EMWA European Medical Writers Association

The Write Stuff

The Journal for European Medical Writers

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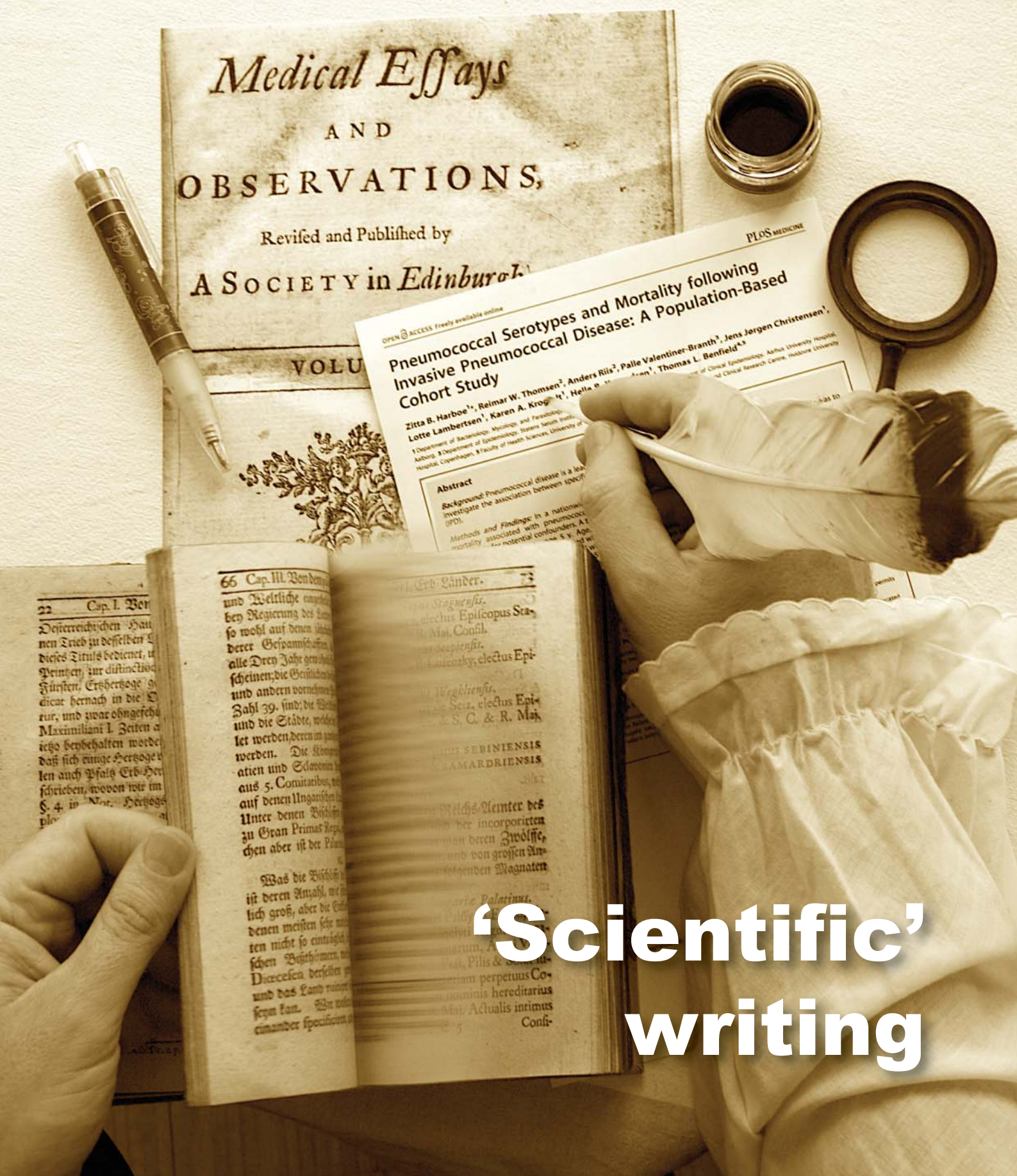

'Scientific' writing

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Journal insights

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

Subscriptions

Subscriptions are included in EMWA membership fees. By writing to 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 800–2500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by email as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

Timelines

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

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Cover picture

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Announcing the
29th EMWA Conference
12-14 November 2009, Westin Grand Hotel, Frankfurt, Germany

We are delighted to announce that the venue for EMWA's 29th conference will be Frankfurt, Germany. This is a very convenient city to travel to from all corners of Europe, and is a perfect location for our 2-day autumn conference to be held from Thursday 12th to Saturday 14th November 2009.

Many workshops will be on offer covering a wide range of medical writing topics for those wishing to obtain credits towards their foundation or advanced EMWA professional development programme certificates, or simply to update their knowledge and skills.

In addition there will be a chance to meet old friends and make new ones at the welcome buffet on the Thursday evening and the conference dinner on the Friday evening. These social events are excellent opportunities for networking with other medical writers from Europe and beyond.

Further details will be posted on the website at www.emwa.org.

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From the editor's desk:

'Scientific' writing

by Elise Langdon-Neuner

The theme of this issue of TWS is 'scientific' writing. The issue gathers together thought-provoking articles that discuss current writing practices and articles that offer valuable guidance on improving writing style. In this editorial I take more space than usual to consider the background for the traditional 'scientific style' of writing, the warnings for those who support this tradition and how we as medical writers can contribute to a future of readability and clarity in medical reports.

Scientific writing, including medical writing, is a marvel. In a world of marketing slogans and sound-bites, archaic text flourishes in scientific journals and overflows into regulatory documents. This editorial concentrates on journal articles but it is notable that Linda Tollefson, Director of the Food and Drug Agency Europe Regional Office, stated at the EMWA conference that badly written documents would be rejected by the agencies (see page 77 of this issue). There is little research on whether badly written papers are rejected by journals. Research on one journal suggested a correlation between the number of papers with shorter sentences and simpler grammatical structures and acceptance rates in that journal [1].

What forces are operating to maintain the grip of 'scientific style'?

Remember while celebrating the 150th anniversary of the publication of Darwin's *On the Origin of Species* this year that the great man published all his books for general readerships. Stephen Jay Gould, an eminent modern Harvard palaeontologist, acclaimed essayist of genius, and co-author of the revolutionary and now generally accepted "punctuated equilibrium" theory[1], believed that "the concepts of science, in all their richness and ambiguity, can be presented without any compromise, without any simplification counting as distortion, in language accessible to all intelligent people" [2].

Yet the hallmarks of 'scientific style' are not easy accessibility, but long complex sentences overburdened with unnecessary words[2], noun constructions in preference to active verbs, and a disproportionate use of the impersonal passive voice. The word choice is pompous (e.g. elucidate, employ, perform rather than explain, use, do), jargon is rife and instead of precision opinions are hedged with uncertainty. Articles in which contributions of medical writers are acknowledged can also adhere to this style. Richard Smith, when he was still editor of the *British Medical Journal*, warned me at the beginning of my career that medical writing would surely kill any writing talents that I might have.

What forces are operating to maintain the grip of the 'scientific style', and are they cutting off the scientific nose to spite its face? Tim Albert describes in his article in this issue how he gave up on his mission to help scientists mend their misguided writing ways. He blames the role of the publishing system. It is true that even the emerging open-access revolution in publishing is having no effect on writing style, as Neville Goodman points out in his commentary in this issue, while blaming the education system for the current state of medical writing. Not only the education system itself but the authorities it relies on might be at fault. The 50th anniversary this year of another book classic, Strunk and White's *Elements of Style*, is not a cause for celebration for the professor of linguistics Geoffrey Pullum or for Alistair Reeves, as you can read in this issue.

I find it hard to avoid the conclusion that the central reason for scientists, who we assume are clever people, writing in such an obscure style is to persuade the confused reader that they are indeed clever people. Linguists who study the genre of academic articles have acclaimed then as a code of communication among experts. They reason that the use of sound-good words and complicated sentences boost the author's status within that community, which they see as the underlying rationale of the scientific paper [3].

That is how we got to where we are today but it doesn't explain why we stay there

Michael O'Donnell, former editor of *World Medicine*, is convinced that typical medical writing prose, which he describes as 'decorated municipal gothic', is merely used by authors to enhance their image [4]. The explanation for him lies in article publication being viewed by scientists as merely another line in their curriculum vitae. Their main aim is to be cited—not read. O'Donnell says the reader has

[1] The theory states that the process of evolution is not gradual, as previously thought, but proceeds in fits and starts with long periods of stability.
[2] see the seventh paragraph of the article by Alistair Reeves (page 90)

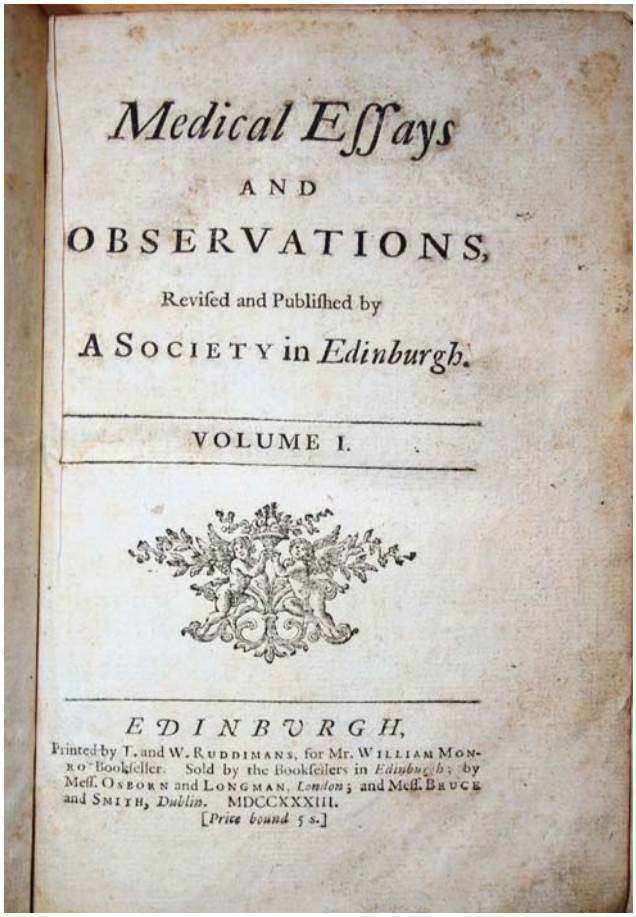
two choices "do the writers' work for them by trying to work out what they are trying to say, or throw the journal aside and set about doing something less demanding like quarrying granite."[5] (See the box on this page for how he believes a simple text written in 1885 might be written today.) Indeed, articles are not usually read cover to cover as Jo Whelan points out in her article in this issue, in which she highlights the problems of journalistic reporting of medical research. But she reasons that articles in medical journals are individual pieces of research only of interest to a few people—a parallel argument to Tim Albert's one of exclusivity.

Nevertheless, some scientists who have no need to prove that they are clever have criticised 'scientific style' for the overuse of the passive and impersonal voice, which leads to complicated text. The Nobel Prize winner Roald Hoffman (Chemistry 1981) lamented that these objective articles present a sanitized account of the study [6]. Most of the obstacles that the researcher faced are omitted—and why?—again because this leaves the text reading like a success story to make the reader think better of the author. But he says it damages the scientist's image, because the scientist's humanity is suppressed and the public is left with the impression that scientists are dry and insensitive people who remain within a jargon-barricaded world and do not deign to explain their work to the public in terms that the layman can understand. Peter Medawar, another Nobel Prize winner (Physiology or Medicine 1960), points out that the inductive format of articles is anyway a nonsense because scientific observation is inevitably biased starting with the choice of method and followed by the selection of results considered relevant [7].

How did this state of affairs come about in the first place? In the 17th century the early experimentalists, in particular Robert Boyle and his fellow members at the Royal Society, were keen to distinguish their empirical methods from the scholarly theories by which classical and medieval philosophers tried to explain Nature. These natural philosophers, as they were called, had told 'the truth' in front of witnesses. The experimentalists sought to style their writing so as to separate the facts, which they presented in detailed accounts of their methods and observations, from their own opinions, which they hedged with caution. Additionally, according to Steven Shapin (as quoted in [8]) early experimentalists wrote with deliberate prolixity, i.e. "ornate sentence structures, with apposite clauses piled on each other". And here we return again to the image problem, such language was used to impress their readers with their intellectual prowess and establish their authority.

Even so, the early experimentalists did not feel compelled to write in the passive voice. They used active-voice verbs and first-person pronouns to emphasise that they had witnessed the experiments themselves. The change in emphasis from active to passive and first-person to impersonal came later.

The linguist Dwight Atkinson specifically traced changes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The front cover of *Medical Essays and Observations*, revised and published by a Society in Edinburgh (1733) reprinted with the kind permission of the College Library at The Royal College of Surgeons of Edinburgh.

BOX

The following is an extract from William Marsden's report relating to the founding of the Royal Marsden in 1851:

A hospital devoted to the treatment of cancerous disease seems to me to hold out the only prospect of progress in the treatment of the malady; an institution conducted by those who recognise in medicine and surgery but one art. The records of such an institution are sure, in time, to narrow the field of incurable disease[1].

This is how Michael O'Donnell judges a lesser Marsden would write the report today:

It would seem to the author that only a specialist centre organised on the basis of concentrating its resources solely to address the treatment of the malignant disease process could offer a potential for realistic improvements in treatment outcome. Furthermore, such an institution would be a de facto resource centre under the direct line management of personnel sensitive to the fact that multifaceted discipline of medicine and surgery are each essentially manifestations of the same single entity

1 This extract is from Sandwith F. Surgeon compassionate. London: Peter Davies, 1960:210 as reported in [5]

>>>

>>> 'Scientific' writing

in medical writing style and gives an insight into how articles in medicine lost their 'personal' character. He examined original articles published in *The Edinburgh Medical Journal* from 1735 to 1985 [8]. Early issues of the journal contained case studies centred on one patient. At that time symptoms were believed to be unique to the patient rather than to the disease. Only those who could afford to pay received treatment. Doctors were eager to please and were 'involved' with individual patients who were their sole source of income. They wrote in a personal and emotional style about their patient and the treatment they applied. At the end of the 18th century the emphasis in original articles started to shift from narrative to non-narrative text, concentrating on the disease and grouping patients according to their disease. Text became more informational, as typified by heavy noun phrases, and also less emotionally involved. Atkinson attributes many of these changes in medical reports to the onset of public medicine.

Emotion was dropped and authors hide themselves behind the facts in reporting other sciences too (see boxes on pages 86 and 88 for examples of emotions previously expressed in science writing). The current frequent use of the passive voice in research articles for instance has been explained as reflecting today's 'instrumental and object-oriented' in contrast to yesterday's 'actor-oriented' science [9].

Scientists at the forefront of in science have all used the media to their advantage

That then explains how we got to where we are today with the scientific article. The early experimentalists felt they needed to impress their readership with their objectivity and authority through prolixity and as time went on social changes supported the demise of first-person pronouns. But it does not explain why, in a changed world, we stay there. Why does writing have to be deliberately complicated, devoid of human emotion, and the active voice and first person pronouns ostracised? The stranglehold of tradition and peer pressure that maintains the status quo is not to be underestimated. I recently read a reviewer's comments on a manuscript admonishing the author for using 'colloquial expressions', e.g. 'huge difference' and 'we guess'. The author wanted his article to be published and made the changes.

Answering his own question as to why the pleas to write in plain language that have been bombarding scientists for the last 300 years have gone unheeded, Martin Gregory, a veterinary scientist writing in *Nature*, says—at one with Tim Albert—that the pleas should instead be directed to editors [10]. John Kirkman, who—like Tim—is an experienced medical writing trainer, reviewed 500 sets of Instructions for Authors and found that 82% of the instructions gave no helpful guidance on writing style [11]. Interestingly, he also found that only two specified an impersonal or passive style suggesting that this 'requirement' of scientific style is a more a myth than a reality. Kirkman felt that editors could do more to guide authors and to dispel the impression that acceptable articles must be written in a traditional style. While for Gregory the problem of unreadable prose could be solved at a stroke by stipulating that editors should have expertise in writing and should reject poorly written papers.

It is certainly a mistake to think that all journal editors commend the traditional style of writing published in journals. In some, like *Nature*, plain writing and the active voice are encouraged (voice should actually be allowed to select itself, see David Alexander's article in this issue). Richard Webster wrote a scathing editorial to mark the end of his term as editor of *European Journal of Soil Science* bemoaning the fact that the papers he had received during his editorial term had been mostly devoid of excitement with the passive voice and third person as the main reasons for the dullness [12]. He also blamed the passive for leading authors into the 'dangling particle'[2] fault. Beyond the passive and third person he had had to contend with long-winded, rambling and pompous constructions and strings of adjectival nouns that leave readers guessing which noun qualifies which other noun.

Ken Hyland, one of the linguists who studies I have already mentioned, accepts that this writing style excludes lots of people, but adds that this is partly the point (personal communication). But this bodes ill for scientists themselves.

Science can be reported in language that is "accessible to all intelligent people"

In the conclusion to his book *Bold Science*, Ted Anton draws together the common characteristics shared by the seven scientists he profiles in the book as those in the forefront of a new wave in science who are changing what scientists are [13]. These scientists, who include Craig Venter and Saul Perlmutter, have all used the media to their advantage breaking down barriers between science and the public. The immunologist Polly Matzinger refused to write her papers in the passive. She felt to write 'I' would be over conspicuous and so as to write 'we' added her Afghan hound's name as co-author in an article published in *The Journal of Experimental Immunology*. When the true identity of her co-author was discovered she was banned from publishing further papers in the journal. She turned to the media to reach other professionals and the public. Anton also stresses the importance of interdisciplinary connections for the future of sci-

[2] A present participle is a verb ending in *-ing*, and is called *dangling* when the subject of the *-ing* verb and the subject of the sentence do not agree i.e. it seems to modify the object instead. http://andromeda.rutgers.edu/~jlynch/Writing/d.html

ence. In an age of high specialisation it therefore becomes more, not less, important to develop skills of communication, not least to facilitate cross-fertilisation between evermore specialised disciplines.

Any doubt that science can still be written in a plain and even literary style is dispelled by the collection of extracts of scientific writing from professional scientists that Richard Dawkins has gathered together in his book *The Oxford Book of Modern Science Writing* [14]. The extracts are not from research articles, but from writings intended for public consumption. Nevertheless they include dry, complex and unlikely topics, e.g. from Primo Levi's *The Periodic Table*. Probably it is no coincidence that a large number of the authors were Nobel Prize winners. Researchers who want to be separated from the crowd would do therefore well to step back and consider how and to whom they communicate their research. Submission to peer-pressure is not the mark of those who excel in our society.

There is another point which specifically relates to medical writing and is ably brought out by David Reese in his article calling for the literary element to be restored to medical writing [15]. He argues that medicine is fundamentally a social and personal act and asks how, if the literature of medicine is devoid of human sentiment, it can truly reflect the methods and aspirations of medicine—a poignant comment in the light of the increasing use of the Internet by patients seeking medical information. The general public stands today on an equal footing with researchers. It demands to be informed and is not impressed by arrogant endeavours by authors to set themselves above the intellectual norm.

Those who stick to traditional 'scientific' writing therefore risk mediocrity and disregard from the general public.

