an insurance policy. But I have had this question on my mind since I got started: I do not hold a law degree and I do not have a lawyer on speed dial—do I need an expensive insurance policy? I think liability is one of the most discussed issues among freelance writers. Please do not expect me to provide a conclusive answer.

When I consulted an insurance agent, I discovered that insurance actuaries do not have a medical writing category. Therefore, I needed to explain what medical writing actually means. As long as I talked about research articles or marketing texts, they categorized me as a journalist and offered me reasonably priced insurance. The moment clinical trials, drug approval or package leaflets were mentioned, the alarm bells started ringing—and the premium increased more than dramatically.

Freelance medical writers wear different hats. Writing, editing, proofreading in the regulatory or the marketing area: it may depend on the field of your business activity if you need liability insurance. Insurance against personal and property damage may additionally be useful if the office of your major client is furnished with priceless Ming vases, or if you welcome clients in your home office and your currish dog does not like strangers. Interestingly, indemnity policies often include passive legal protection. This means that claims are examined and handled by the insurance company first, and unjustified claims can be rejected without the need of a lawyer. Germans like their security quite a bit, so you will not be surprised that I am still occupying myself with such insurance matters.

I came to the conclusion that I could waive liability insurance for the moment. I decided to reduce my personal liability firstly by avoiding liability clauses like those mentioned above and secondly by drawing up general terms and conditions (allgemeine Geschäftsbedingungen, or AGB, as they are abbreviated in German). As far as I know, a freelancer is not obliged to provide general terms and conditions. But if you do so, they should be stated in legal, watertight terms. The help of a lawyer might be required.

My general terms and conditions cover my own responsibilities, the duties of the client, and also copyright matters. Most importantly, they ensure that the client is responsible for checking the texts for errors and inaccuracies and, fur-

thermore, that the client generally accepts responsibility the moment he or she signs off on my work. In Sam Hamilton's article "Presenting freelance support for the freelance membership", you will find additional points that should be included in freelance medical writing agreements [1]. I believe that medical writing has a fairly low exposure to liability claims if one carefully considers these points. You may not need an expensive policy, but, as already said, it depends on your business area.

One final comment concerning insurance before I drop this subject: as a freelancer in Germany, you do not have to pay unemployment insurance. However, since February 2006, you can do so voluntarily. If you plan to go freelance, you should consider this possibility because the monthly contribution is low and does not depend on your actual income. You have to file an application for voluntary unemployment insurance at your local employment office by no later than one month after you registered as self employed.

Clients and how to find them

Liability claims, lawyers, and more and more insurance—sounds like I was running out of money before I ever saw my first client! Time to ask how to find any.

There are hundreds of how-to books written by real experts offering secrets of success. Thousands of websites disclose the ultimate marketing programme: newsletter services, cold calls, give-aways, Internet marketing, yellow pages, business cards, and networking. Before I could check out any of these promising tools I ran into my first client: a former colleague, and also a writer, who works for a research organisation asked me to assist them in writing some articles. Very soon, some brochures and website content were added. I was occupied for weeks. Moreover, while working on the websites, I came in contact with a web design agency that brought me a further assignment.

First, I praised my luck in finding clients just by chance. Then I realized that it was not a lucky coincidence but rather the consequence of a fledgling network. I was staggered: "Networking? Not me! I do not belong to the pinstriped suit-wearing business people, who meet for breakfast at an espresso shop". Far from it! I learnt that a network at its simplest level consists of the people around you. If you have more than the names of your personal friends and family in your address book, you are probably already networking. Obviously, networking just makes you visible: business comes later. After I had accepted that I was already networking, I asked how I could further increase my "visibleness".

The Internet makes you visible to potential clients; as visible as one out of 500 million web pages can be. No matter how brightly coloured or professional looking your website might be—how will you show prospective customers the path to your online door? Primarily through good search engine placement. But is it expensive? Do you have to pay to ensure that search engines will find your page? Not necessarily. Getting a good Google ranking depends on the number of links that lead to your site from other websites. To increase that number, you can easily register your homepage in many different web directories. In this respect, do not forget to join the EMWA freelance list. Meanwhile, I had many contacts from this source, and I realized that companies especially go through this list if they have decided to hire a freelancer.