However, before we resort to a journalistic style of reporting in scientific articles, the practices currently adopted by journalists that Jo Whelan refers to in her article need to be replaced by responsibility for content. Richard Clark likewise, in his article in this issue which tackles medical writers' responsibility, is concerned about a lack of attention to content. There is an evasion of responsibility implicit in traditional scientific writing which has been brought about by the objective, inductive format mentioned by Peter Medawar. Surely this will become increasingly unacceptable in a world that is learning tough financial lessons consequent upon its failure to impose responsibility on the managers of its finance. Is health not more important even than finance? Should a change in writing style not be part and parcel of the tremendous pressure for authorship transparency reflected in ghostwriting guidelines and surveys such as the one of EMWA and AMWA members reported by Adam Jacobs in this issue. The logical sequel to these important concerns of editors and the public should be the use of 'we' and 'I', more writing what we mean rather than evasive hedging.

Besides taking responsibility for our own work and persuading authors to do likewise, what can medical writers do for the future of medical writing? We are writing an ever-increasing number of scientific articles and we claim to be experts in writing who add value by writing well. Therefore, we can hearten the disillusioned trainers and add our voice to theirs and those of enlightened scientists and editors by recognising that complicated or pompous writing should be avoided in the interests of good quality, even for the run-of-the-mill researchers who are only looking for their next promotion rather than a Nobel Prize. We can write and defend—by demanding explanations to make misguided editors and reviewers reflect on their position—language that is "accessible to all intelligent people".

This issue of *TWS* offers many excellent articles including one on writing for readability in which David Alexander advises on the principle of subject-topic agreement, judicious use of the passive, preferring active verbs to nouns and distinguishing between terminology and jargon. While Alistair Reeves explains the correct use of the preterite and present perfect tenses and Iain Patten contributes suggestions on clarity in describing and using secondary citations. With these articles and more in *TWS* the future of medical writing could be marvellous.

Acknowledgement

I would like to thank Tim Albert for critically reading the manuscript.

Elise Langdon-Neuner

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Message from the President

by Helen Baldwin

I'm really thrilled to be writing my first President's Message for this issue of *TWS*! I have been EMWA Vice President for the last 2 years and then became President at our recent conference in Ljubljana. It's a great honour for me to take on this job for the next 2 years. I will do my best to ensure that EMWA continues to be the successful organisation that it is today and goes from strength to strength as our profession continues to grow and develop.

I will be supported by our new Vice President, Laurence Auffret. Laurence and I have much in common, for example I am British and live in France whilst she is French and lives in England. I think most people could understand why a girl like me, who grew up in rainy England, decided to move to the sunny South of France....but why on earth someone would choose fish and chips in Manchester instead of 'moules frites' in Brittany is something I hope to find out during the next 2 years of working with Laurence! We also have 3 other new EC officers: Laura Hollyhead as Honorary Secretary, Andrea Palluch as Public Relations (PR) Officer, and Gillian Pritchard as Treasurer. I would like to thank them all very much indeed for generously agreeing to dedicate some (but hopefully not all) of their spare time to EMWA over the next 2 years. I would also like to thank the other EMWA members who responded positively to our email asking for EC candidates and who are now helping on our subcommittees.

With around 900 members today, EMWA is still growing fast, and the challenges behind the scenes to keep the association running smoothly are substantial. Nevertheless, EMWA is in excellent shape and I feel very confident taking over the helm of this ship under such fair-weather conditions! There are several people who deserve a special mention here as we owe our excellent health to them.

Firstly, I would like to say an enormous thank you to Julia Forjanic Klapproth (Julia FK) who was President until a few weeks ago. Julia FK's involvement with EMWA started 11 years ago when she became Membership Officer. Since then she has been Vice President twice and President twice! During her most recent period of office, Julia FK instigated the idea of conference themes. She has run conferences with the themes of 'medical communications', 'medical translations' and 'regulatory writing', and each time she put together a fantastic line up of plenary talks, seminars, and discussion panels. There's something about Julia FK: people just can't say 'no' to her! (I know that for a fact as I ended up as EMWA Vice President even though my husband and colleagues told me to phone her and just say 'no'!) Julia FK is truly one of the most brilliant and dynamic women I have ever met and I was very lucky to have her train me for my present role.

Three other members of the EC recently stepped down and all deserve an enormous show of hands for their dedication to EMWA. Julia Cooper (Julia C) was on the EC for 12 consecutive years as Education Officer, Vice President, President, Past President, and most recently Honorary Secretary; last year she oversaw the transition from our previous head office in Switzerland to our new head office in the UK. Wendy Kingdom was on the EC for 6 years as Education Officer and then Treasurer. EMWA's finances are under control largely thanks to the great care that Wendy has taken of our money! Under her guidance, EMWA has invested its funds wisely and has built up a reserve to cover the possibility of having to cancel a conference at the last minute (due to Mexican flu for example!) Finally, Kari Skinningsrud was PR Officer for 4 years helping to spread the good name of EMWA far and wide by attending conferences and designing promotional materials including a very attractive brochure and a useful career pack for would-be medical writers. Thank you to them all and I hope they can now have a good (well-earned) rest!

There's one more person that I really need to mention here, and that's Stephen de Looze. I am delighted to announce that Stephen was awarded a Nick Thompson Fellowship at the banquet in Ljubljana. Stephen joined the EMWA Professional Development Committee (EPDC) in 2000 and was Education Officer from 2001 to 2003, expanding the EMWA Professional Development Programme (EPDP) from about a dozen workshops to over forty. He subsequently developed, with other EPDC members, the advanced curriculum (launched in 2005). During his second term as Education Officer (2007-date), Stephen has further expanded and improved the education programme (we now have around 80 EPDP workshops) and has participated very actively in many other aspects of running EMWA. I am delighted that Stephen has agreed to continue in the role of Education Officer for the next two years and I warmly congratulate him on his well-deserved award.

I'm happy to say that the Ljubljana conference was a great success and again I would like to thank everyone who participated as a workshop or seminar leader, plenary speaker, or panellist. All of these people give their time on an entirely voluntary basis, they are not paid, and the conferences

could not exist without them. I would also like to mention that our new head office provider, MCI, did an excellent job of running the conference and I have received many compliments about how professionally it was handled.

With all those people to thank, I haven't got much space left to tell you about the programme for this year, so I'll have to save some for the next issue! Our next conferences will be in Frankfurt (12-14 November 2009), Lisbon (May 2010) and Nice (November 2010). We also plan to run our third joint symposium with the Institute of Clinical Research (ICR) in February 2010. The theme of the Lisbon conference will be 'Medical Writing in an Electronic Era' and we are currently looking for plenary speakers, seminar leaders, and discussion panel topics—so please do contact me if you have any suggestions. We are also launching a new idea of a 'call for brief presentations' for the Lisbon conference: the aim is to increase the opportunities for EMWA members to present and share their knowledge and opinions with others.

Well that's all for my first President's Message. It was easier than I expected (rather like abstract writing—the hardest thing is keeping the word count below the limit)! I wish you all a wonderful summer and I look forward to catching up with you again in a few months time.

Helen Baldwin
EMWA President
president@emwa.org

What's news at EMWA?

The EMWA Spring Conference, Ljubljana, 2009

EMWA's 28th Conference took place from 26-30 May in Ljubljana, the capital of Slovenia. 264 EMWA members registered for the conference. There were over 60 sessions, primarily workshops for credit in the EMWA Professional Development Programme but including 4 plenary lectures, a keynote lecture and discussion forums. Although the theme of the conference was regulatory writing a remarkable diversity of topics of interest to medical writers was on offer and the conference clearly achieved the goal of having 'something for everybody'—medical writers working in pharmaceutical companies, medical communications, clinical research organisations, academia, government institutions, hospitals and last but certainly not least, freelancers. Opportunities for informal discussion were provided by the lunchtime discussion tables and, of course, the social events provided great opportunities for networking.

The Annual General Meeting (AGM)

Over 90 members registered for the AGM. Ziga Arh, *TWS's* publisher who is based in Ljubljana, gave an excellent presentation in which he traced changes in the journal's development since 2002 when he took over the publication process. Not only have the number of issues increased from 3 to 4 per year but the number of pages has increased from 32 to 70. Added to this the change from the single column 'letter' design to a 2-column format doubled the words per page. Ziga explained the production process, including examples of the designer's work on tables and images and the preparation and checking of galley proofs, as well as the distribution process. Finally he considered the potential for further developments: gathering boxes under section headings, reintroduction of quotation boxes, a bound journal with thinner paper, improved photographic and illustration quality, moving the list of contents from the back cover to release this space for conference announcements and adverts and more.

Laurence Auffret Laura Hollyhead Gillian Pritchard Andrea Palluch

This conference was the first to be run by our new head office MCI and they provided each of us at the AGM with 2 voting cards: a 'Yes' card with a green background and a 'No' card with a red background. That red card was ever so tempting, but the opportunity to use it never arose. The motions that were passed were:

- to approve the annual accounts for 2008, together with the budget and membership fee for 2010
- to release the EC, i.e. to sign off on the activities of the current EC since the last AGM
- to allow EMWA to re-activate the UK registered company and a second motion to close down in Switzerland
  - to allow the EC to invite current members of the Swiss entity for admission to membership of the UK entity
  - to close down Swiss EMWA subject to, and conditional upon admission to membership to the UK entity by a majority of the current membership of the Swiss organisation.

Finally EC officers were elected for all open vacancies. Helen Baldwin moves from the position of Vice President to President, Stephen de Looze continues in the position of Education Officer. Shanida Nataraja remains as Web Manager and I remain as Journal Editor. These last two positions are non-elected and appointed by the EC. The new EC members are Vice President: Laurence Auffret, Treasurer: Gillian Pritchard, Honorary Secretary: Laura Hollyhead, Public Relations Officer: Andrea Palluch. ■

Elise Langdon-Neuner
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>>> What's news at EMWA?

Plenary and keynote lectures

The plenary lecture titled 'Fraud in medical research and scientific communication' presented by Frank Wells will be the subject of an article by Catherine Mary to be published in the September issue of *TWS*.

Plenary Lecture: Regulation on the Publication of Clinical Trials

Presented by Kathy B. Thomas-Urban

The latest status of clinical trial disclosure was summarized. This fast developing regulatory field affects disclosure of information on clinical trials in a public domain (Internet) with prospective registration for ***new or ongoing*** clinical trials and ***retrospective disclosure of the results*** for ***completed*** clinical trials, and has global implications for all sponsors of clinical trials.

Stringent demands for increased public transparency of clinical trials came from the International Committee of Medical Editors (ICMJE), the WHO, The World Medical Association, governments and drug regulatory authorities in many countries around the world, as well as from the patient groups and general public.

Requirements for Clinical Trial Disclosure differ between countries. ***Laws in force*** have been established by the European Parliament for all 27 countries of the European Union (EU); some of parts of the laws apply to the European Economic Area (Iceland, Lichtenstein, Norway). ***National laws*** exist in Argentina, Canada, Croatia, Czech Republic, France, India, Israel, Hong Kong, South Africa, Taiwan, and USA. ***National guidelines***, set up by the health authorities or ethics committees on this topic exist in: Australia, China, Germany, Iran, Japan, The Netherlands, New Zealand, and Spain. In some countries registers are in the national language in addition to English; some allow a crosslink from an international register to avoid duplication of entries. The most widely used database for clinical trials is the register www.ClinicalTrials.gov administered by the National Library of Medicine, USA. It contains information based on the study protocol on new and ongoing studies as well as results of completed studies is the register www.ClinicalTrials.gov administered by the National Library of Medicine, USA. A global search for information on clinical studies can be done through search portals such as the http://www.who.int/ictrp/en/, administered by ICTRP (International Clinical Trial Registry, at the WHO).

The applicable law for clinical studies with drugs, biologics, and medical devices in the USA or studies that are part of a regulatory FDA application is the 'FDAAA of 2007' (Law 110-85, Section 801 (Title VIII). It mandates the reg-

EUROPEAN ASSOCIATION OF SCIENCE EDITORS
Tenth General Assembly and Conference
Second Circular, Programme and Registration Information

Integrity in Science Communication

At the Palazzo dei Congressi, Pisa, Italy, 16 – 19 September 2009

Plenary sessions
- Opening lecture by Professors Lucia Tomasi Tongiorgi & Romano Coppini
  Keynote lecture by Professor Ele Ferrannini
- Physical Integrity
- Moral Integrity
- Editorial Independence and Responsibilities

Parallel sessions
- Publication of full datasets
- Cultural issues relating to non-English journals
- Authorship
- Misconduct in science communication
- University Press Challenge
- Cultural integrity of journal guidelines and their translation
- The role of editors and journals in fostering responsible conduct of research
- Promoting the public perception of science through clear communication

Optional Workshop
Managing a Journal Editorial Office

See www.ease.org.uk for details

European Association of Science Editors
EASE

photo: Crispin Hodges

istration of ***all*** applicable clinical trials (Phase II to IV) on the database www.ClinicalTrials.gov, within 21 days of first patient enrolment and regular maintenance of the enrolment status and the trial completion. Results of the trial must be shown on the same database. This applies to completed trials (Phase II to IV), performed with ***FDA-approved products***. The timing for results disclosure depends on the stage of product development, i.e. for trials with an *approved product* studied in an *approved clinical indication*, the timeline is 12 months from the completion of the primary parameter (specified in the trial registration); for *unapproved products*, the timeline is 30 days after product approval; the disclosure of results applies to applicable clinical trials (dating back to trials that were ongoing in or after September 2007). The format for registration and results disclosure of clinical trials must follow the information fields specified by the database on www.ClinicalTrials.gov. The requirements of the FDAAA of 2007 are being introduced gradually over 3 years and should be completed by the end of 2010: •registry information for new and ongoing trials is generally required as of December 2007, •basic results disclosure of completed studies is required as of September 2008, •adverse events reporting will be required from September 2009, •lay summaries of the trials result, by the end of 2010, and •potential expansion of the law to disclose clinical trial information for ***unapproved products*** is expected by September 2010. It is the trial sponsor who is obliged to disclose the information; most FDA regulatory drug applications require a proof of compliance; the law specifies penalties for non-compliance.

photo: Crispin Hodges

Two regulations by the European Commission apply for clinical trials in the EU. They deal separately with the clinical studies involving children ['Paediatric Regulation' (EU) Article 41 of Regulation (EC) 1901/2006]; and those with adults ['All clinical trials' Article 57(2) of Regulation (EC) 726/2004]. In contrast to the situation in the USA, the clinical trial information in the EU will be released automatically to the public by EMEA (European Medicines Agency) from its database EudraCT via the EudraPharm. The released information will be based on the data supplied by the sponsors to EudraCT as part of the clinical trial application and as part of the results reporting. The requirements apply to ***all*** products (***approved and unapproved***) studied in Phase I to IV clinical trials with children, but Phase II to IV for clinical trials with adults. For results disclosure, the proposed format must follow the Synopsis used for Clinical Study Reports (ICH E3 guideline). After completing the clinical trial, the timelines for results disclosure are 6 months for trials with children and 12 months for trials with adults. Both regulations are in force already, although the technical aspects of the publicly available information are still under construction. The planned release of the information to the public for registration is expected by the end of 2009 and for disclosure of results by the middle of 2010. ■

Kathy B. Thomas-Urban
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Keynote Lecture: Harmonization of the Clinical Parts of the Common Technical Document (CTD) Dossier in the EU & US: Is it Possible?

Presented by Craig McCarthy and Linda Tollefson

Although ICH guidelines were introduced to achieve harmonization of the CTD, a single harmonized dossier is often impeded by different regulatory requirements in the US and in Europe. Craig McCarthy (President and Fellow of The Organization for Professionals in Regulatory Affairs [TOPRA]) pointed out some of the major differences between a US and a European CTD, including the requirement of 2 placebo-controlled studies in the US vs. a single active comparator study in Europe, or the way that clinical data are reviewed 'bottom-up' by the FDA vs. 'top-down' by the EMEA. He concluded that unless the different agencies come up with harmonized requirements, the only way to achieve a reasonably harmonized CTD dossier is to obtain scientific advice from both the US and European authorities. He then handed over to representatives from the FDA (Linda Tollefson, Director of the FDA Europe Regional Office) and the EMEA (Segundo Mariz, Medical Assessor at the Medicines and Healthproducts Regulatory Agency [MHRA]) with the question if and when we can expect harmonization of the clinical parts of

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the CTD. Both were not able to give a clear answer to this question. They both presented an overview of their agency requirements and processes, and emphasized that scientific advice meetings are absolutely essential to a successful clinical development programme and should be used proactively and wisely. Linda emphasized that 70% of major deficiencies of a CTD can be identified at presubmission meetings. Furthermore, they pointed out that relevant guidelines issued by the agencies are often not considered appropriately. During the panel discussion, the fundamental question if documents can get rejected by the agencies if they are badly written was answered by Linda with a clear yes. On the other hand, Segundo said he does turn directly to the study reports and source data if he gets a clinical overview that is not understandable, but that this is usually a disadvantage to the applicant since it is likely he will oversee important messages that the sponsor may want to get across. The resounding opinion of all the panel members was that sponsors should seek more contact with the authorities, both FDA and EMEA, to try and clarify as many things as possible before submissions. ■

Wolfgang Jacob, Christine Wendel
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Plenary Lecture: The FDA Takes Up Residence in Brussels—There Goes the Neighbourhood!

Presented by Linda Tollefson

The FDA is coming to Brussels. The question you may be asking is, why? On Thursday morning at the conference in Ljubljana, Linda Tollefson, the director of the new Brussels office, gave an enlightening plenary lecture to answer just that question. The FDA has been charged by the US congress to proactively find ways to harmonize itself in a global world. To do this, the FDA has opened offices around the world to develop and nurture relationships with other regulatory agencies. The hope is that by working together, the agencies can save time and resources by not having to duplicate efforts. For example, the auditing of drug production facilities, clinical study sites and organisations involved in the development of new medicines, devices and even cosmetics could one day be performed by one agency and the report produced accepted by others. Similarly, there is a goal to find ways of avoiding redundancies in the drug approval process in different regions and thereby speeding up getting new drugs to the market. One way they plan to do this is by having joint scientific discussions with EMEA when pharmaceutical companies ask for scientific advice during their drug development programmes. While Linda admitted that this is no guarantee that both agencies will provide similar advice, it will hopefully make both sides aware of other perspectives, and in some way aid the general consolidation of ideas. It is certainly an interesting idea for the FDA to open an office in Brussels and I am interested to see how it will impact on the attempt to harmonise the global drug approval process. The question I have now, is when EMEA will open an office in Washington... ■

photo: Crispin Hodges

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Plenary Lecture: The Precautionary Principle: An approach to Risk Management

Approach by Stuart Woods

The Precautionary Principle is a principle that has been in existence for millennia. The expression 'better to be safe than sorry' captures the concept very well. In the medical field Hippocrates embraced it when he advised "first do no harm".

In more recent years the Precautionary Principle has been applied as a regulatory principle, most obviously with respect to the protection of the environment. There have been many definitions–and interpretations–of the principle, but all relate to the management of risk in situations of scientific uncertainty, and adopt the position that a lack of scientific certainty is not a justification for regulatory inaction.

Today the Precautionary Principle is a compulsory principle of European law. Although the law only mentions it in relation to environmental issues, according to the European Commission it may be applied to all risk regulation activities within the European Union.

Two key factors have perhaps combined to lead regulators to extend the scope of application of the principle beyond the environment: increasing consumer access to information (especially via the internet) and increasing aversion to risk.

Regulators face a dilemma. In today's world the level of media/consumer attention directed towards a particular topic may be such as to oblige that they take decisions before scientific investigations are completed. Thus, in the words of the Commission, the application of the Precautionary Principle is a "political decision exercised in conditions of scientific uncertainty" that "reflects the need to take action in the face of a potentially serious risk without awaiting the results of scientific research".

The finding, in the mid 1990s, that the agent of bovine spongiform encephalopathy (BSE, mad cow disease) was transmissible to, and caused a spongiform encephalopathy in, man was perhaps the first stimulus for the application of

the principle in the pharmaceutical arena. Bovine-derived materials are not only eaten, they are widely used by many industries, including the pharmaceutical industry.

Spongiform encephalopathies are invariably fatal neurological diseases. The diseases have long incubation periods. The agents that cause them are difficult to inactivate. The infectious dose may be small and the pathogenesis of the diseases is (still) not fully elucidated. In addition, the geographical distribution of BSE in the 1990s was uncertain and the level of public concern was very high—a classic scenario for the application of the principle.

Regulators and the pharmaceutical industry worked very closely together to address possible BSE-associated risks and the controls that have been put in place are universally supported and applied. Reassuringly, scientific findings to date have shown them to be appropriate.

Could it be that a legacy of BSE–an increased focus on precaution and the principle of precaution–remains?

In 1999, the European Council of Ministers urged the European Commission "to be in the future even more determined to be guided by the Precautionary Principle in preparing proposals for legislation". Did the Council have BSE in mind? I suspect that they did.

Current pharmaceutical legislation does not specifically mention the Precautionary Principle, but recently issued draft regulatory guidance relating to vaccine products does. This draft guidance advises that there are perceived concerns in the public arena that relate to vaccine safety and that these must be addressed. It links a precautionary approach to a need for greatly increased emphasis on proactive and ongoing post-licensure regulatory management, including safety and other studies, throughout the life-cycle of the product.

Will this life-cycle approach extend to other therapeutic areas? In my view, this is inevitable. Regulators are obliged to react to the increasing risk aversion of the consumer and to media attention. There have been a number of high profile therapeutic product withdrawals as a result of safety concerns. A recent publication authored by senior European regulators noted that "the point of approval should not be the last call for major regulatory action" and that "a sharp increase" is to be expected in post-marketing clinical research activities" as part of "life cycle regulatory management".

Will it happen? I am sure of it. Consumers, the media and consumer concerns are not going to go away.

Will the Precautionary Principle have played a role in provoking this change of emphasis? I believe so.

Will it impact medical writers in their work? I think that it most definitely will. Some, perhaps many, of the studies that are required will be of a type that is unfamiliar to us. The players that are likely to be implicated, together with companies, are going to be different from those that have conventionally supported product development–for example health authorities, authority advisers and health care providers. It is probable that different skill sets will have to be developed.

It will pay us all to be prepared! ■

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Lunchtime discussion tables

Lunchtime discussion tables were held on the Thursday and Friday. In addition to the reports below, Phil Laventhal has written an article in the Out on Our Own freelance section about the discussion at the table with the theme 'Freelance or employee: Which is better?'

photo: Crispin Hodges

Frames of reference; regulatory versus marketing messages
Discussion leader: Leanne Walsh

This round table was intended to encourage medical writers to exchange their experiences and share advice on being caught between the needs of regulatory departments and the desires of marketing departments when writing documents. The discussion table was held twice and the participants had diverse personal experience with the topic. We animatedly discussed the difficulties some of us have experienced in final decision making responsibility, and tactful teamwork;

- we agreed that all statements need to be based on sound scientific data
- one group concluded that in fact non-scientifically sound statements are more frequently made by external experts rather than from within pharmaceutical companies
- the other group concluded that marketing departments in pharmaceutical companies may push for overstatement

It seems that a lot of medical writers feel caught between the scientific and marketing forces of the pharmaceutical messaging world but the round table discussion produced some good tips for resolving conflicts when confronted with difficult situations as well as the recognition that great support can be offered amongst medical writers on this topic.

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>>> What's news at EMWA?

Medical writers and pandemic influenza

Discussion leader: Robert Kahn

This discussion group considered the possibility of an influenza pandemic and what we as medical writers could do in practice. At present, the situation with such mild, but widespread, influenza is not too alarming. However, the key question is how the virus will mutate when the H1N1 virus with its high transmissability links up with the H5N1 virus with its high virulence, perhaps this winter in China. As medical writers we felt a responsibility to communicate, both with other medical writers and with the public. It was the failure to communicate during the 1918-1919 pandemic that led to a breakdown in trust between government and the public, as John Barry pointed out in his open-access 21 May article in *Nature*. The reality now was that viruses in any country were a threat to the rest of the world, as David Brooks wrote in "Globalism goes viral," in *The New York Times* of 28 April, on the web at: www.nytimes.com/2009/04/28/opinion/28brooks.html. However, such threats needed to be faced locally, with small groups of people committed to better hygiene, social distancing, and hopefully antivirals, and later vaccines. The importance of dealing with the media was considered, as set out by Debra E. Blakely in her book, *Mass mediated Disease: A Case Study Analysis of Three Flu Pandemics and Public Health Policy* (Lexington Books, Plymouth, UK, 2007). Interest was expressed in forming a group of medical writers who communicated regularly with each other by e-mail, and possibly later through a website. Those interested in being part of such a group, either as contributors or as readers, were asked to contact Robert Kahn at: rs_kahn@hotmail.com.

Medical writing management challenges

Discussion leader: Kari Skinningsrud

4-8 people participated in the lunch-table discussions at each session on Thursday and Friday. We discussed how the formal role of project manager is usually given to others rather than to medical writers (MWs), but that MWs have to take on a manager's role anyway to be able to complete the work they are expected to do within a given timeline. It was mentioned that MWs need to educate their customers—including other professional groups within companies—and be able to explain how their work can be split into packages with time allocated to each one. This makes it easier to present arguments for delays. Causes for delay should be recorded and systematised so the last person in the chain (the MW) is not automatically identified as the problem, but this needs to be done wisely so it doesn't all reduce to distributing blame. Medical writers need to develop management skills and accept that this part of the job will often not be acknowledged, it is just an inherent and unavoidable part of any MW's job. Multidisciplinary, multicultural teams are typical work situations for MWs. It's one thing to communicate exactly what our job implies, but another to do it to people who often know very little about our job and qualifications, and are even situated in other countries with quite different cultures.

Online social networks—kick-starting a freelance career

Discussion leaders: Laurence Auffret, Joeyn Mieke Flauaus and Laura Russell

Marketing yourself online is not an easy task, and around this lunch table, experts and newer users were at hand to discuss how useful social-networking tools can be and share their experience and thoughts on how to best use them.

This was a very stimulating and animated discussion that reached its objectives of both introducing the topic and consolidating the skills and confidence of online-network users. The issues involving practicality, usage and effective networking were discussed, and queries ranging from "Which online network shall I use?" to "What is the best way to attract attention?" served as a basis to cover many aspects of online networking. We examined the specific questions raised by participants in greater detail, and our various levels of experience allowed us a thorough examination of each issue. Thanks to the way delegates enthusiastically engaged with the topic, regardless of their experience, we managed to cover a great deal of ground within a mere 45 minutes. The discussion will be continuing electronically, on the EMWA discussion forum and via email, and several participants have already reported about steps they took after the lunch group met.

More details about our collective progress, concerns and experience are currently being compiled for an article which will appear in the next *TWS*.

EMWA Book Discussion: Lucky Man by Michael J Fox,

Discussion leaders: Wendy Kingdom and Alison McIntosh

This year the book we chose to read and discuss at the conference was *Lucky Man* by Michael J Fox, however, due to a clash in timings, and other EMWA commitments no lunch time discussions were able to take place. Apologies then, to those who read the book but were unable to join in discussions. Hopefully the following review of the book will help allay any disappointment.

Fans of *Back to the Future* will recognise Michael J Fox as Marty McFly, cheeky young chap and time traveller. Born in Canada, Michael became famous in the USA playing the part of Alex P. Keaton in the sitcom *Family Ties*. He has won an impressive list of awards and has starred in a host of movies and television productions.

In 1991, when Michael was just 30 years old and at the height of his career, he was diagnosed with Parkinson's disease. He did not disclose his condition to the public until 1998.

The first half of Lucky Man is an entertaining description of Michael's early years in Canada, followed by an honest and insightful look at his life in Hollywood. It is interest-

Stephen de Looze, who received the Nick Thompson Award (centre). Kathy Thomas-Urban (left) and Beata Wieseler (right)

ing to read about the living conditions of the actors who are 'resting', the people who help celebrities to spend their money, and the uninhibited living of the rich. The "I'm famous, you're famous" club is, apparently, a gathering of people who know each other, not as we mortals might understand friendship, but in the sense that they recognise each other because they are all famous and they know what it's like to be known by everyone else.

Michael was diagnosed with Parkinson's disease about a year after he first noticed a tremor in one finger. For a long time, he tried to pretend that it wasn't happening. The section of the book in which Michael describes his period of denial about the disease is heartbreaking. He turned to alcohol and spent hours in the bath with the lights turned off. He hit rock bottom when he was so drunk that he missed an important appointment and his wife, Tracy Pollen, said to him, "Is this what you want? *This* is what you want to be?" This shocked him into recognising that he had to face up to his condition and learn to live with it otherwise he could lose his wife and children.

As with many autobiographies, the writing does not always flow well. In particular, it is difficult to follow the chronology in the first half of the book. However, the descriptions of what it is like to live with the progressive symptoms of Parkinson's disease are interesting. Michael has tried all of the drugs that are available and he tells us about the pros and cons of each. He has even had brain surgery whilst being fully conscious.

The *Lucky Man* of the title is how Michael sees himself because he has the love and support of his family. Ultimately, this is a moving story by a man who has had to face an abrupt change in his expectations of life. Michael now uses his celebrity status to raise awareness of Parkinson's disease and to raise money for research.

As an addendum, the second instalment of Michael's autobiography has been released recently and is entitled *Always looking up. The Adventures of an Incurable Optimist*. In this new book, he describes the last 10 years of his life, when he has been working out how to have a fulfilled life whilst living, coping and struggling with what he describes as "the ravages of Parkinson's disease."

References:

1. Lucky Man: A Memoir. Ebury Press; New edition edition (2 Jan 2003). ISBN: 978-0091885670. 304 pages.
2. Always Looking Up. Ebury Press (16 April 2009). ISBN:978-0091922641. 288 pages.

Social programme

The social programme included walking tours, a boat trip, wine tasting and dinners in typical Slovenian restaurants. The banquet was held at the conference hotel, The Grand Union, in a beautiful room that has seen former days as a cinema. At the banquet each of the Executive Committee members who stood down at the AGM including Julia Cooper (Honorary Secretary), Wendy Kingdom (Treasurer), Kari Skinningsrud (Public Relations Officer) received well-deserved thanks from the new president. Stephen de Looze received The Nick Thompson Award in acknowledgement for all his hard work for EMWA over many years.

photo: Crispin Hodges

The highlight of the other social events was a trip to the Postojna cave.

Spelunking for dumplings

by Geoff Hall, with Lisa Chamberlain James doing the walking

". . . and if we're lucky we might see a human fish." Now, I've been on enough tour buses and complimentary conference airport transfers to be very wary of the information imparted by the guides. Try listening to what one of these people has to say about your home city if you doubt that a lot of this guff is inaccurate, based on legend rather than history or simply designed to deceive mischievously.

We were on our way to the Postojna cave—two busloads of medical writers and accompanying persons taking advantage of the Ljubljana conference social programme. When our courier raised the issue of the human fish, my incredulity level peaked.

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photo: Rainer Bishoff

Still, he added a few bits of supportive detail, none of which, however, was too convincing.

The bus ride from the city would take less than an hour and, as we turned off the highway, I was surprised to see that, after such a short journey we were only a few tens of kilometres from Trieste in Italy. Slovenia is only a small country. The Postojna Cave (pronounced poshtoyna) must be nearly as big. The whole system comprises over 20km of underground caves,

And what caves.

One of Slovenia's most popular tourist attractions today, the various people who have governed this part of the world over the last couple of centuries have all realised and enhanced this potential. Though the caves had been known since at least the 1600s, the discovery of new networks of caverns led to them being opened to the public in 1819. The authorities installed electric lighting in 1884 providing a brilliant spectacle for millions of visitors since. The Postojna cave had 'street lighting' before the capital Ljubljana.

Those of us who are not quite as agile as we would wish were delighted to find that our 5 ½-km journey into the cave was not to be on foot. A 4-km train ride into the cave system, through cathedral-like caverns, concussion-threatening tunnels and dramatic drip formations of rock, took us to the start of the subterranean trek.

The rails date from 1872. In those days, muscles of the cave guides provided the power. These days electricity does the job, providing easy access to the longest publicly accessible depth of any cave system in the world. An abiding memory of this conference was of immediate past-president Julia borrowing various items of ill-matched clothing in order to keep vaguely warm. This was certainly needed in the cave. The temperature is a constant 10°C and Julia became almost certainly the first woman to tour the caves in a Marylebone Cricket Club member's sweater.

The official guide says "Well kept paths for tourists comprise the greater part of Postojna Cave, making it a 'horizontal' cave. Thus a visit to the cave does not present any difficulties for most visitors."

I've no idea whether that is so or not. I, together with one of our plenary speakers, Dr Frank Wells, opted to stay on the train. Although this followed the same track as the way in, the experience was very different. Just the two of us in silence taking in the spectacle.

Lisa Chamberlain James takes up the story of the caves on foot:

I have to admit to a feeling of grave foreboding when faced with the suggested 'head-to-foot hooded blanket cave attire for hire' on a model at the entrance to the caves (I was sensibly dressed in a summer frock with no sleeves….). However, after the wind chill on our thoroughly enjoyable (although slightly white-knuckle) train ride, we alighted to a positively balmy atmosphere and dutifully set off after our guide up a rather steep incline.

At this point, the group began to fracture into the seriously well equipped and fit (at the front), the rather less well equipped and/or fit (in the middle), and the not at all fit, and/or well equipped, and/or just talking too much (at the back—of which I was a firm member). What was very noticeable was the unanimous 'oo-ing' and 'ahhh-ing' that emanated from all three groups (think firework night but without the loud bangs).

It is hard to describe the sheer scale and beauty of the caves. Every corner revealed a different colour or formation, and we were carefully led through the different 'galleries' by our very informative and patient guide, who explained the formation of the stalagmites and stalactites, their different colours, and the incredible length of time it takes for them to form (one variety takes 100 years to grow 1 mm). We even passed through the 'spaghetti gallery'—thousands of stalactites on the ceilings all looking like elongated macaroni, and were introduced to 'the diamond'—the emblem of the caves and a beautiful, pure white stalagmite.

The tour ended in the 'concert hall'—a truly amazing space with an echo that lasts around 6 seconds. I must confess to being slightly disconcerted (if you'll excuse the pun) by the thought of loud noises echoing around caves full of lethal-looking (albeit beautiful) stalactites…but then, I can think of worse ways to go than being impaled by a glittering shard of spaghetti-shaped rock that's taken thousands of years to form!

Admittedly, I was a little torn when I booked the cave trip. There were plenty of other exciting trips on offer that night, and a cold, damp, tramp around underground is not my usual choice of pastime. However, I'm SO glad that I was persuaded to go—I saw sights that I will never forget, and that a camera will never be able to reproduce faithfully. It was a truly special, almost magical place, and I would urge anyone to go back and see it (but maybe give the summer frock a miss….).

Back at the bar (sorry) restaurant

Frank Wells and I spent a convivial hour or so reminiscing about old times and enjoying an excellent Slovenian chardonnay before the rest of the group rejoined us for dinner. The package had included dinner in the caves restaurant and I was expecting something pretty ordinary from a tourist attraction diner. How wrong can you be? A beautiful room where we were served a delightful starter with a beautifully tender steak in a hunter's sauce for main course. Unfortunately, like so much grub in central Europe it was accompanied by dense heavy, but pretty looking dumplings. Then an apple strudel that impressed even the non-pudding-eaters.

A great trip. If you have a chance to go—don't miss it.

Oh and the human fish? Well it's true. A cave-dwelling blind creature completely adapted to life in the dark—*Proteus anguinus*. It's also known as the olm or the cave salamander. Part of the tour through the caves used to include a pool with some human fish in it. These have been removed due to the effect flashes from visiting tourists' cameras had on the sensitive human-like (hence the name) skin of the creatures. The official guide tells me that "To see one now, you must visit the Vivarium outside the cave." Missed that. We were in the bar. ■

Photograph taken in South Africa by Maria Wendt

Call for Abstracts for Brief Presentations

30th EMWA conference: 11-15 May 2010, Lisbon

For next year's spring conference, EMWA has decided to try out a new idea of opening the floor to all participants who would like to give a brief presentation on any interesting topic related to medical writing. The format will be 10 minute slide presentations followed by 10 minutes for questions/discussion. The topic should be of interest to other members and may include: hot topics, controversial areas for discussion, new guidelines or technology, etc.

If you are an EMWA member, you should have received an email inviting you to submit an abstract for a brief presentation on the appropriate form (maximum 200 words). You can also download the form from our website or e-mail head office for a copy (info@emwa.org). The deadline for submitting abstracts is 31st July 2009.

Once all abstracts have been received, a subcommittee will review them, and the most interesting ones will be selected to be presented at the 30th EMWA conference in Lisbon next May.

This is your opportunity to stand up and tell your colleagues about an aspect of medical writing that you feel strongly about. We're looking forward to hearing from you!

Helen Baldwin
EMWA President

Themes of upcoming issues of *TWS*

The September issue of *TWS*, which will be guest edited by Adam Jacobs (ajacobs@dianthus.co.uk), will have a statistics theme. December's issue will have a medical communications theme and will be guest edited by Ursula Schoenberg (u.schoenberg@t-online.de). Articles are also invited on preclinical regulatory topics. Future issues featuring business and electronics for medical writers are also planned.

Articles (up to 2500 words) and short reports/boxes (up to 1000 words) on these topics or any topics of interest to medical writers, medical translators, or trainers in the field are very welcome.

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Let's stop moaning about 'bad' medical writers—They are only producing what medical journals want

by Tim Albert

When I made the move from editing to training, I went with a mission. After a solid training in journalism, I had found it hard to accept the extraordinary ways that medical scientists insisted on writing. I felt that it was just a question of ignorance, and that, being bright people, they would transform their horrendous styles as soon as I had introduced them to the delights of writing short simple sentences, choosing short simple words, and cutting out flabby, meaningless phrases.

Of course it didn't happen like that. After only a few weeks it became clear that the medical scientists were just not interested. Whenever I started showing how what they had written could be expressed more simply, they looked at me in bewilderment. "Why would we want to do that?" they said. "We are not writing children's books. We are professional people writing science."

I abandoned the fight to persuade people to write their papers in good English

I adapted quickly, which is how I ended up running an effective writing course that spent less than an hour on style—and a lot more time looking at how effective writing could be defined, how writing projects could be measured, and how drafts could be written, tested and improved.

When it came to my course on getting papers published (dubbed internally the *ineffective* writing course), I ended up dealing with style in 10 minutes. "Look in the target journal" I said, "and follow what they do. If they write in a boring and pompous manner, then you should write in a boring and pompous manner."

Thus I abandoned the fight to persuade people to write their papers in good English. While others kept up a solid stream of articles bemoaning the fact that those writing for journals 'couldn't write', I kept a watching brief.

Why do journals find 'bad writing' advantageous?