After my website had gone live, I tried to make myself a little more visible: I wrote some articles and press releases about the services I offer (during the first months of my self-employment I had abundant free time to write). The goal was to promote my business, and it worked just fine. The more texts I published, the more contacts I had. Recently, a university took note of an article I had authored about academic writing and asked me to hold seminars.

Invoicing

Finally, the day arrived when I wrote my first invoice! I had a little fun making up a simple template and filling in the specific work I did, along with the agreed price. For the first time, I felt like a real freelance writer, sending out my first invoice. I felt even more like a real freelancer when the invoice was paid. Let me expend a few words about a field of bureaucracy that is important and anything but boring.

What else would you expect from Germany? What an invoice must contain is defined by law [2]: the word "invoice", your name and address and, not surprisingly, name and address of your client should be mentioned. Make sure that you note the exact recipient of the invoice. Furthermore, the date the job was done, the type of work, and the date the invoice was written must be stated. The invoice amount should be given as the net amount broken down by tax rates. If no VAT is billed, this must be explained: e.g. exempt from tax as a small business. Finally, the invoice needs a unique consecutive invoice number, your tax number or VAT Identification Number, and a statement that you are not registered for VAT, if applicable. It is up to you whether you want to add a breakdown of the costs that make up the total and the preferred method of payment.

My first assignments have gone pretty well, and I have enjoyed every day of my self-employment. Now, after being a freelancer for about six months, I have the impression that time has speeded up enormously. Since I have been freelancing, I no longer watch the clock ticking slowly toward the end of the working day. Instead, I am always surprised that the sun sets so early. Let's see if I am still so optimistic in a couple of months. Whatever, I'll let you know!

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References:
1. Sam Hamilton. Presenting freelance support for the freelance membership. *The Write Stuff* 2007;16(3):135-137.
2. Bundesministerium der Justiz [cited: 27.03.2008]. § 14 Ausstellung von Rechnungen. available: http://bundesrecht.juris.de/ustg_1980/__14.html.

Country-specific tips: Artist(e)s' Social Fund for freelancers in Germany

I mentioned the '*Künstlersozialkasse*' (Artists' Social Fund; KSK) in Germany in a previous issue of *TWS* and would like to say a little more about this to complement Stefan Lang's article in this issue. You never know whether to translate 'Künstler' as *artist* or *artiste*. Using the latter, it sounds like an organisation that offers sheltered accommodation to retired actors, which it may well: the main thing is it may have something to offer you if you are a writer or editor in Germany as far as health and pension insurance are concerned.

Writers, editors and journalists are classed as 'artists' in Germany, and if you have been in full employment and then apply for any grants from your local employment office when you set yourself up as a freelance writer or editor, they will check to see whether you are in the Artists' Social Fund, and you will have to join. If you do not get any money from the unemployment office, you do not have to join, but you can join voluntarily, and it is certainly worth considering. Quite a few EMWA members in Germany are in the KSK.

Being a member means that you stay in the state pension scheme (which gets bad press in Germany, but still beats what is available in most other countries), and that the KSK pays half your pension contribution and half your health insurance contribution. Health insurance including income protection insurance in Germany can be upwards of €500 per month if you are privately insured, or about 13% of your salary per month if you opt for state insurance as a freelancer. Freelance writers, editors and journalists are the only group of self employed people in Germany who enjoy this privilege from the KSK. And this really is a privilege, because being insured in the state pension scheme means that you qualify for an invalidity pension if you can no longer work. You do have to wait 78 weeks for this (this is why you need income protection insurance until then if privately insured), but if you were a self-employed architect or IT expert, for example, you would not qualify for a state invalidity pension. Members of the KSK are also the only group of self-employed people who can benefit from the '*Riester-Rente*' (small state subsidy for the state pension named after a former Employment Minister). I know the amount involved is only small, but it is especially worth it for young people. Why miss out on a present of money from the government and a small tax break in later life?

You can find more information on **www.kuenstlersozialkasse.de.**

Since everybody is in a different situation, every financial decision you take should be obviously be evaluated thoroughly by your accountant and a pensions advisor (*Rentenberater*). The possible benefits of being in the KSK are, however, still not generally known in Germany (even amongst accountants and pension advisors), so they should be taken into consideration.

We look forward to receiving similar tips from members in any country to help fellow members in that country.

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Is giving the same presentation at different conferences acceptable?

This question has yet to be raised for medical and medical writing conferences and seminars but a current debate in the field of political science gives food for thought. The debate began in the *Political Science and Politics* journal where Nelson C. Dometrius, a professor of political science at Texas Tech University, wrote that when he posed the question "If you are going to give a talk at a scholarly meeting, do you need new material?" to senior faculty members he received a mixed reaction but the same question posed to graduate students usually produced "a blank stare—a lack of comprehension that presenting the same paper as many times as you wished would be viewed by anyone as an unusual or questionable practice."

One investigation found no double up until 1992. In the mid-1990s one or two papers were presentated twice a year but now presenting more than once has become fairly common.

The traditional reason given for double presentations—getting feedback and then revising—remains a strong justification, according to the articles in the journal. But questions have been raised as to whether the real motivation for repeated presentations is CV padding rather than making these revisions. There are also other ethical issues as to whether it is fair to allow repeat presentations when many conferences are turning away a record number of paper proposals.

Source: Jaschik S. Double Dipping in Conference Papers. Posted on In Inside Higher Education on 20 May 2008: Available at http://insidehighered.com/news/2008/05/20/double

Report from the Freelance Business Forum—Barcelona 2008

by Alison McIntosh

The Freelance Business Forum (FBF) has now become a regular feature at all EMWA conferences, and the Barcelona FBF was well attended. Sam and Alistair had put together a packed agenda which we covered in the allotted hour.

The first agenda item concerned the new-look EMWA website. A huge amount of work has gone into the new website, and various things have changed regarding the freelance listing. Shanida Nataraja, the website manager, came along to discuss the changes and receive input from the freelancers. She was willing to work with a representative group of freelancers to address any issues we had about the listing. The option to have our own freelance-only discussion forum was discussed, and we agreed that this would be a very useful tool. She also suggested that the website could become a place to promote freelance opportunities.

The freelance listing is an important source of clients for those of us who advertise there, and it is essential that anyone who needs to find a freelancer is able to navigate through the listing easily. To facilitate this, it was felt that the introductory text and layout could be improved, and Jo Whelan volunteered to work on the text and also act as a point of contact to co-ordinate input. She will send out an email with collated points for comments which will then be discussed with Shanida. Anyone willing to help with this should contact Jo directly (jo@textpharm.com).

Questions were asked about the ordering of the listing within each country because it is no longer in alphabetical order and changes according to the number of hits each freelancer receives, with those receiving the fewest hits being cycled to the top of the listing. Shanida confirmed that the alphabetical listing is not presently possible using the new system, and will take a couple of months to address and solve. A request was made for the hit counter to be hidden.

Positive aspects mentioned included that the freelance listing fits in with the rest of the website with the same appealing new look, and the 30-word text on the front works well.

We were updated on a series of freelance initiatives introduced in the last year, including the 'Out on Our Own' section in *TWS* and the email discussion group. It was also confirmed that the FBF is to be held at every EMWA conference, although unfortunately, it is impossible to get around the tight time slot. All of these initiatives were seen as a positive contribution for freelancers and for EMWA as a whole. If you have any suggestions of what you would like to see covered on behalf of freelance members, or you would like to contribute to the freelance section of *TWS*, please contact Alistair and Sam.

There was a good response to the latest round of email discussion questions raised in February 2008, and a summary of responses received up to the end of March was distributed before the FBF. There was debate around distribution, and most felt it was best circulated by email, with names attached to comments unless otherwise requested. It will remain a closed list open only to EMWA freelance members, and may in the future become more immediate by using the freelance section of the website.