I wrote an article in simple English that was rejected by a prestigious journal, then accepted when I got cross and rewrote it in a pompous and prolix manner. In training sessions I saw countless drafts becoming increasingly dense as they went through the reviewing and editing processes. And I was asked to do a short and dirty piece of research looking at articles before and after technical editing: dense styles were made less dense, not surprisingly, but simple styles were made more complicated.

All of which led one day to my epiphany: we were all looking in the wrong direction. The question we were all trying to answer was: *Why do people write so badly for scientific journals?* But journals didn't seem to be suffering, so perhaps we should have been taking a broader view—and asking whether this so-called 'bad writing' was actually benefiting medical journals.

In other words: *why do journals find 'bad writing' not just acceptable, but advantageous?*

One reason is that it makes them more international. The style is based on the vocabulary, and possibly the constructions, of the classical languages of southern Europe. So those with a grounding in Latin and Greek find *commence* and *terminate* easier to understand than *start* and *stop*. (Which is fine up to a point—but that point stops at central and northern Europe, India, China, Russia and many other parts of the globe that are becoming increasingly important.)

"Scientific publications… serve the needs of their authors above the needs of their readers"

A second—and related—reason is that 'bad writing' makes journals exclusive. This makes the content more private, which in turn allows a relatively small—and stable—number of insiders to acquire status and power—and benefit from the vast amount of money poured into the world of medical publishing.

Bad writing also reduces risk. When only a few people understand the articles, then science becomes a more or less private activity, carried out by a small group (equipped with special skills, like reading articles from the bottom up!).

From the publishers' point of view, they can concentrate more on making profits than bothering about improving the quality of the writing. Thus 'bad language' saves them millions in technical editing costs (one journal I know spent about three times the amount of money on reviewing than they did on technical editing).

And the attitude has spread. Earnest organisations like COPE and WAME talk constantly of publishing etiquette (can you turn a thesis into an article? when is an author

Let's stop moaning about 'bad' medical writers

really a contributor?) and virtually nothing about how to improve the way journals actually communicate.

The key point is that the role of medical publishing has changed. In one of my favourite quotes, Shortland and Gregory (*Communicating Science*, Longman, 1991, p51) sum it up beautifully: "Scientific publications have purposes other than the communication of ideas: they represent the productivity and therefore the 'value' of the research team; they establish hierarchies by the ordering of their author lines and by whom they chose to cite; and, most importantly of all, they stake their author's claim to the new knowledge they contain. They serve the needs of their authors above the needs of their readers."

Of course medical journals have made major contributions to our understanding of medicine that have benefited public health—and will continue to do so. But all this concern on poor language skills is a sideshow. The real cause for concern is not that authors write badly, but that our current medical publishing system doesn't really require them to write better.

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Tim Albert's latest book is reviewed on page 130.

For more thoughts on medical writing see page 114.

Check the subject in clauses connected by conjunctions

In one of these studies, POP was examined in relation to sexual activity and concluded that sexual activity is independent of PFD.

This sentence reads well until you reach the word *concluded*; you subconsciously search for a subject for this verb (because that is what you do even if you don't realise you do). You have borne in mind that POP was the subject of the previous clause, and, as is frequently the case when two clauses are connected by *and*, the expectation is (unless it is followed by a comma, see below) that the subject of the first clause is also the subject of the second clause, and the subject is not usually repeated. But pelvic organ prolapse is certainly not doing any concluding here. And we have an inappropriate mix of the passive (*was examined*) and active (*concluded*) which further complicates reading. So you understand what the sentence is saying, but the author could have taken more care to avoid all that happening in the reader's mind.

The problem here is that the author started the sentence with the prepositional phrase *In one of these studies…* which modifies the verb *examined* in the first clause (as an adverbial) and had this in mind as the subject of the second clause, which does not work here. So the sentence needs recasting, and the simplest way is to avoid the prepositional phrase: *One of these studies examined POP in relation to sexual activity and concluded that sexual activity is independent of PFD.* Now *One (of these studies)* … is the subject of both clauses and the sentence reads more smoothly and does not throw up any questions in the reader's mind.

If you absolutely insist on starting with *In one of these studies …*, then it could be recast as follows: *In one of these studies, Smith et al examined POP in relation to sexual activity and concluded that sexual activity is independent of PFD.* The sentence could, of course, be reformulated with two different subjects, but these two possibilities show that the result is not as smooth as the solutions with the same subject: (i) *In one of these studies, POP was examined in relation to sexual activity and the conclusion was that sexual activity is independent of PFD; (ii) In one of these studies, POP was examined in relation to sexual activity and it was concluded that sexual activity is independent of PFD*. In the latter two sentences, I would prefer to put a comma before the *and* because this signals to the reader that the next clause has a new subject. This is a convention I always try to observe as a guide for the reader. Without the comma, as we see above, the assumption is often that the same subject applies to both clauses.

Whatever the solution, I am all for repeating the term *sexual activity* because it would not be clear whether an *it* referred back to *POP* or *sexual activity*.

PS: Of course, the simplest solution would be: *One of these studies concluded that sexual activity is independent of PFD*, but I assumed that the author wanted to retain the fact that POP was examined in relation to sexual activity.

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Bad science and good writing or good science and bad writing?

by Richard Clark

Most of us, I hope, would prefer good science badly presented to bad science written expertly—or would we? Given the recent celebrations surrounding the joint anniversaries of Charles Darwin's birth (1809) and the publication of *On the Origin of Species* (1859) (Figure 1), imagine he could be transported to the present day and agreed to give a short lecture. Would it matter that he had no knowledge of projectors, computers and PowerPoint? Would that put you off listening to him? Imagine you had the alternative of listening to someone else instead, such as the present-day geneticist Steve Jones, who (I hope) would freely admit to not being in the same league as Darwin, but is well known for his erudite, amusing and informative lectures. Anyone for Steve Jones? (The reader should note here that I hold Professor Jones in the highest esteem, and can actually remember many things he said 20 years ago when I attended his lectures at University College London. Despite this, I would still opt for listening to Darwin. Steve Jones is now what one might call a 'media personality' as he is one of the very few scientists who seems to talk in language that most people can understand and appreciate.)

We are in danger of regarding the quality of medical communications as more important than the facts

The point I am trying to make with this example is that we, as medical writers, are in danger of regarding the quality of medical communications as more important than the facts they should be communicating. An example of this corrosive mindset is that, when giving my talk on slide presentations *not one* professional medical writer thought that the slide content (i.e. the scientific evidence or data) was more important than the way it was presented (preferred options picked from a list were generally 'the look of the presentation' or making presentations 'clear, simple and easy to understand'). You might disagree with me, but a rationale for this view has been published in a previous issue of *TWS* [1]. However, I will write here that without good content, what is the point of communicating, however excellently?

The client wants you to 'miss out the bad bits'

You might say as a writer that you cannot control your subject matter to a great extent anyway, and you have to do your best with what you have been given. To some extent this is true. Nevertheless, there is often scope for improving the content of a primary manuscript, review, poster, slide presentation or other materials, as we usually 'pick and choose' our sources and which data to include. Here comes the dangerous bit: the client wants you to 'miss out the bad bits' (as I was asked only this week), or to skew or 'spin' the article substantially by the use of specific language and sourcing of references. You are asked to mention all the drug 'key messages' with their supporting references, as supplied by the marketing department. No studies should

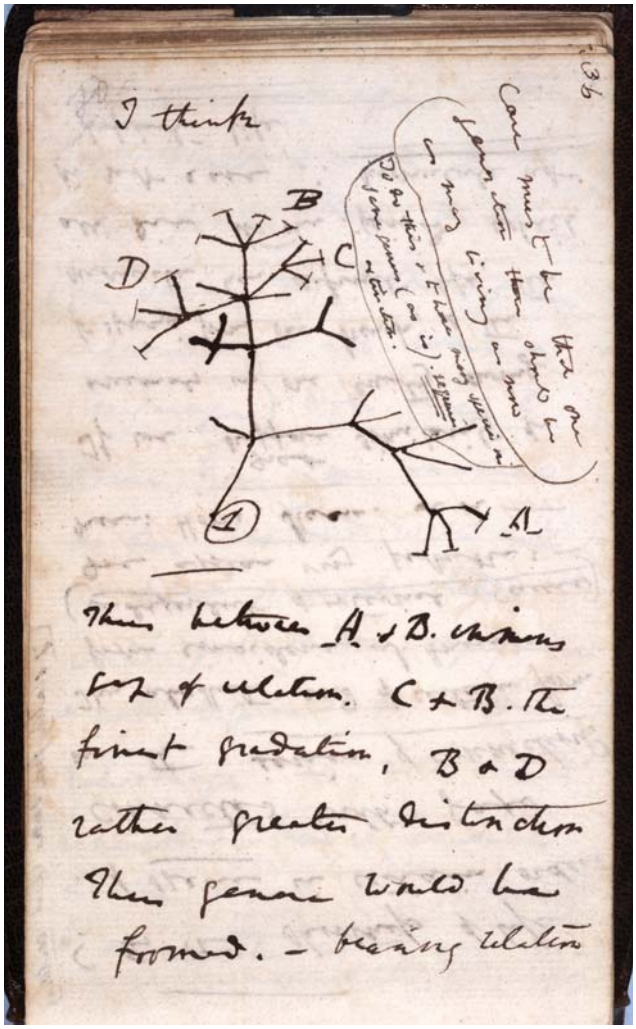

Figure 1 **Darwin's first known sketch of an evolutionary tree, above which he wrote "I think" (Tree of life sketch from Darwin, C. R. Notebook B: Transmutation of species [1837–1838]). Reproduced by kind permission of the Syndics of Cambridge University Library**

Bad science and good writing or good science and bad writing?

be mentioned that are not favourable to the drug in question! However, an overtly biased approach is counterproductive: it fools few people and makes the rest who are aware of the deception wary of the pharmaceutical company and their drug. In this situation I would advise the client of any misgivings (in writing) and attempt to steer them in the right direction. It is particularly important in these situations to save all early drafts—if you don't do this already—just in case later drafts are produced without your knowledge that are substantially biased or inaccurate, and there is always the 'nuclear' option of withdrawing your labour if you feel very strongly that what you are being asked to do is wrong.

Where does this leave us? What overall approach should we take to medical writing? I feel we should concentrate on the *content* that makes bad writing bad rather than the method of presentation of good or bad science. The one guiding principle for me is *would I be unhappy for this poster, review or slide presentation to appear with my name on it as a co-author*? If any of us think we would feel wary or ashamed to see our name on something we've written, then we haven't done our job properly. This is why people feel that 'ghostwriting' is somehow unethical; that the real, professional author who has been paid for using their writing and scientific skills is hiding. I'm not, however, suggesting that we should be authors on everything we produce, rather that we use authorship as a state of mind with which to approach our work. As the Nobel prize-winning scientist Joshua Lederberg recounted "Above all, the act of publication is an inscription under oath, a testimony"[2,3], and I'll go along with that.

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Impact factors (IFs) vs objective language

Adjectives that attribute status or significance to an otherwise neutral claim were counted in 12 journals using a bias score, e.g. 'crucial' was given a high score of 3 and 'important' a lower score of 1. The research raised the question "Does a reward-seeking-model of publication—as reflected in the current desire to publish in high impact journals—influence the use of language in scientific manuscripts? The adjectives' use increased statistically significantly from 1985-2005 in biomedical research journals with high IFs but not in clinical journals. The authors argue that subjective stances on the relevance and implications of results should be tempered with discretion. 25 years ago scientists selected journals for their publications primarily based on the audiences they reached but IFs have increasingly swayed their choice as the emphasis on IFs in assessing researchers and their departments has increased. The authors thought that the potential to influence clinical practice might be the reason for language being more likely to be tempered in clinical journals.

Source: Fraser VJ and Martin JG: Marketing data: Has the rise of impact factor led to the fall of objective language in the scientific article? *Respiratory Research* 2009;10:35-39. http://respiratory-research.com/content/10/1/35

Expression of emotion: A comparison of extracts from medical papers written in the 1800s and late 1900s

The following are examples of the emotion expressed in medical prose in the 1800s:

a. I was alarmed by the *great* apathy and *great* prostration. I found the fever and pulse *very much* moderate (1826)
b. I do not recollect having *ever seen such excrescences of such a length* as are here (1836)
c. I do not know any operation in surgery where *so great an amount of relief* is given with *so little* trouble (1855).

The following examples are of how conflicts were tackled in the 1800s compared with the second half of the 1900s. The characteristic personal attacks and emotion in the extracts from the 1800s is absent from the 1900s' extracts, which are characterised by detachment.

1800s

a. Mr. Bloch and Mr. Dumeril obtained the same results. It is easy, however, to perceive that both these respectful gentlemen were profoundly mistaken. (1832)
b. Dr Lawrie is disposed, incorrectly I think, to consider the amputation of the leg more fatal than that of the thigh. (1840)
c. The mortality is considerably greater in the Glasgow Infirmary, which Dr. Guthrie, a highly respectable man, attributes with no reason at all to the pseudo–improvements of the late years in surgery. (1840)

Late 1900s

a. We have carried out both the test of Akerfeldt and Gibbs and have been unable to confirm the findings of either investigator. (1960)
b. The randomized controlled cross–over trial of Engleman et al. has important weaknesses. (1995)
c. Our data are statistically different and conflict with the information previously reported. (1990)

With thanks to **Françoise Salager-Meyer** (francoise.sm@gmail.com) for providing these examples

Communicating science to popular and academic audiences

by Jo Whelan

"What are the differences between the writing in biomedical journal manuscripts (generally exceedingly boring) and the sort of things we read in BBC Focus, New Scientist or Scientific American (generally fascinating)?" This was my brief from the *TWS* editor, who went on to say that "more and more science journals are going in the direction of magazines because people would prefer to read something more readable than biomedical journals, which are hardly read anyway." I can't pretend to have any scholarly insight into this, but as a writer who has earned a crust doing both types of writing I will try and pull together a few observations.

I don't suppose many of us read original research papers at bedtime (unless we have a really serious insomnia problem). Similarly, I imagine that few people read biomedical journals from cover to cover. Most are likely to cherry pick one or two articles that draw their interest, either from an electronic or printed table of contents or through a Medline search. The proportion of papers that get read in anything like their entirety after a glance at the abstract is likely to be smaller still. This isn't to denigrate the writing in biomedical papers or journals. The reason they are not read from cover to cover is not that the writing is boring but because they describe many individual pieces of research, each of which, in isolation, is only of interest to a small number of people.

Few of us read original research papers at bedtime

Would more people read original research papers if the writing was more compelling? My guess is probably not. To communicate their research to a wider audience, institutions, journals and sponsors increasingly produce press releases at the time of publication. These are placed on news services such as Medwire (http://www.medwire-news.md/default.aspx), AlphaGalileo (http://www.alphagalileo.org) and Eurekalert (http://www.eurekalert.org/), all of which are good sources of serious and original medical and healthcare news. They sit at the top of a whole chain of websites which feed on and digest the original stories (e.g. the BBC News site), or digest the digests. The lower down the chain, the more likely it is that a Chinese whispers effect will come into play and distort the original story, and the less reliable the data on which some of the stories are based (non-scientific surveys carried out by PR companies, for example).

There are problems with this approach. Over-eager press officers often introduce interpretations that go beyond what is justified by the study. It appears that some authors either don't insist on approving press releases, or else feel unable or unwilling to challenge what has been written. Alternatively, researchers may feel that it's OK to say things in a press release that you wouldn't say in a journal article. Press releases also offer the chance for researchers with large egos to grandstand without peer review and make inflated claims for the significance of their work.

Is explaining research to a general audience 'easier'?

More serious is the situation where research findings are communicated directly to the media in the absence of a peer-reviewed publication. In his book Bad Science (Fourth Estate, London, 2008), Ben Goldacre describes how this was the case with several of the key scientific claims in the MMR vaccine scare in Britain. Supposedly important scientific claims "were being reported in newspapers and magazines, at meetings, in fact anywhere except proper academic journals where they could be read and carefully appraised," Goldacre notes. He also stresses the importance of 'publication in full'. If full details of the methods used and the data collected are not published, readers are not in a position to critically appraise the research.

From a writer's point of view, is explaining research to a general audience 'easier' than writing a manuscript for an academic journal? In my experience, the answer is "no". Good popular science articles (ones that get the science about right and manage to tell an interesting story in the process) can be as or more challenging to write than the average academic review or clinical paper, although they don't take as long. The writer must create a narrative that acknowledges the background issues, the different approaches, the conflicting research results and the links to other findings and ideas that make up real-life science, and then explains them to the general reader. It is this element of giving an overview of a complex subject to a non-specialist audience that is demanding, especially when the writing must be both engaging and concise as well.

Speak to the people at the centre of the story

Communicating science to popular and academic audiences

Einstein said, "If you can't explain it simply, you don't understand it well enough." While Einstein-like levels of understanding are fortunately not necessary, a good grasp of the topic is.

Journalists who have written medical stories for both high-end and mass-market publications will often say that writing for the mass market is more difficult. For higher-level readers we can write in the way that we ourselves think, which is not so far removed from the way in which research is presented. Writing for the mass market requires writers to present the subject using a very different type of discourse from its source material. Similarly, the challenge of popular science writing is to translate the subject matter from its native scientific style of discourse into the narrative and stylistic requirements of the popular form.

Popular science writers must give the big picture, but can skimp on the detail – both on the page and in their own understanding. In scientific writing it's often the detail that's important. Unless the paper contains groundbreaking new concepts (and most don't), we can assume a greater level of knowledge in our readers and the need for explanation and context-setting is less.

What are the differences in writing style between scientific and popular science writing? An important part of writing a science feature is interviewing. It's not enough to search and summarise the literature, as you would for a scientific review. You need to speak to the people at the centre of the story. Editors will usually expect quotes from at least two experts, including people from opposing points of view if opinion is divided. For me this is the most rewarding part of the job; it is a tremendous privilege to be able to ring up top people in their field and get them to talk about their work. Most are happy to talk to writers from the science press. Their insights and anecdotes will usually supply most of the material you need to bring the article to life.

Popular science pieces must be written in a clear and direct style, so that any hard work by the reader comes from understanding the concepts, not fighting their way through the sentences. I think scientific writing can learn from this. Popular writing uses colourful and idiomatic language to create interest, and often adopts a semi-conversational style. For scientific writing that is not necessary or desirable. Nevertheless, the aim of scientific writing is fundamentally the same – that is, to communicate with the reader. It achieves this better if we state what we mean as simply and directly as we can. Complex language can also be a way of fudging, perhaps unconsciously, to hide the fact that we aren't sure exactly what we mean.

Clearly, both scientific and popular writing have their place in the communication of science and medicine. Each type of writing can learn from the other. Editors who commission stories should perform the function of peer reviewers and point up flaws, ask for evidence and request clarification of arguments. Science editors will usually do this. Unfortunately the average generalist editor won't, and the woeful results can be seen in some of the medical stories that make the national newspapers, at least in Britain. Scientific writing can perhaps take on board the fact that readers like narrative, and can learn from journalism's use of plain language.

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Some emotions absent from modern scientific articles: Sand hoppers

In Cladaigh Chonamara Seosamh Mac an Iomaire, [1] an Irish fisherman in 1926 describes the sand hopper: "The tonachan tra ia always working at ebbing tide, making small holes under the sand. He raises his hard pointy head from time to time to look around and see how the labour is going. He does not live in his holes. Usually there is a huge crowd of them together, helping each other loyally and stoutly."

The English Archdeacon W.Paley wrote in the early 19th century in *Natural Theology* [cited in 2]: "walking by the sea side, in a calm evening, on a sandy shore, with an ebbing tide, I have frequently remarked the appearance of….young Shrimps, in the act of bounding into the air from the shallow margin of the water or from the wet sand. If any motion of a mute animal could express delight, it was this; if they had meant to make signs of their happiness they could not have done it more intelligibly."

C.M. Yonge wrote in *The Sea Shore* in 1949 the sand hopper [2], "…[it] may occur in immense numbers: "not millions but cartloads" was the comment of one observer. It burrows in sand under weed and other debris along the strand line".

Ed Ricketts wrote in *Between Pacific Tides* in 1938 about sand hoppers; "Observers with a trace of sympathy for bohemian life should walk with a flash light along a familiar surfy beach at half tide on a quiet evening. The huge hoppers will be holding high carnival—leaping about with vast enthusiasm and pausing to wiggle their antennae over likely looking bits of flotsam seaweed [3].

A similarity in opinion between a 19th century Church of England clergyman, a Californian biologist and an Irish fisherman suggests a worldview of a fairly universal appeal. However science has conquered this universal appeal. These authors expressed feelings the animal inspired in them but feelings are absent from modern scientific articles.

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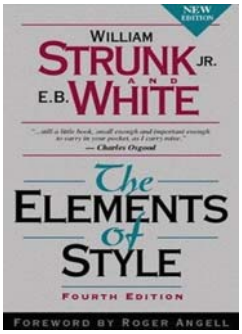

Braving The Elements

by Alistair Reeves

"There were a great number of dead leaves lying on the ground" is not a passive construction except in Strunk and White's *The Elements of Style*

The Elements of Style is the American Bible of grammar. April 2009 saw the 50th anniversary of the book's publication accompanied by much celebration. However, Geoffrey K. Pullum, who is head of linguistics and English language at the University of Edinburgh, saw no cause for celebration. In an article, which is 'a must' read for anyone interested in grammar or who views grammarians as shrinking violets, he slates the book for giving stupid advice [1]. For him it answers that mystery of why Americans have not been able to master English grammar. The book provides just about all the instruction American students receive on grammar but its authors Strunk and his pupil White were not qualified grammarians with the result that "The book's toxic mix of purism, atavism, and personal eccentricity is not underpinned by a proper grounding in English grammar."

An example of their personal eccentricity is the advice that a sentence should not begin with 'however' used in the sense of 'nevertheless'. There is no research to back up this advice. Indeed searches have found that good authors use the word in varying ratios at the beginning of the sentence and after the subject [Mark Twain (7:3), Henry James (1:15)]. Another example is the advice not to use 'which' to introduce a restrictive clause. Either 'which' or 'that' can be used and there has never been a rule to the contrary.

Pullum also gives several examples of mistakes in the book and of where the authors contravene their own advice. In particular he tackles the advice to avoid using the passive. "What concerns me" he writes "is that the bias against the passive is retailed by a pair of authors so grammatically clueless that they don't know what is a passive construction and what isn't". Pullum analyses three examples given in the book, including the 'dead leaves' example above, and shows that they are not passive constructions. Worse still, even though Strunk and White state that writers should not totally discard the passive language, tutors and Microsoft Word's grammar checker tend to overlook this modification insisting on a blanket prohibition against passive sentences.

The expert's conclusion is that "English syntax…is much too important to be reduced to a bunch of trivial don't-do-this prescriptions by a pair of idiosyncratic bumblers who can't even tell when they've broken their own misbegotten rules".

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Strong words indeed from Geoffrey Pullum. What a good read his article is! I can only recommend it.

I, too, have sometimes found myself uttering the word 'stupid' to myself when consulting *The Elements of Style*, but because I am not a respected professor of linguistics with many published works on grammar, I have never dared to criticise it in so swingeing a way. I agree with most of his criticisms—and have some more—but unlike him, never felt that the 'rules' and principles were quite so pernicious.

I have never regarded it as a key resource

I also think that a good deal of the advice is useful to novices, as long as they are aware that much more comprehensive style guides are available, some specifically written for the life-science and medical fields. I have therefore never regarded it as a key resource.

The Elements of Style is not a grammar book, and if I wish to clarify a point of English grammar, I prefer to consult such a reference work, of which there are plenty (see box). I suspect that the astonishing success of the book has been due to factors largely independent of its content: it obviously filled a niche, offered the security of 'rules', and bears the name of an eminent author, EB White. It is short, small and cheap, was probably marketed very well—and still is evidently being marketed well, what with a 'special' anniversary edition and 50-year anniversary celebrations—and was probably placed on the compulsory readings lists of schools, colleges, universities and other institutions throughout the USA. Some of its contents have obviously slipped into other style guides, because they say exactly the same. Because of this, the "real damage" (G Pullum) of some of the misinformed advice it gives on grammar has been silently propagated for two generations, and not only in the USA.

Some students have 'never had a grammar lesson in their life'

I suspect that in all English-speaking countries, the USA included, grammar teaching in schools has reached an all-time low. I am often told by students (many of them PhD scientists), especially from the United Kingdom, that they 'never had a grammar lesson in their life' and find I have to explain the simplest concepts to them (even what the subject of a sentence is) before I can even start talking about how to improve their writing.

When training writers, I am often confronted with the lingering myths engendered by the *The Elements of Style*,

even though most of my students are not from the USA. Throughout my career, I have seen evidence that the raised forefingers of Strunk and White have managed over the past 50 years to penetrate areas of the globe distant from the USA, no doubt accelerated more recently by Microsoft Word's grammar checker, the Internet, 'globalization', the dominant role of English in scientific documentation, and research fellowships and study periods in the USA.

Unlike Geoffrey Pullum, I am not a grammarian, nor am I an expert in linguistics (I am just a linguist with a good grounding in grammar with a passion for the way any language works), and this has prevented me from speaking out quite as radically as this eminent professor, although I have made my small contribution in these pages to exploding some of the myths about English disseminated by *The Elements of Style* and other sources. I was particularly pleased to read what Professor Pullum had to say about the ever-recurring claim: "But you should only use the active voice". Variants are "I thought you shouldn't mix the active and passive voice" or "When I was on a research fellowship in the USA, I was told you're not allowed to use the passive", and, of course, nowadays, "But it is underlined green in Microsoft Word!". I have sometimes felt very alone in defending the use of the passive voice and the mixing of the active and passive voices, because it is impossible to write sensibly, sensitively and concisely in our field without doing so. I also searched in vain for the passive voice in the examples provided by Strunk and White in *The Elements of Style*—an unforgiveable error that has persisted for 50 years.

Professor Pullum states that much of the advice given in *The Elements of Style* is "useless", including *Omit needless words*, because "students who know which words are needless don't need the instruction". I disagree with him on this point. My experience is that many authors do not know which words are needless, because they are constantly seeing and hearing needless words in wordy locutions, and—without thinking—assume that the needless words are needed, or that they 'sound better'. Writers do, therefore, need instruction, with appropriate examples. I see this every day: *before surgical intervention* instead of *before surgery*, *to decrease the length of* instead of *to shorten*, *a greater length of time* instead of *longer*, *cut into two equal parts* instead of *halve*, *during the course of* instead of *during*, something *first began* instead of *started*, *period of time* instead of *period*. I have a list of hundreds of such common terms that trip off the tongue when speaking but never need to be written and I impress upon students that they should look at every sentence critically and ask themselves: *How can I make this shorter and retain the meaning?*

I am glad that Professor Pullum seizes upon the blatantly ridiculous statement "Write with nouns and verbs, not with adjectives and adverbs", which shows a poor appreciation indeed on the part of Strunk and White of my observations about good English, at least in our field. Pullum says that "the motivation of this mysterious decree remains unclear to me". A colleague from the USA obviously appreciated the motivation: she told me that in this respect she had fully embraced the rule (*sic*) in *The Elements of Style* and "never used adjectives or adverbs". Quite how she managed to produce cogent texts is a mystery to me, because she obviously had no idea what adjectives and adverbs are.

My advice for good English in our field is 'It is more often appropriate to put the activity in your text into verbs and not nouns, and to modify these with adjectives and adverbials to give it meaning'. Professor Pullum would probably describe this as platitudinous, but such statements obviously have to be fleshed out with enough appropriate examples, e.g.:

> *The diameter of the invasive tumour regressed considerably by 2 cm after drug x was instilled twice into the bladder.*
>
> instead of
>
> *Instillation of drug x twice into the bladder brought about considerable regression of the diameter of the invasive tumour by 2 cm.*

Neither can exist without adverbs or adjectives—nor indeed nouns or verbs—but the first is certainly better to read, although the second would probably have been preferred by Strunk and White according to their advice.

Despite their decree not to write with adjectives and adverbs, under the heading *Use definite, specific, concrete language*, Strunk and White provide an example (two long paragraphs from a novel) of "how prose is made vivid by the use of words that evoke images and sensations". And guess what—the two paragraphs are teeming with adjectives, adverbs and adverbial phrases. This example, indeed all examples in *The Elements of Style*, definitely show that the target audience for this book were not authors in the life sciences and that it is not a reliable reference work for our field.

The target audience is not writers in the life sciences

The actual target audience for the book is not clear. As Professor Pullum states, much of it is concerned with grammar, but it actually only covers the tip of the grammatical iceberg as far as English is concerned, and then only sketchily. The *Elementary Rules of Usage* and *Principles of Composition* sections are disorganized groupings of 22 arbitrarily chosen topics, including a small selection of simple and complex aspects of English grammar, and these are referred to as 'rules'. At best, about one quarter of them are actually what could be termed rules. All are peppered with examples that sometimes do not illustrate the point clearly, or sometimes sound stilted and outdated: who nowadays says *The culprit, it turned out, was he* or *Sandy writes better than I* (*Use the proper case of pronoun*), who would ever use the word *bedchamber* today unless writing a historical novel (*Use of the hyphen*), and, amongst English speakers born in the last 30–40 years, who can seriously claim that they still think it is important to rigidly preserve a distinction between *I shall* and *I will* (*Misused Words and Expressions: Shall/Will*)? Professor Pullum points out that some of the examples contain errors

> > >

>>> Braving The Elements

or do not actually illustrate the point. To this I add that examples are often not provided to illustrate important points. Because such books live from the examples given, it is alarming that *The Elements of Style* ever took such a firm hold, but as I suggested above, there must be many other reasons for this.

One of the problems with language is that people want rules. In other areas of life, they are happy to take a flagrant rules-are-there-to-be-broken attitude, but when it comes to language, they clamour for the security of rules. And this was probably where *The Elements of Style* also scored points. But this is one security that English cannot offer. We have rules, of course, but there are many exceptions and unregulated areas. Different resources often contradict one another. We have no *Duden*, like the Germans, nor do we have an '*Académie Anglaise*'.

When it comes to language, people clamour for the security of rules

Rule 1 in *The Elements of Style* is *Form the Possessive Singular of Nouns by Adding 's* and states "Follow this rule whatever the final consonant". The first two examples given are not nouns, but proper names (Charles's and Burns's [Burns's is highlighted as an error in the MSWord spellchecker for both 'U.K. English' and 'U.S. English']). We are then informed that Jesus' (for some strange reason) is an exception to this 'rule'. Inasmuch as this is still taught in the UK, for example, the 'rule' is that you do not add *'s* to any name ending in 's', unless the terminal 's' forms part of a voiced syllable—with exceptions. White highlights 'Rule 1' in his introduction to the 1979 edition by commenting that a British newspaper headline from 1957 (Charles' tonsils out [Prince Charles had had a tonsillectomy]) got it wrong. But the newspaper was doing nothing but reflecting common British English usage in the 1950s, which I was taught and still persists today.

Jesus' (for some strange reason) is an exception to this 'rule'

One of the problems with Strunk and White's small selection of 'rules' is that they offer blanket statements and too little information on exceptions or do not mention that there are exceptions, or contradictory usages, which obviously led to the rules being interpreted as absolute. It is also likely that many readers will have just skimmed the section headings and text, and that the messages contained in the section headings are the ones that have stuck.

After the 'rules', except for *Write with nouns and verbs* (see above), the subsequent sections, *A Few Matters of Form*, *Words and Expressions Commonly Misused* and *An Approach to Style*, generally offer sensible, if sometimes superficial, advice. Even so, the sections *Write in a way that comes naturally*, *Be clear* and *Do not overwrite* do not actually tell you how to achieve any of these, despite being several paragraphs long!

A few other 'rules', some trivial, some serious, not discussed by Professor Pullum are worthy of mention:

- "The abbreviation *etc.*, even if only a single term comes before it, is always preceded by a comma". This is not a rule.
- "A participial phrase at the beginning of a sentence must refer to the grammatical subject". It is easy to find amusing and confusing examples of badly constructed sentences starting with participial phrases that do not refer to the grammatical subject (*Wondering irresolutely what to do next, the clock struck twelve* is given as an example). A more realistic and ambiguous example that occurs in our type of text is *Based on the guidelines, they issued a study report.* 'They' were not based on the guidelines. So care is certainly due. There are, however, plenty of instances in common usage where the participial phrase quite legitimately does not refer to the grammatical subject without confusion—so there is no 'must' about this. What about *Concerning your study, I feel that we should rather ...* (I am not doing any concerning), *Given the high values, we decided to change our policy* (We were not given the values), or *Generally speaking, diabetic patients are well informed about their condition* (The diabetic patients are not speaking).
- "In summaries, keep to one tense". This may be true for the literary examples given by Strunk and White or the blurb on the back of a book. For the purposes of writing in the life sciences, don't even bother to remember this 'rule'.

And there are some absolute space and time wasters:

- Do not use hopefully to mean *I/We hope that*: a completely lost cause that became an old chestnut tens of years ago.
- Do not use *contact* as a transitive verb: "the word is vague and self important. Do not contact people; get in touch with them, look them up, phone them, find them, or meet them". Although this *may* have been 'correct' in the distant past (according to Merriam Websters Online Dictionary, *contact* used this way was first documented in 1834), this is rubbish today. You can happily *contact* anyone you want.
- "Place the emphatic words of a sentence at the end". The emphatic words in this quotation are at the end, but that is not why they are at the end—they are there because that is where this adverbial phrase syntactically and grammatically belongs in this command. At least in our field of writing, my observation is that what you want to remain in the reader's mind should be at the beginning of your sentence, or as near to the beginning as you can position it. The careful writer has control over their sentence and puts the emphasis where they want it, sometimes by using words that emphasize, or by deliberately deviating from unstressed, expected word order.
- Do not use *they* as the pronoun for a singular subject (as in the previous sentence). *The Elements of Style* decrees that you should say 'he' instead. It is astonishing that

this 'rule' has survived in a recently revised style guide. Whatever you feel about political correctness, using the plural to enable the use of 'they', or using 'they' as the pronoun for a singular subject, and other ways of avoiding the male pronoun 'he' have now established themselves in all fields of writing.

- Do not "press nouns into service" as verbs. This is illustrated by 5 "suspect" examples, 3 of which are normal English usage: *The candidate hosted a dinner for fifty of her workers*, *The meeting was chaired by Mr Oglethrop*, and *The theatre troupe debuted last fall*. There can be no objection to any of these three verbs—this just reflects the evolution of language. According to the *Oxford English Dictionary*, *host* as a transitive verb was first documented in British English in 1676, and *Merriam Websters Online Dictionary* records the date of its emergence as the 15th Century. But even if it were a neologism, the respectable use of *hosted* in this sense can easily be defended: you can *give* a dinner, but you do not necessarily need to be there in person, but if you *host* a dinner, it would be unusual if you weren't present. Also, if you *give* a dinner, this usually means that you (or your company) paid for it; if you *host* a dinner, you may not be responsible for the cost. A better 'suspect' example here would be *The paper was authored by …* , which I still think is unnecessary, because we have the word *written*, but this has come into such common usage that it is silly to object to it. It is important to be able to distinguish between personal preferences and the realities of common, acceptable usage.

It is important to distinguish between personal preferences and the realities of common, acceptable usage

Amongst all of this, there are some pieces of advice that, for our purposes, deserve only praise:

- "Respective/respectively: These words may usually be omitted with advantage"
- "Why say *utilize* when there is the simple unpretentious word *use*?"
- "In formal writing, *etc.* is a misfit"
- '6 April 1988' is "an excellent way to write the date" (not the opinion of the *Chicago Manual of Style*!)

In his 1979 introduction, EB White affectionately refers to *The Elements of Style* as a "dusty rule book". But, to be unaffectionate, this is, in parts, just what it is: dusty. The publisher would have done better to use its 50th anniversary to give it a good dusting off, expunging obvious errors, getting away from the concept of 'rules', taking a critical look at the examples used to illustrate different points, and bringing it into the 21st Century. As it stands, it should not rank high in the reference books used by science writers, not only because of Geoffrey Pullum's and my comments, but also because much more comprehensive style guides with direct relevance to our field (see box) and comprehensive dictionaries of grammar are available.

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Grammar books and style guides

There are, of course, countless grammar books and style guides available. Some that I refer to frequently are given below, but there are many other good resources.

English grammar

The Oxford Dictionary of English Grammar. Chalker S, Weiner E. Oxford/New York: Oxford University Press, 1998.

A Student's Introduction to English Grammar. Huddleston R, Pullum GK. Cambridge/New York: Cambridge University Press, 2008.

Dictionaries of collocations

The BBI Dictionary of English Word Combinations. Eds: Benson M, Benson E, Ilson R. Amsterdam/Phildelphia: John Benjamins Publishing Co., 1997.

LTP Dictionary of Selected Collocations. Hill J, Lewis M. London: Cengage Learning, 1997.

Both especially useful for prepositions and adverbs

Style guides

Chicago Manual of Style. Eds: University of Chicago Press Staff. Chicago: Chicago University Press, 2003.

Scientific Style and Format: The CSE Manual for Authors, Editors, And Publishers. Eds: Council of Science Editors. Cambridge/New York: Cambridge University Press, 2006.

American Medical Association Manual of Style. A Guide for Authors and Editors. Eds: Iverson C (chair). New York: Oxford University Press, 2007.

Medical English Usage and Abusage. Schwager, E. Phoenix: Oryx Press, 1991.

The Careful Writer. A Modern Guide to English Usage. Berstein TM. New York: Atheneum, 1985.

Troublesome Words. Bryson B. London: Penguin, 2001.

Oxford Guide to Plain English. Cutts M. Oxford: Oxford University Press, 2007.

Statistics in medicine, presentation of data

How to Report Statistics in Medicine. Lang TA, Secic M. Philadelphia: American College of Physicians, 2006.

The Visual Display of Quantitative Information. Tufte ER. Cheshire, Connecticut: Graphics Press, 1995.

Plain Figures. Chapman M, Wakes C. HMSO London, 1996.

Presentation of clinical data. Spilker B, Schoenfelder J. New York: Raven Press, 1990.

English for Medical Purposes at Tokyo Medical University

Abstract

This brief introduction describing the teaching system of English for medical purposes (EMP) organized by the International Medical Communication Center (IMCC) of Tokyo Medical University (TMU), which is playing a leading role in Japanese EMP development, focuses on the following perspectives: curriculum design, teaching methods, teaching material development, examinations, teacher training, related societies and the optimal environment for EMP development.

The original purpose of the IMCC when established in 1991 was to provide high-level professional editing support for investigators from Tokyo Medical University who wrote and submitted papers to international journals. This included giving full support in answering any questions from reviewers of the submitted manuscript. The result was an 800% increase in the number of papers from Tokyo Medical University accepted annually in Medline-listed journals. However, this is not enough, as it is only one-tenth of the annual production of the Mayo Clinic in the US. The ever-increasing awareness of teachers and students of the importance of EMP prompted the IMCC to develop an EMP curriculum in close cooperation with the TMU clinicians in charge of the organ-system-based clinical lecture series that students receive in their third and fourth years.