Of note: if you are a freelance medical writer and HAVE NOT received the discussion e-mails and would like them please send an e-mail to info@emwa.org (copy in sam@samhamiltonmwservices.co.uk and areeves@ascribe.de) asking to be added to the list (freelance members are not automatically added to the list; they are added only if they specifically request it).

The value of advertising on the EMWA freelance listing was discussed and one member confirmed that about 50% of hits on her website are directed from the EMWA website. A show of hands confirmed that no-one in the room presently advertising on the website would remove their entry!

Continuous training for medical writers was discussed, including Good Clinical Practice (GCP) updates. One member from the UK confirmed that earlier this year she had taken part in two Medicines and Healthcare Regulatory Agency (MHRA) inspections (as the writer of the Clinical Study Report [CSR] for a study that the auditors were inspecting). In both cases, the inspectors questioned her about how she kept her training up to date and wanted to see documented proof of this, in particular proof of yearly GCP update training. Via the email discussion forum, members were asked to register their interest in basic GCP training tailored for medical writers with periodic updates thereafter. A total of 52/61 responses were positive, and this request is now being considered by the EMWA Professional Development Committee (EPDC).

Suggestions for specific training or information events for freelancers were discussed and topics mentioned included: overview of guidelines being developed (e.g. Paediatric Investigation Plans [PIPs]), new and revised national guidelines, changes in data protection legislation, and trial design issues. The email discussion forum was identified as a place to ask for information and also as a way of disseminating changes to guidelines/legislation.

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>>> Report from the Freelance Business Forum – Barcelona 2008

One member asked a question about another person or company using your chosen domain name, and if there is anything that can be done about it. The overwhelming feeling was that nothing could be done about it. If you do register the name, it is usually only within your own country. Laura Russell volunteered to investigate protecting your logo and domain name and will write an article for *TWS*.

Another question concerned the offer of extremely low-cost editing and writing from some countries, and whether there was anything we could do to counter this. In essence, it seems nothing can be done about it. The standard of work returned is very low, and often the client has to have the work upgraded by more proficient writers and editors. However, it was felt we should not be complacent and should continue to monitor the situation.

Another topic covered was offering an editorial service similar to that offered by a centrally organised group of editors drawn from PhD life science graduates and students at the 'top ten' universities in the USA. After some discussion it was agreed that this might be a business opportunity for someone, but probably too complex to undertake as a band of freelancers under the aegis of EMWA.

To maintain the theme of the Barcelona conference: Translation, Gabi Berghammer agreed to write an article around the issue of medical translations for a future edition of *TWS*.

Freelance writers are encouraged to contribute articles, either for the 'Out on Our Own' section, or for elsewhere in *TWS*. Also, the series of articles on starting up in business as a freelancer will continue with a country other than the UK and Germany after the present series by Stefan Lang on setting up in Germany. So, please email Alistair with any suggestions for our own section of *TWS*. The September 2008 issue of *TWS* will be guest-edited by Alistair (theme: Can you manage your time?), and Sam is guest-editing the March 2009 issue (theme: Lesser known regulatory issues). Start thinking now about what you might contribute to these editions. And don't forget: it doesn't have to be an article; there is always plenty of room for smaller comments and tips in 'boxes'.

And finally, a huge thank you is due to both Alistair and Sam for undertaking these freelance initiatives. They are welcomed by the substantial EMWA freelance membership (about 15% of members) and we appreciate the time and commitment it takes to make these initiatives a reality.

The next FBF will be held at the 27th EMWA Conference in London, UK, 20–22 November 2008.

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Groping for words: A warning

I work on website texts and give clients links to the websites if they want to see examples of my work. I recently did this and thought I would take a look at the breast cancer website concerned, because I hadn't checked it for a while (and it mentions my name, albeit on a very deep-down level). On the first page, in the middle of the screen, in bright red, I was faced with this:

"I have groped a small knot in my breast. Is this serious?"

It certainly is serious (but tell me you didn't smile!); and if discovered by someone else while 'groping', probably even more serious. But it is also a serious and unforgivable error (many more had also been introduced by updates), and I requested correction. Maybe I should just stick to paper references or my own Word documents in the future!