The responsible clinicians provide the IMCC with materials for their students written in Japanese. The IMCC translates the materials into English and comprehension questions are also developed. Furthermore, each EMP teaching module, in addition to the vocabulary and clinical concepts described above, contains two other extremely unique features. Originally the book *English for Doctors* by Maria Gyorffy, University of Pecs, Hungary was used to acquaint students with the medical interview. However, now a series of completely authentic patient-doctor interviews videoed in the UK in cooperation with Dr. Nic Blackwell of Leicester University is incorporated into the curriculum. Permission to display the medical interviews on the Internet was obtained from both patients and doctors. The other unique feature is that the *New England Journal of Medicine* has given the IMCC permission to use the Introduction sections from any original research paper in the journal. These are used to develop speed reading and comprehension techniques. All of these materials are on the IMCC's website at www.emp-tmu.net and can be accessed free of charge but the IMCC would like to know if they are used by other institutions to create any related exercises, teaching materials etc. as we would like to add or link the new material to our site.

Related societies include the Medical Interpreters and Translators Association (MITA) which was founded in 1993 by Patrick Barron and can be located at www.linguamedica.jp. MITA holds monthly meetings consisting of a presentation by one of the members, with a discussion following. In addition, the Japanese Society for Medical English Education has been founded by Professor Ken'ichi Uemura, and in 2004, Patrick Barron proposed to the society that it establish an examination in proficiency in English for medical purposes (EPEMP). In 2007 two pilot examinations were held, and in 2008 the first formal test of levels four and three were held in several locations throughout Japan. The purpose of the examination is to assess the English for professional needs of students and doctors and help them with their applications for residency programmes and for positions abroad. The other main goal is to help achieve some kind of standardization in EMP. Training suitable teachers is a serious problem in developing EMP programmes and in developing medical communications in general. To some extent, MITA is trying to address this problem but there is a need for an international society to promote medical communications. One of the first pioneers in this field was the University of Edinburgh in Scotland, which for almost 30 years has been providing courses in teaching EMP, as well as teaching EMP itself, in a series of summer school programmes. Several students and one or two teachers from TMU take part in the University of Edinburgh programmes each year.

If the number of people qualified in medical communications and the teaching of medical communications increases, it should be possible to teach medical communications in English departments of non-medical universities to encourage students of humanities to consider a career in English education and communications in medical schools. In addition, establishing a diploma programme for EMP teachers and medical communications specialists would be beneficial.

The important thing is to have a standardized approach to EMP not only within one country but also internationally. We will contribute to achieving this in the future as we greatly assist in the flow of information and provide information that is otherwise unavailable to audiences in the west.

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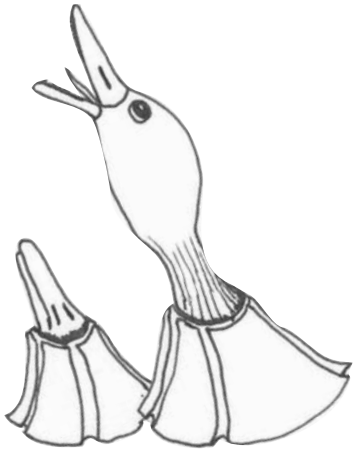
The four-eyed tarantula and the barnacle goose: Accurate citation or the perpetuation of hearsay

by Iain Patten

A historian friend of mine recently drew my attention to two interesting stories about scientific communication in 16th-century Europe [1], both centring on the Dutch cartographer and naturalist Abraham Ortelius. In the first account, the London physician Thomas Penny wrote to Ortelius to ask for confirmation of a story he had heard from Ortelius's nephew, James Cole. It was claimed by Cole that Ortelius was in possession of a tarantula specimen with four eyes, but all of the evidence Penny had in the form of zoological drawings from Italy showed tarantulas as having only two eyes. Penny's surprise and curiosity led him to request direct confirmation from Ortelius that the information was indeed accurate and to ask that he have drawings made to illustrate them. In another exchange, the Italian naturalist Niccolò Stelliola asked for any information Ortelius might have on the barnacle goose. It was claimed that the goose hatched from barnacles that grew like fruit on a tree in northern Scotland. The story had prompted naturalists to search for the mythical creature, but, not surprisingly, nobody had ever presented evidence to confirm its bizarre provenance. Stelliola believed that if anybody would be likely to have reliable information on the barnacle goose it would be Ortelius, and he hoped that in going to a reliable source he might be able to move beyond hearsay and see some actual evidence.

What I find striking in these stories is the similarity to modern scientific discourse in the emphasis on direct observation and referral to primary sources. If we adapt the story of the four-eyed tarantula to the 21st century, for instance, we might imagine Thomas Penny reading an article by James Cole in which the claim that tarantulas have four eyes rather than two is supported by a reference to a description of the tarantula specimen published by Ortelius. Penny then need only go to the cited description to, presumably, find pictures of the animal—later descriptions would actually show the spiders as usually having not four but eight eyes. Niccolò Stelliola, on the other hand, might well find citations alluding to the story of the barnacle goose, but he would never be led to any direct observations, since the story had no basis in fact. But before we laugh too much at the expense of those who may have set off on an Elizabethan wild-goose chase, it is worth thinking about the faith we place in the sources of information used in scientific texts.

If Thomas Penny were to write an article about tarantulas, how might he cite the information he had received from



James Cole? If he were to state simply that "some species of tarantula have four eyes (Cole, personal communication, 1580)," the natural assumption of most readers would be that Cole had described a species of tarantula with four eyes and that the original description had been provided in a personal communication from Cole to Penny in 1580. Of course, this would not be accurate, as Cole was a secondary source. The primary source of the description would instead have been Ortelius. However, since Penny had not seen any description from Ortelius, he would not have been in a position to cite him directly. Instead, in order not to mislead the reader, he would have had to provide a more extensive description of his sources; for instance, "It has been claimed that some species of tarantula have four eyes (Abraham Ortelius, quoted in Cole, personal communication, 1580)." or perhaps "James Cole (personal communication, 1580) reports that the naturalist Abraham Ortelius is in possession of a tarantula specimen with four eyes." By ensuring that the language of the text is consistent with the nature of the citation, readers are left in no doubt about the reliability of the information source. They can infer that the author might not stand by the claim that tarantulas in fact have four eyes but is sufficiently versed in the latest developments of the field to allude to the possibility. In the face of such clarity, the reader's confidence in this author may be increased. In contrast, to state that "some species of tarantula have four eyes (Cole, personal communication, 1580)" would be little different from saying that "barnacle geese hatch from barnacles that grow on trees in the north of Scotland (Stelliola, 1585)," in other words, nothing more than the perpetuation of hearsay with no basis in verifiable observation.

Citing secondary sources in a manner that confounds the natural expectations of the reader is a dangerous path to

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>>> The four-eyed tarantula and the barnacle goose...

follow in scientific writing. Its first effect will be to reduce the confidence that at least some readers will have in the author's scholarship. Inevitably, somebody will know the literature well enough to recognise that the cited work is not the source of the information under discussion. Those who are less familiar with the field may instead be at risk of perpetuating the inaccuracy, or taking hearsay as fact, and as such, the disservice to them is even greater. Some writers may be tempted—be it through pressure of time, naivety, or worse—to circumvent the issue by simply providing the references cited in the secondary source they consulted, without going back to the primary sources themselves. However, the consequences of doing so may be more serious, since, in passing off another's scholarship as one's own, it can be reasonably considered plagiarism, and at best risks perpetuating errors that leave the author's laziness apparent [2]. We can avoid falling into the traps presented by secondary citation, though, if we are vigilant to the clarity of our language and its relationship with the citations used to support it [see Box]. If we accept that the aim of scientific writing is not to create mythical creatures but rather to advance knowledge by building carefully on the work of those who come before us, then we must pay careful attention not only to what we write, but also to what we cite, and ultimately to the close but sometimes overlooked relationship between them.

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1. Harkness DE. *The Jewel House: Elizabethan London and the Scientific Revolution.* First Edition. New Haven and London: Yale University Press, 2007.
2. Rodgers JR. *Plagiary and the Art of Skillful Citation.* Available from: http://pdfind.com/48caeb2b16230. Accessed 30 March 2009.

Secondary sources in medical writing—a question of clarity

Writers often make use of secondary sources such as review articles when developing their ideas, but difficulty may arise when it comes to citing the information obtained. The source of the information *consulted* is clearly the review article, but much of what it contains will have been derived from primary sources, i.e. those articles in which the information was first described. When the intention is to cite specific information and not just direct those who are interested to a source of further reading, the original, primary sources must be provided. However, this does not mean that you can never cite a secondary source. In fact, there are times when it is essential to do so, because in truth it has become the primary source of the information you are referring to, namely, the opinion expressed by the authors.

Imagine if you read the following in a review article:

> "Trial X reported that superpill significantly reduced the rate of cardiovascular events in apparently healthy subjects, with no apparent increase in the rate of adverse events.[1] However, the authors failed to recognize that the trial was insufficiently powered to detect small increases in the rate of gastrointestinal disorders."

The first sentence is specific information that you must go back to the original article and confirm before citing, if nothing else to ensure that it is accurate and to assess whether you may want to highlight other aspects in your own writing. The second sentence is the opinion of the authors of the review article, however, making that article the primary source of the interpretation. If you want to refer to that same interpretation of the data from Trial X in your own article, you must clearly cite the review as the originator of the opinion. However, you can go further than simply citing it, as shown in the following examples:

> "Trial X showed cardiovascular benefit with prophylactic use of superpill and reported no evidence of potential safety issues.[1] However, the statistical power was inadequate to identify predictable increases in the rate gastrointestinal events.[2]"

> "Trial X showed cardiovascular benefit with prophylactic use of superpill and reported no evidence of potential safety issues.[1] However, it has been argued that the statistical power was inadequate to determine whether gastrointestinal events were more common in treated individuals.[2]"

In the first example, the provision of a reference after the second sentence does not make it clear that you are referring to another author's opinion rather than presenting your own interpretation or understanding of the information contained in the reference. However, by changing the wording in the second example, readers should be left in no doubt about the source of the opinion. Thus, what is important is not just provision of the correct reference but also appropriate integration of language and citation to achieve true clarity.

Key points:

- Do not cite original data without having referred to the primary source.
- Citing review articles may be reasonable when the purpose is to provide a source of further reading, but not when referring to specific information obtained from primary sources.
- When the purpose is to cite opinion offered in a secondary source, that source in effect becomes the primary source of the information.
- Be careful to ensure that the language you use clearly reflects the source of the opinions expressed.

Natural patterns: How native and non-native speakers of English can avoid unnecessary complexity in scientific writing

by David Alexander

Synopsis

Scientific writing would be much clearer if it followed the patterns of ordinary written English. Using examples written by non-English-native researchers in biomedicine, I show that writers could build arguments more effectively by ensuring that the sentence topic is consistently the same as the sentence subject. This would also enable them to disregard much spurious advice on the active and passive voice. Writers should also express action using verbs, not nouns; and should inflict complexity on their readers only when it is unavoidable. These rules apply across all scientific disciplines.

Even in their own language, few people find writing easy. In the first session of my writing courses for PhD students in biomedicine, I am therefore unsurprised when most participants—all second-language writers—admit that they don't really enjoy it.

Neither do they always enjoy scientific *reading*. Many published texts yield their information unwillingly, often forcing their readers to read the same passage more than once—not because the science is difficult to understand, *but because the writing is*. As a result, scientific readers must quickly become skilled in the art of decoding—in working out, by intuition and experience, *what the writer probably meant to say*.

This may be a practical necessity, but it raises an important question: why should such information be encoded in the first place? Because this is certainly what happens: in my work I see it regularly in the writing of young researchers, who, often misguided by older colleagues, struggle to achieve properly 'scientific' formulations—by which I mean the empty and redundant constructions that clutter, confuse and deaden so many published articles.

Sentence topic? Sentence subject!

As such attempts can lead to a caricature of scientific style, they can often be instructive. Take this example from the results section of a biomedical paper:

> *For several hypermethylated genes we observed down-regulated gene expression.*

This short sentence contains two problems. The first is one of absurdity: the redundancy of the word 'for'. An ordinary reader would expect this word either to refer to duration, which it does not; or to mean 'on behalf of', which would be nonsense ('*On behalf of several hypermethylated genes, we observed down-regulated gene expression*…'?).

But the second problem is much more important, as it is so common in scientific writing: the failure to ensure that the sentence *subject* is the same as the sentence *topic*. In ordinary, non-scientific language, subject-topic agreement is standard practice: as a result, the reader easily understands what a sentence is about.

Is science so special that different rules must apply to its description? No. For despite appearances to the contrary, the statement 'we observed down-regulated gene expression' is not *about* 'we' the researchers, but about the expression of several hypermethylated genes. All the writer needed to do was to tell us what this expression *was* or what it *did.* Did she doubt her observations? No. There was therefore no need to resort to a pseudo-scientific ploy ('well, this is what I *think* I saw, but of course in science you can never be sure').

When asked, the writer was in fact relieved to be allowed to put things plainly, and confirmed that she had really wanted to state a simple fact:

> *The expression of several hypermethylated genes was down-regulated.*

Failure to follow the principle of subject-topic agreement is devastating for scientific writing. First, the rule is essential to argument-building. Second, as William S. Robinson has pointed out [1], its proper application invalidates a lot of vague and illogical advice on the use of the active and passive voices. The following example illustrates both of these points:

> **Background**: *Congenital heart defects (CHDs) have a multifactorial aetiology, in which subtle genetic factors and periconceptional exposures interact. In this aetiology, derangements in the homocysteine and detoxification pathways may be involved. The recently identified nicotamide N-methyl transferase (NNMT) gene and its substrate nicotinamide play a role in both pathways.*

This paragraph starts out well, but quickly loses focus: the second sentence does not seem to follow on from the first. Although this starts by alluding to 'old' information—the aetiology—an allusion is not explicit enough. The point is that this sentence is *about* the aetiology. However, this is not immediately apparent, because derangements—not the

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aetiology—are the subject of the verb ('may be involved'). In other words, there is an important mismatch between grammatical subject and sentence topic.

The resulting dissonance sows seeds for confusion, which is compounded when the third sentence does not link up clearly with the second. Even though they have been slightly wrong-footed, readers might still expect the writer to develop the idea of pathways, which was introduced at the end of the previous sentence. Instead, the grammatical subject contains new information—NNMT and its substrate—for which they are entirely unprepared.

If the two mismatches between sentence topic and subject are corrected, the true topics are allowed to express themselves as they should:

> **Background**: *Congenital heart defects (CHDs) have a multifactorial aetiology, in which subtle genetic factors and periconceptional exposures interact. This aetiology may involve derangements in the homocysteine and detoxification pathways. An important role in both pathways is played by the recently identified nicotamide N-methyl transferase (NNMT) gene and its substrate, nicotinamide.*[1]

In this way, the paragraph gains its intended focus: the NNMT gene and its substrates—which were in fact nothing less than the theme of the ensuing article.

Active or passive? Let the topic decide

These changes bring me to my point about the active and passive voice, which is illustrated in the corrected version of the third sentence, '[a] role in these pathways is played…'.

Rightly, this sentence is now *about* its subject. So if writers are to observe the rule *that the main verb should always be the one linked to* the sentence subject, how much freedom do they have to choose between the passive and the active voice? None! This is because the voice is not actually chosen by the writer, but dictated by the sentence subject.

This invalidates widely published injunctions to writers on the use of the active and passive voice. It makes no more sense to 'always' use the passive than it does to 'mainly' use the active, or to 'judiciously balance' the active and passive. All such advice fails to take account of the fundamental role of voice in an English sentence. Voice selects itself according to what is being said! If this is not properly understood, a misguided 'principle'—or is it a prejudice?—will prevail over linguistic practice. And principles based on a fundamental misunderstanding of language provide a poor basis for good advice.

Nouns can't do the work of verbs

Scientific writing is badly affected by a third misunderstanding. The following sentence was presented in an abstract by one of our students, who added—in my view significantly—that no-one in her department had been able to get it 'right':

> *FK506 may be useful to facilitate retention of chondrocyte phenotype for cell-based therapies, or for in-vivo application to enhance the repair of focal chondral lesions and may contribute in treating osteoarthritis.*

Though the solution was actually extremely simple, simplicity does not present itself easily in disciplines where complex language is assumed to be *de rigueur*. When the student was asked 'What precisely is it that FK506 may *do*?', she was immediately able to reformulate the sentence. In the redrafted abstract, it read as follows:

> *FK506 may help maintain the chondrocyte phenotype, which is essential for cell-based therapies. In vivo, it may also improve the repair of focal chondral lesions.*

The clue here, of course, is not just her substitution of the simple verb construction 'may help maintain' for the much heavier 'to facilitate retention of': it is also her use of another simple verb construction—'is essential for'—which allows her to end the first sentence with a new and much more powerful idea. This sets the scene for a second, verb-based sentence ('it may also improve…'), which now lends much greater power to the second idea.

Such simple but effective corrections highlight the profound failure of so much scientific writing to capitalise on the power and dynamism of verbs. For, at best, most writers seem to use verbs grudgingly: as a necessary grammatical evil—an irrelevant, barely scientific element whose only function is to ensure that a sentence is nominally a sentence.

The result is the endless repetition of a limited range of empty, lifeless and *unnecessary* verbs—'showed', 'was found', 'were observed'. Whether the voice is passive ('measurements of bile accumulation were conducted in splenetic toads') or active ('we performed quantification of excessive nominalisation by science writers'), the result is not only turgid, but also vague. For if science is supposed to be all about precision, verbs can help you achieve it: 'heart rate was measured…' or 'we quantified…'.

Distinguishing between terminology and jargon

The fourth misunderstanding concerns an apparent inability or unwillingness to distinguish between scientific terminology, which is necessary and therefore unavoidable, and wordiness or jargon, which are not. By often expressing their dislike of what John Kirkman calls 'the unnecessary use of specialised terminology', my students are no differ-

[1] On several occasions, these two sentences have been shown to groups of PhD students from non-biomedical disciplines, who were therefore unfamiliar with the vocabulary. Though few understood the content, nearly all found the second version to be more accessible than the first. In short, good writing is not just about key words; it is also about how they are connected.

ent from the native-speaking members of the Biochemical Society who participated in Kirkman's test of style preferences [2].Why do scientist readers dislike jargon? Because it blurs, confuses or even hides the message.

Many writing textbooks warn against both jargon and wordiness. On occasion, so do the journals, though I wish that advice such as the following were published—and heeded—much more widely:

> Strive for clarity above all else. Avoid unnecessary jargon. If a $1 word will do the job, choose it over a $10 word. Readers will find a clear manuscript more persuasive and enjoyable than one that attempts to make its authors sound scholarly. [3]

With reference to wordiness, the same editorial—in *The Archives of Pediatrics and Adolescent Medicine*—continues:

> Brevity is a virtue. Omit unnecessary phrases, sentences, and paragraphs. Carefully examine your work for empty phrases. For example, 'a majority of' can be replaced with 'most.' 'It is of interest that' can just be deleted. Search for useless sentences at the start and end of paragraphs; they are often lurking there.

Writers should also be urged to apply Kenneth Hudson's 'key test':

> '[ask yourself]: "Could this have been expressed more simply without communication suffering in the process?" If the answer is "Yes" then you've got a piece of jargon.' [4]

Four reminders and a warning

Non-English-native-speaking scientists may be pardoned for assuming that scientific writing is an arcane science of its own. It is not. Most editors (for, unfortunately, there are exceptions) are like nearly everyone else: whatever their discipline, they seek brevity, transparency and clarity. By observing the principles outlined above, writers might go a long way towards achieving it.

Naturally, specialised vocabulary and formulations play vital roles in science writing—but the main story in all genres and disciplines *is nonetheless told by the underlying linguistic structures*. These principles should therefore apply across all academic disciplines. Used sensitively, they provide guidelines that are just as relevant to proteomics—for example—as they are to psychiatry.

For my students, who are indeed drawn from a very wide range of disciplines, I sometimes summarise these points as follows:

1. Remember that the first purpose of scientific language is to be clear, precise and accurate (it being understood that precision and accuracy are not the same thing).
2. The only difficult words in a scientific text should be the scientific ones, which were invented only because ordinary language has no other words to describe what needs to be described.
3. Any other words you use should be the same as those you'd use in the ordinary language. Few readers want texts to contain unnecessary words (or unnecessarily complicated words), as they make the text harder to understand. People who *do* want such words are simply being pretentious.
4. To the greatest possible extent, all these ordinary words should be combined with the scientific ones according to the patterns and constructions of ordinary language.

Ever the teacher, I also end with a warning:

Failure to follow points 1 to 4 has led to what people mistakenly call 'scientific' language. Much so-called 'scientific' language has therefore developed as a result of misunderstandings about the kind of style that is required. All too often, an unnecessarily complex approach leads to less clarity, precision and accuracy. Sometimes it makes scientific communication totally unreadable.

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Short guide to cancer symptoms and treatment

An article published by BBC News in conjunction with Cancer Research[1] starts with the alarming statement that one in three of us will be diagnosed with cancer during our life. While the number of new cases of lung cancer is actually falling following the trend of fewer smokers, cancer is becoming more common overall. The good news is that treatment is improving. The article gives a brief but useful guide to the symptoms of the different cancers and possibilities for treatment.

[1] http://news.bbc.co.uk/2/hi/health/3444635.stm

Tense matters: The preterite and present perfect in scientific texts

by Alistair Reeves

English has an impressive array of tenses to inflict on the reader. Amongst these are the:

Preterite: *I took a blood sample.*

(also called the simple past tense and sometimes the imperfect)

And

Present perfect: *I have taken a blood sample.*

(past tense constructed with the auxiliary verb 'to have' and the past participle, also called the past perfect)

In this series, I will be looking at their use in scientific *writing*, which is different from other areas of writing, and from *speaking*—and very different from the use of English in informal emails. You will hear and see both tenses used loosely when people speak and in e-mails. In the field of formal writing, I have rarely seen differences between the use of these tenses by authors of American and British English. There is no pattern, so I shall not be looking at any differences in this respect. There are some differences in use of these tenses between spoken American and British English, but these do not lead to confusion and are not our concern here.

To begin with, I will be looking only at the principal differences between the use of the preterite and present perfect in the types of document we write. Even in their simplest contexts, this involves describing some fine nuances in meaning, and I will progress to other niceties that distinguish these two tenses in later articles. Examples of these are the use of the preterite continuous (also sometimes called the imperfect) and the present perfect continuous (*We were investigating*; *We have been investigating* …), and how to reflect in writing the stress on the verb or auxiliary verb that we so often use when speaking (Yes, we ***investigated*** that, but ...; Yes, we ***have*** investigated that, but ...).

Most documents have sections that broadly correspond to an Abstract or Synopsis, Introduction, Materials and Methods, Results, and a Discussion, and I try to provide some guidance on which of the two tenses is more appropriate depending on the document section. There is, however, overlap, and I illustrate this too.

A linguistic aspect as sensitive as the use of tenses in English means that examples out of context sometimes illustrate only one specific use of the tense, which may be altered by a preceding or subsequent sentence. Nevertheless, there are basic differences between the preterite and the present perfect, regardless of text.

A. Basic difference between the preterite and the present perfect

Because they are past tenses, the preterite and present perfect are concerned with things that have happened. The basic distinction in use between the preterite and the present perfect is simple:

Preterite: The preterite describes actions completed in the past with no implicit reference to the present (time of writing), and may also be accompanied in a sentence by explicit references to specific periods in the past.

Present perfect: The present perfect describes actions that occurred in the past which either have been completed or form part of an uncompleted whole. It contains an implicit reference or link to the present, often made explicit by the addition of more information to this effect, or reflects the effects of past events on the present, and even the future, and it cannot be used together with references to specific periods in the past.

Examples of basic difference

[1a] *We investigated the pharmacokinetics of Drug X in rats.*

[1b] *We have investigated the pharmacokinetics of Drug X in rats.*

1 The preterite does not permit time elements which extend to the present or into the future

It is not possible to say: [2a] *To date, we investigated the pharmacokinetics of Drug X in rats.*

This is because the use of the preterite means that the investigations are complete. In [2a], although the pharmacokinetic investigations in rats are finished, the addition of *to date* means that other investigations are (likely to have been) planned in other species and that the entire programme of investigations is not yet complete; we are reporting on what we have done *so far*. Any link in such a sentence from the past into the present requires the present perfect, and is often implicit, as in [1b]. *To date* or some-

thing similar could be added for emphasis to [1b], but even without this, this sentence means that the pharmacokinetics were investigated at some point between the dawning of eternity and the last second before writing. It will therefore now be clear that if [1b] were preceded by a time-limiting element, the preterite would be appropriate as in [3a]:

[3a] *In the first phase of our preclinical progamme, we investigated the pharmacokinetics of Drug X in rats. Similar investigations in dogs are now planned.*

2 The present perfect does not permit a time-limiting element in the past

It is not possible to say: [4a] *We have investigated the pharmacokinetics of Drug X in rats last week.*

This applies to time-limiting elements such as *last week*, *between January and November 2006*, *after performing the same investigations in rabbits*, or *before performing pharmacodynamic testing*.

3 Context determines whether the preterite or present perfect is appropriate with other limiting factors

Limiting factors are either evident time-limiting factors in the past (*last week, during our study*) or factors that are not evidently time limiting (*under the following conditions, in the elderly*). When reporting on results, the preterite is more likely to be used with the latter as in [5a]. But it is also possible to use the present perfect as in [5b]:

[5a] *We investigated the pharmacokinetics of Drug X under the following conditions.*
[5b] *We have investigated the pharmacokinetics of Drug X under the following conditions.*

[5a] states that the investigations have been completed, and the assumption is that there will be no further investigations. Although the investigations in [5b] are also completed, the use of the present perfect suggests two things which will *probably* be explained in further text:

- This is what we have done so far and further investigations are planned under other conditions.
- This is what was done so far, and because of the results, we may have to repeat some investigations and possibly also perform further investigations under other conditions.

There is obviously some overlap here, because a further explanation as for [5b] might also follow [5a], but [5b] is more likely to be used in an introduction or discussion section. See also [6b] and the related comments below.

B. Strict division between the tenses

When reporting on methods or results, this division between the tenses is strictly maintained; in the introduction or discussion, however, there can be overlap because of the context, as you will see below and in the next article.

Reporting on methods

4 The preterite is the appropriate tense for reporting on methods in the 'Methods' section of a document

It means, as in [6a]: 'This is what we did'.[1]

[6a] *An extended dorsal approach was attempted with radial retraction of the extensor pollicis longus tendon under brachial plexus block.*
[6b] *An extended dorsal approach has been attempted with radial retraction of the extensor pollicis longus tendon under brachial plexus block.*

[6b] is a typical sentence for an introduction or discussion section and the use of the present perfect has several implications:

- 'Others' have tried this approach and it is not important when they tried it.
- I am about to tell you more about this.
- I am about to limit or negate this statement in some way, and the nature of the limitation or negation will probably be obvious from the subsequent text.

Reporting on results

5 The preterite is the appropriate tense for reporting on completed results in the 'Results' section of a document

Let us start with the present perfect:

[7a] *The patient has reported three episodes of vomiting in the last 30 minutes.*

This is a finished event in the past, but could only be written immediately after the 'last 30 minutes' had elapsed. Because of the use of the present perfect, 'the last 30 minutes' actually means 'the last 30 minutes I have just experienced', so the statement extends up to the present. It is reporting from the present backwards for 30 minutes, and is largely restricted to spoken use.

Now for the preterite:

[7b] *The patient reported three episodes of vomiting in the last 30 minutes of the infusion.*

Because of the use of preterite here, the 'last 30 minutes' in this sentence are not 'the last 30 minutes I have just experienced' but 'the last 30 minutes up to a time-limiting element in the past' (in this case, the end of an infusion). The preterite is required here, because the sentence is reporting on events up to a defined end in the past, whether the infusion finished only a few minutes before writing (basically still 'now') or several months or even years before.

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[1] The use of 'was/were to be' or 'was/were' in 'Methods' sections is controversial. For simplicity's sake, I prefer to stick to plain 'was/were' when describing methods and point out any exceptions in the results, amendments or protocol deviations sections. Obviously, for major deviations (half of your patients did not fulfil a certain condition, you changed randomization mid-study from 1:2 to 1:3, or a change in a major inclusion criterion), you can resort to 'was/were to be' and give an explanation, since this sort of information should not be withheld from the reader until much later in your text.

>>> Tense matters: The preterite and present perfect in scientific texts

The following examples further illustrate the difference when reporting on results:

[8a] *In 2008, fake consignments have included the antipsychotic Zyprexa.*
[8b] *In 2008, fake consignments included the antipsychotic Zyprexa.*

Although both sentences include the time-limiting element 'In 2008', [8a] could only have been written *during* 2008 (and this means right up to 23:59 on 31 December 2008), and therefore means that these results are interim. The present perfect indicates that up to the time of writing, Zyprexa had already been amongst fake consignments impounded in 2008, and by the end of the year, consignments of other drugs worth mentioning may be impounded. The present perfect is therefore suitable for reporting on interim results (a later article will give further information on using the preterite and present perfect when reporting on interim results). [8b] could only have been written after the end of 2008. The preterite indicates that all fake consignments impounded included Zyprexa, and, for whatever reason, Zyprexa is the one that we have singled out to mention in this sentence.

In the next article, I will be looking at the use of the preterite and present perfect in the active and passive voices and in more detail at cases where there is overlap between the two tenses.

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An International botanists' symposium on bogs (1935)

Not only manuscript writing but also reports of international scientific symposia were different in the 1930s from those of today as the following extract[1] demonstrates:

"The great bogland behind Errisbeg recalls a quaint scene on a very wet day in August 1935. A number of botanists had foregathered at Roundstone, (Co Galway,) and the particular occasion was a kind of symposium on bogs, held in the middle of one of the wettest of them. There were A.G. Tansley from Oxford, H. E. Godwin from Cambridge, Hugo Osvald from Stockholm, Knud Jesen and H. Jonassen from Copenhagen, G.F. Mitchell from Dublin, Margaret Dunlop from Manchester. We stood in a ring in that shelterless expanse while discussion raged on the application of the terms soligenous, topogenous and ombrogenous; the rain and the wind like the discussion, waxed in intensity, and under the unusual superincumbent weight, whether of mere flesh and bone or of intellect, the floating surface of the bog slowly sank until we were all half-way up to our knees in water. The only pause in the flow of argument was when Jessen or Osvald, in an endeavour to solve the question of the origin of the peat, would chew some of the mud brought up by the boring tool from the bottom of the bog, to test the presence or absence of gritty material in the vegetable mass. But out of such occasions does knowledge come, and I think that that aqueous discussion has borne and will bear fruit…"

With thanks to **Paul Dunne** (pdunne@iol.ie) for providing this extract.

1 The extract is from Praeger RLl. 1937 *The Way That I Went*, An Irishman in Ireland, Allen Figgis, Dublin 1980, ISBN O 900372 93

Until or by?

One of the most frequent errors I see is the use of *until* instead of *by* in clauses with times, dates and days meaning ***at any time up to a specified deadline***. *Until* is **wrong** in all the following sentences:

- We shall send you our comments *until* 13:00 today.
- All responses received *until* end-of-business on Monday next week will be included in the preliminary evaluation.
- Please return your completed patient diary *until* 31st July 2009.

In all cases, *by* is correct, and always means that the time specified is the latest at which an action may be completed, but that the action may be completed before.

Until usually indicates that an action cannot be started before another action has been completed, as illustrated by the following:

- We shall send you our comments *by* 13:00 today, but cannot do so *until* we have received approval from head office.
- All responses received *by* end-of-business on Monday next week will be included in the preliminary evaluation. However, we shall continue collecting responses *until* Friday, and these will be included in a later evaluation.

Until can be used with the meaning ***at any time up to a specified deadline*** in the following way:

Participants have *until* 13:00 on Monday 12 January to respond. Only responses received *by* then will be included in the evaluation.

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Series on medical writing: reaching beyond the obvious

High performance medical writing Step one: Stop writing immediately

by Richard Watson

Despite the appearance of simplicity and clarity that defines even the most complex of high quality documents, medical writing, as all medical writers know, is a master of disguise. Multiple layers of complexity have to be unravelled, coordinated, and tamed for a perfect end result to be achieved. When faced with such a dizzying array of hard facts and subjective elements it is easy to lose sight of the task in hand. This occasional series of articles aims to step into this storm of information and take a sideways look at the concepts that define successful writing projects

I doubt that my dictionary is trying hard enough. The only definition of performance it offers (beyond the obvious about singing and dancing) is to 'carry out an action or to fulfil a request'. That is undoubtedly true if we strip the term to its most basic level, but can there be more to good performance than that? Should we as medical writers be content to sit back and relax just because we've carried out an action or fulfilled a request?

Only outcome mattered…an absence of information was a frequent complaint

The most suitable measure of performance to be applied depends on the task that is being undertaken. As a student in 1986, I landed a part-time job that made enough money to cover my simple needs. Assembling toy chemistry sets on a production line would not seem a great career move for most people, but it had some excellent benefits: the hours were flexible, the pay wasn't bad, it was virtually stress-free, and, above all else, it was immense fun. Endless hours of putting little vials of sodium chloride and plastic safety goggles into boxes induced a weird hysteria amongst the troops, and the daily riot of mischief and mayhem that ensued offset the tedium many times over. The performance of this often distracted student workforce was easy to measure: if we filled 10000 boxes we had performed; if we filled 9999 boxes we had failed. The manner of the performance was of no consequence because delivery was everything. No-one gave a second look if the workplace resembled a playground as long as 10000 boxes were stacked at the end of the day. Performance was rated in simple, quantifiable, factual terms.

Despite the fun of the factory, I eventually moved on to spend the summer with the girl I would marry six years later, and embarked on a whole new temporary career. The job description of a hospital housekeeping assistant was limited to say the least. Cleaning the bathrooms and making the tea just about covered the entire range of responsibility. Perhaps I'm doing an injustice to all the housekeepers and their assistants out there, of course there was more to the full-time version of the job than this, but no-one was going to risk giving the temporary new boy control of anything dangerous like the floor buffing machine, so cleaning the bathrooms and making the tea became the entire focus of my working life. I know I should be more grateful but it seemed a dreadful job after those happy days playing in the toy factory. The hours were unbelievably bad (do people really want to drink tea morning, noon, and night?), I never fully mastered the finger-scalding mysteries of the Victorian tea urn, and the blue nylon uniform was almost too much to bear. The crease on each leg had been sown in with such force that the trousers could stand unaided. I spent most of that summer looking like a cheap version of the Tin Man from the Wizard of Oz. Quite unexpectedly, however, it was an experience that changed my concept of good performance for ever.

Most patients on the ward were gravely ill, so the basic measure of performance was simple—did they recover? Using this metric, performance levels were extremely high. The health professionals made their diagnoses, appropriate actions were taken, and the final outcome was good, with patients living to tell their tale. Despite such a positive scenario, from my lowly position the ward appeared a very impersonal, almost robotic environment. Most beds were surrounded by complex equipment, sometimes to the extent that the individuals beyond the tubes and wires were almost invisible, each trapped in their own world of discomfort into which my appearance with the tea trolley seemed little more than an intrusion. My first days in that environment felt uncomfortable and alien, and I began to wonder what I was doing there.

Medical writers exist to remove another layer of hassle

So why didn't I walk away, admit defeat, and return to the world of toy science that had been so much fun? Quite simply, because I soon discovered that my first impression was wrong. The real heart of the ward was not an artificial world of monitors that were scanned day and night, but of

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>>> High performance medical writing

the patients and their stories, a human environment, not a mechanical one. Funnily enough, it was the horrible blue nylon uniform that allowed me to make that discovery. The moment I wore that hideous outfit I fell to the bottom of the ward food chain. I was just the guy pushing the tea trolley, with none of the authority of the medical teams that some patients found intimidating. So they found it easy to tell me their stories, their hopes, and their fears. From the confused old soldier who was convinced I was one of his army comrades to the obsessive football fan who discussed tactics for hours, I won their confidence and spent less of my time pushing the trolley and more keeping them company. My listening ear was undoubtedly of a higher quality than the tea I was meant to serve.

The stories I heard were remarkably consistent. The patients loved the medical teams and appreciated everything that was being done for them. They acknowledged the fantastic level of care and considered themselves lucky to have access to such hard working and talented professionals. But there was also a feeling that the workload kept those teams at a distance, that their focus was on the equipment rather than the patient, that the outcome was all that mattered, with the patient's experience of the journey to recovery a secondary factor. As a result, an absence of information was a frequent complaint; why certain procedures were conducted or planned events delayed often a mystery. Frustration was not uncommon, confusion sometimes inevitable. At best, this constituted a series of annoying experiences for the patient concerned. At worst, it could lead to anger, occasionally threatened violence, and, without doubt, cloud the good work that was being performed. In terms of measuring performance, a basic assessment of the obvious, quantifiable variables failed to convey the overall picture of the patient experience.

We need to switch off our computers and observe, listen, and talk

As summer turned to autumn the tea makers of the world breathed a sigh of relief as I hung up my blue uniform and returned to student life, eventually following a winding career path that led to medical writing, from which I have never looked back. My experience on that ward lasted a brief few months, but the lesson I learned remains with me today and, in my opinion, is remarkably applicable to the role of the medical writer.

What constitutes high performance in the world of medical writing? If we take the toy factory philosophy, delivery of a quality document on time is the obvious measure—but is that a little too easy? Surely delivery of a quality document on time is the lowest fundamental unit of performance that a medical writer can have? Performance that achieves anything less than this can be nothing but failure. Have we really given a high level of performance just by meeting the request and performing the action?

To understand how far we can extend our measure of performance it is necessary to go back to basics: why do medical writers exist? Stripping away reflex responses such as to deliver documents, summarise data etc., the simple reason is to make our clients' lives easier. Not just to deliver what they have requested but to remove another layer of hassle from their working day. Which means building a relationship of trust. Generating confidence that their project is safe in our hands. Allowing them to divert their attention elsewhere. To achieve this, our performance has to be measured in terms beyond that of simply handing over the document. As a patient can incorrectly fear the worst if the doctor remains hidden behind the monitor, so will a client if we remain hidden behind our deliverables, failing to make them a part of the process.