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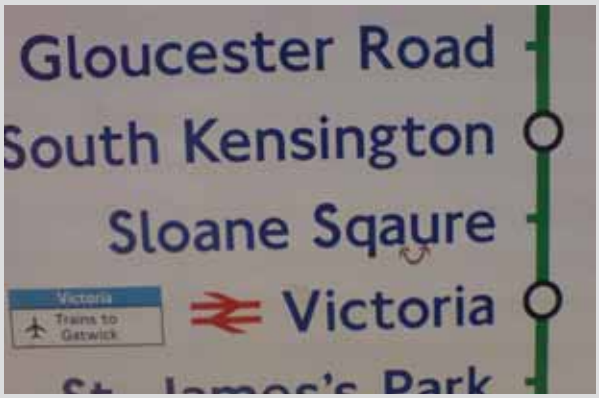

Why a mobile phone is always handy[1]

If you don't proofread your signs in time there's no alternative but to add edits to the final product. Andrea Palluch photographed this official sign at Hammersmith underground station in London on her way to work: She sent it to *TWS* with a comment that it's a good thing we have camera phones these days.

1 Apologies to German-speaking readers.

Ten questions for …

Debbie Jordan

by Debbie Jordan

In 100 words, what is your background and how did you become a freelancer?
I started my working life looking at the physiological effects of relocating animals involved in reintroduction projects, primarily red squirrel reintroductions in the UK. However, after a few years of getting bitten by both midges and squirrels, I looked for a new career that paid more than research grants! I took a job with Cyanamid Pharmaceuticals and worked as a CRA and then as a Project Manager. I moved into Medical Writing with a CRO when my first son was born and then became freelance to spend more time with my family when my second son was born.

What is your most important piece of advice for people setting up a new business?
Be friendly and do a good job. You don't know where your work will come from, and building good relationships will generate more work than hundreds of pounds worth of advertising. But remember the old saying that you are only as good as your last piece of work …

What do you like about being a freelancer?
I like the flexibility of deciding my own working pattern and being able to work hours that fit in with my family and other aspects of my life. I also like having the control in deciding what type of work I take on and so can make sure I have some variety in the types of writing I do. Another advantage is managing to avoid most of the office politics!

What do you dislike about being a freelancer?
Sometimes it can be a bit lonely since I am working at home on my own most days, but neighbours and non-working friends are usually around to have a coffee with if it gets too bad, and there are always other freelancers available at the end of a phone. I also don't like the fact that sometimes it is difficult to get away from work, and some clients expect you to be always available (not helped by mobile phones which mean you can be reached almost anytime and anywhere).

What are your main sources of work?

I don't really have one main source of work—I have about 10 regular clients and then another 10 or so who give me occasional pieces of work, so I am quite lucky that I have a good range of work sources. The main type of work I do is clinical study reports and other regulatory documents, but I also do manuscripts, posters and other marketing material, so my scope is quite wide.

What are the most rewarding projects to work on?
The ones that involve a nice team of people. If the people are nice and you are all working together to meet a deadline then it doesn't really matter what the work is.

What are the least rewarding projects to work on?
I guess the opposite of the above, and working for nasty clients! Luckily it doesn't happen very often, but very occasionally you come across a client who seems impossible to please, however much you try. That's when having the flexibility to decide whether to work with someone again or not comes in very useful …

Do you have a preferred type of client? If yes, why?
The reasonable ones! I like working with clients who see the process as a 2-way collaboration and include me as part of the team and don't just dictate what I need to do and by when. I also like the clients who are realistic and ask me what time I need to do a project because however much they pay me, I can't create more hours in a day!

What is the best way to say 'No' to clients?
I am not very good at saying 'No' to clients, I guess because the ones I work with regularly I like working for, so when they need me to help on something I find it impossible to turn them down because I know I will enjoy the project.

Would you ever consider working for a company (again) as a fulltime employee? If yes, why?
This one is easy - definitely not! I love working as a freelance writer and I hope to continue doing so for as long as I can still see my computer screen and type on my keyboard.

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Date for the diary

EMWA spring conference 26-30 May 2009 in Ljubljana, Slovenia

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