No matter how skilled we are at putting words on paper, high performance as a medical writer is dependent on the manner in which that performance is achieved. This can be a surprise for those new to medical writing who naturally focus on the technical aspects of the role. I regularly encounter interviewees who stumble as I explore their ability to interact and cooperate with clients and colleagues, an ability they will need no matter how well they understand the documents they will be required to prepare. There is still a belief in some quarters that ours is a solitary occupation. This couldn't be further from the truth. Medical writers are at the heart of a complex web of professional interactions in which every party has to be fully informed and comfortable with ongoing events. Communication is, as always, the foundation of the solution, but even basic communication is not enough for the high performer. The highest levels of performance are forged from a genuine desire to step out from behind the deliverable and to truly understand all participants in the writing process. We need to switch off our computers and observe, listen, and talk.

On my office wall hangs this quote from Danny Blanchflower, the 1960s football legend who had a way with words that didn't always match his talented footwork: 'football is about glory, it is about doing things in style and with a flourish, about going out and beating the other lot, not waiting for them to die of boredom'. This needs to be read with a wry smile I admit, but it is on my wall because it conveys a message that is applicable to us all. Just as a great game of football cannot be measured simply by the number of goals scored, high performance medical writing is not solely about the words on the page. In Danny's terms, it is about seeking glory in every aspect of our role: how we manage the writing process; how we interact with our clients; how we work with and develop the people around us.

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Harnessing the power of Web 2.0 for medical writers

by Juliet Roberts

Even if Web 2.0 has crept up on you almost unknowingly, it is probably changing the way you work. Although Web 2.0 sounds like a spanking new second-generation Internet (like a second-generation drug), it is really a catch-all term for various concepts and trends that are changing the way we use the Internet. There are a variety of definitions for Web 2.0 but, essentially, it means that the Internet may not have changed so much as the way we use it—we have moved from 'passive' browsing to 'active' participation through collaboration and engagement with user-generated content on the web platform. Emergent uses include: social networking, image-sharing, production of Wikis, Podcasts, blogs, and the practices of tagging and commenting.

This is not intended to be a definitive article on how Web 2.0 affects medical writers—we will all use it differently and the medical communications/PR writers will probably access a different range of Web 2.0 services and applications than regulatory or grant writers. My background is in medical communications so this article will cover appropriate Web 2.0 services for this area but I hope it sparks further articles on how other writers are using Web 2.0. It is a rapidly moving area with tremendous potential so, with much to cover, this article will, necessarily, run at a gallop and provide only a fleeting overview of some potentially useful services.

From Web 1.0 to Web 2.0

The Web is becoming a more collaborative animal, where information is shared and distributed, and where views, comments and opinion are on the ascent. The informational content remains—so e-mail, PubMed and similar on-line information resources remain valuable web stalwarts for medical writers. But now you can post your bibliographies on social bibliographic sharing sites, like Connotea (from the Nature Publishing Group) and CiteULike (see box). Some sites even allow you to import and export via your own bibliographic software like EndNote. The advantage of such sites is that you see what others are reading and learn what they know about the studies/references via their tag notes of shared references. These tags provide a way of bookmarking (and tracking popularity) of websites and blogs. Some publishers include icons at the end of articles so you can bookmark very easily. Another way tagging is being used is by on-line patient communities (like patient support groups found at www.patientslikeme.com) to provide their own ranking of the quality of on-line health information.

Examples of social bookmarking sites/social citation sites:

Research www.CiteULike.org www.Connotea.org www.bibsonomy.org	**Images** www.Flickr.com
Business www.Connectbeam.com	**General** www.StumbleUpon.com Faves.com Delicious.com (formerly del.icio.us) Simpy.com
News www.Reddit.com Digg.com www.Newsvine.com	**Patient information** Patientslikeme.com

Web 2.0 helps with working from home

As medical writers begin to work from home more often, useful Web 2.0 services include on-line classrooms for training purposes or on-line web conferencing, which allows simultaneous reviewing of documents from remote locations. Although most writers within companies have been used to remote server access for some time, now freelancers can take advantage of affordable, secure remote access with services like GoToMyPC and Back to My Mac or Apple Remote Desktop. The alternative is to store all your office work online, on a secure server free of charge, with a service like www.Zoho.com. When working remotely and without access to a dedicated ftp site, files too large for email can now be sent by trusted commercial sites like www.yousendit.com or http://goaruna.com/.

Health services and Web 2.0

Health services are also beginning to embrace Web 2.0. On-line medical record services like Google™ Health (https://www.google.com/health) or Microsoft® Healthvault™ >>>

>>> Web 2.0 for medical writers

(www.healthvault.com) are being touted as a way of improving health through empowering patients by helping them make informed decisions, and this is one of the options President Obama is looking at to update the USA's paper-based system. Another example of the applications of Web 2.0 is a virtual clinic in SecondLife, set up and staffed by real Spanish clinicians, for shy young Iberians who would rather discuss emotional and sexual issues in a Web 2.0 environment (for more information, see http://www.guardian.co.uk/technology/2008/may/10/secondlife.spain).

The value of online communities

Social networking (online communities of people with shared interests) is being used to promote healthcare in inventive ways. For instance, in the US, Johnson & Johnson/McNeil has launched a group called 'ADHD Moms' on Facebook so that they can listen directly to patients (and their guardians) who use their products. Of course, similar sites could be used to create disease awareness by mobilising patients, as demonstrated by Gardasil's Facebook page (Take a step against cervical cancer), which has over 100K members. In the UK, social networking sites used by teenage girls (www.habbo.co.uk and www.lolasland.com) were used to place Government advertisements for HPV vaccination.

Well-organised professional networking sites for the healthcare community, including the UK sites www.doctors.net.uk, www.pronurse.co.uk, the international http://doc2doc.bmj.com/ and the popular German site www.dooox.de, which was established by specialists, are also appearing. With the latter, as well as on-line chats, medical doctors and other professionals can access on-line tutorials, films and Podcasts.

What next for these professional networking sites? Well, one scenario is expansion with pharmaceutical industry funding, as happened in the US with www.sermo.com. After 2 years of independence, Sermo hooked up with Pfizer. Of course the direct access to doctors and potential for building professional relations is valuable for Pfizer.

Blogging and Tweeting

If you want to tap into the medical and scientific zeitgeist, another way is to subscribe to relevant blogs (originally 'weblogs' were personal commentary and opinion sites, similar to on-line newspaper columns). Examples include Ben Goldacre's www.badscience.net and Hungarian medical student Bertalan Meskó's http://scienceroll.com (which focuses heavily on Web 2.0 and medicine). The reciprocal arrangement may also be productive—your own (or your client's) blog could inform others and be used to disseminate chosen tidbits of information. The useful blog statistics provide instant readership data for measuring the efficacy of your blog campaign.

Blogging is being complemented by microblogging services (limited to posts of 140 characters), like Twitter.com, which can be done to or from computers or mobile phones. For a summary of some of the health applications for Twitter try this link (http://tinyurl.com/6rutq2). An example of where the immediacy of Twitter can be important includes the almost instant support for patient compliance programmes (such as, giving up cigarette smoking).

Marketeers have been quick to leap onto the Twitter bandwagon (some potential marketing applications of Twitter are outlined at: http://tinyurl.com/5vxyax), including syndicating news stories, publicising events, and canvassing followers for their ideas/experiences. Maybe writers can now hop on Twitter too, 'follow' each other and swap tips (useful websites or breaking news, such as on the experimental Twitter at: http://twitter.com/Renshaw01).

I did a quick test to gauge how easy it was to start a blog, feel free to join up at http://medicalcommunicators.ning.com/

For the purposes of this article, I carried out a quick and dirty test to gauge how easy it was to start a blog (http://renshaw01.wordpress.com/) and a linked networking site (complete with forum, feel free to join up at http://medicalcommunicators.ning.com/) with the aim of seeing what would ensue. Well, although no technical genius, I managed to set up the sites and the combination with Twitter helps drive traffic to the blog.

Youtube and patients

The direct-to-consumer advertising permissible in the US means that pharmaceutical companies can use Youtube channels to directly target patients. AstraZeneca's asthma channel and the companion website myasthmastory.com is directly calling for patient testimonial videos and SanofiAventis's diabetes channel (with the website goinsulin.com) also features testimonial videos. Johnson & Johnson take a more generic approach: http://www.youtube.com/user/JNJhealth. Outside the US, Pfizer's UK channel appears relatively inactive http://www.youtube.com/user/PfizerUK.

Using news aggregators and rss feeds

So alongside 'traditional' sources (like journal articles), social networking, Twitters, blogs and other Web 2.0 services carry potential value for monitoring 'noise' around par-

ticular areas of interest, such as drugs, medical devices and therapy areas. To avoid visiting multiple websites, several times a day to keep tabs on new developments, newshounds use a news feed aggregator to instantaneously download, in one location, a range of media, including news feeds (subscribe by clicking on the orange rss button), current contents of journals, regular PubMed searches, and new blog or Twitter postings from various sources. There are several aggregators available to download free on the Internet. Your choice of aggregator will depend on your computer's operating system, browser and preferred format, among other factors; visit www.aggcompare.com for an overview.

To get up to speed quickly on rss and news aggregators, try reading the www.journalism.co.uk website's 'How to' articles, such as 'How to: use rss and social media for news gathering' and 'How to: tame your rss sources using feed rinse'. The feed rinse is important because, with a few key words you can filter out extraneous information. That said, no doubt some agencies and allied companies are already producing bespoke news feed aggregators for clients to monitor noise surrounding particular drugs, devices and therapy areas, or the efficacy of particular campaigns. If, on the other hand, you would like a ready-made medical news aggregator, try www.medicalcavity.com or www.webicina.com (you have the option of personalising the journals from which you receive feeds on Webicina).

For a retrospective view of your area of interest, www.medworm.com searches out past and archived rss feeds. MedWorm is also useful for disseminating information or advertising events through rss feeds (there are some restrictions on what information they will accept).

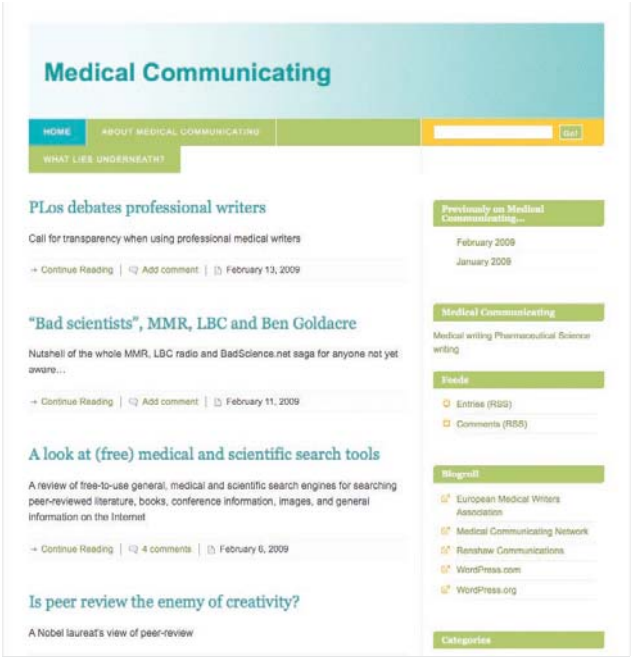
Podcasts

Keeping up-to-date can be eased with Podcasts and videocasts. For instance, you can subscribe and download *The Lancet* and *New England Journal of Medicine*'s Podcasts to your ipod or mp3 player and listen while you are at the gym, in the car or on the train. The uses and potential uses of Podcasts are many; other examples include Podcasts of interviews with the movers and shakers in the US Pharmaceutical sector in Pharma Marketing Talk, www.pharmavoice.com and www.futurepharmaus.com.

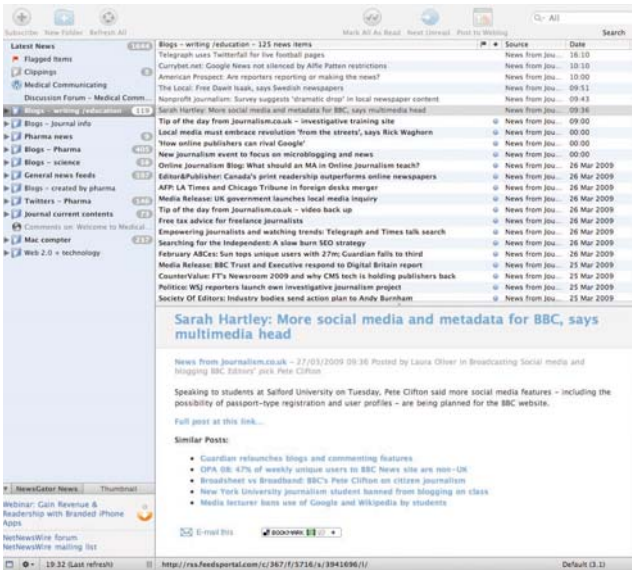
Educational applications of Web 2.0

Undoubtedly, e-learning has added another dimension to distance learning and Continuing Medical Education courses, with websites offering downloadable course material and on-line quizzes, for instance. Web 2.0 steps the game up a notch, enabling a host more services like CME Podcasts, webcasting/video streaming and virtual dynamic patients. Writers in the CME environment will know more about the changes to their way of working brought about by Web 2.0. I look forward to reading about their experiences.

Higher education is already using a mixture of traditional lectures, seminars and practical work with collaborative learning in Web 2.0 social network-type forums and, perhaps soon, in second life, virtual worlds (for an overview of how this might work for medical students, visit http://tinyurl.com/bjzgkg). As medical education changes so, inevitably, will the way medicine is practiced and this is bound to have an impact on medical writers. The scienceroll blog provides a slide show suggesting how medicine may change as Web 2.0 becomes more entrenched—he calls it medicine 2.0 (http://scienceroll.com/2008/02/17/medicine-20-at-home-again/).



Whether medical Wikis (Wikis are collaboratively produced web pages that allow users to contribute and modify content, exemplified by the collaborative encyclopaedia Wikipedia) will contribute to medical education remains to be seen. Examples of this type of Wiki include Dr Wiki (www.askdrwiki.com), www.ganfyd.org and the newly launched Medpedia.



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>>> Web 2.0 for medical writers

Browse more efficiently...

With the increasing importance of online resources, medical writers could spend more time on-line and therefore tools that make searching easier and faster are likely to be a bonus. Rather than staying with PubMed, experimenting with different search strategies and engines could pay dividends by improving your search capabilities and efficiency; Emerging Technologies Librarian, Patricia Anderson has some tips in a slide show at: http://tinyurl.com/65exac. For a list of useful search engines, visit http://renshaw01.wordpress.com/2009/02/06/a-look-at-free-medical-and-scientific-search-tools/.

Most search engines will allow you to set the preferences so that results are opened in a new window. This saves having to click back to see your original search (and the danger of losing track of it if you've clicked through several screens).

Are you using the fastest browser for your operating system? An eye-opening comparison of the speed of different browsers, including Internet Explorer, Safari, Firefox and Opera, is available at: http://tinyurl.com/63tw7 but be aware that this comparison is no longer updated. Unless you get very seasick, plugins like Cool Iris (www.cooliris.com) can speed up browsing by adopting a cinematic method of scanning through images. Cool Previews (www.coolpreviews.com) is probably of greater use to writers. With this plugin, hovering your cursor over a link provides a quick preview of its content, which avoids clicking through unnecessarily.

You could also try making your own personalised home page with all your web favourites as 'flakes' (small, movable versions of the webpages), which can be shared with a community. This could be useful within companies or departments to share useful websites. An example is the collection of pharmaceutical industry news and blogs at: www.pageflakes.com/pharmacentral.

A health warning

Although Web 2.0 offers exciting possibilities and a more personable relationship with the Internet, it should come with health warnings. Compared with the pre-Web 2.0 Internet, it is more about people (after all, the term 'social media' was coined to encapsulate some of the Web 2.0 and mobile-based tools that allows the sharing of information and its subsequent discussion among groups of people). As a result, much of the new information disseminated through Web 2.0 services is opinion and comment, and could be biased.

Obviously, many blogs and Tweets are opinion, nevertheless, they can be useful for sharing information about new studies and sources of information. However, for most copy produced by medical writers, the underlying sources need to be tracked down and verified. In addition, although it is simple to drag or grab images and tables of data from a website or blog and drop them into new copy or a web page, writers need to be aware of the danger of infringing the copyright of the original publisher.

And what about complying with guidelines, like ABPI and PhRMA? Would feeding RSS links for a medical educational website into Twitterfeed or a Friendfeed account be considered as educational dissemination or promotion? The regulations are likely to lag well behind developments in Web 2.0, so no wonder pharmaceutical companies are cautious. However, if you think Web 2.0 is too dangerous for pharma, ask a Pfizer employee about Pfizerpedia. This is Pfizer's internal, company-wide, user-generated Wiki of R&D information, directories, discussions groups and databases. It enables communication and sharing of information in a global company between people who might never have got together and who may never meet in person. As a result of its success, Pfizer is now apparently considering a Pfacebook social network.

Endline

I am aware that this article has merely flirted with Web 2.0 services. Innovative medical writers are probably already devising wonderful ways of using Web 2.0 to research and communicate about medicine and science, which are at the far reaches of my imagination. I admit to being a Web 2.0 amateur who is still studying—for me the best way to get to grips with Web 2.0 is to use it and adapt it to my needs (if you want to learn more, try following some of the links in this article). Finally, my challenge to other, more informed medical writers is for you to provide your take on Web 2.0 so that we can learn from each other too.

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Medical writing tips: Tables, Results and the Discussion

Tips on presenting data in tables, and writing the results and discussion sections manuscripts can be found in recent articles published by the *CHEST* journal in its Medical Writing Tip of the Month section. Access to the section is free. See http://www.chestjournal.org/cgi/collection/mwt

Writing for web-based media: Some pros and cons

by Raquel Billiones

I am a broad-spectrum medical writer and have Alison McIntosh to thank for this wonderfully apt term [1]. Although 75% of my revenues come from regulatory writing, I dabble in medical communications and write scientific and health articles for web media. Considering the size and scope of the Internet, it is not surprising that there is also room for medical writing. Countless websites provide health information and somebody has to write material for them. The question is, is web writing for everybody? Here I present the pros and cons of writing scientific and health articles for web media, based on 2 years' experience.

It doesn't pay well

Good pay is relative, I know, but medical writers used to regulatory writing hourly rates will find that web-based media writing does not pay very well. Unless you are copywriting for big pharmaceutical companies or reporting for the likes of *Nature News*, web media writing is unlikely to be your main income source. To give an idea of the pay scale, an 'About.com' guide is associated with a base payment of US$ 675 per month for writing four articles, plus regularly updating a blog [2]. About.com (www.about.com), a New York Times company, offers 'about… guides' on many topics, including diseases and medical conditions. Many health guides are written by health professionals and medical students. In a good month, including incentives and revenue shares, a guide could earn $1000. This is equivalent to what a regulatory writer makes in a day (on average) based on EMWA's 2007 Freelance Business Survey [3]. About.com guides, by the way, are among the best-paid bloggers in the blogosphere.

Word count counts

Regulatory writers keep it short and sweet. I was trained to write clearly and concisely and not to worry about word counts. However, every word counts when writing for the Internet. After all, there is a lot of web space to fill up. Depending on the project, writers are paid on a per-word basis or have a quota of words to deliver for a flat-rate fee. Either way, a writer may have to 'stretch' the piece a bit. I remember one assignment where I had to write a patient's guide to acne, broken down into three sections: pathology, diagnosis and treatment. Each section was supposed to be at least 300 words in length. I ran into problems when writing the diagnosis part and this is how far I got: *Acne is diagnosed visually by a doctor. No laboratory or diagnostic tests are needed to diagnose the condition.* Along the way, I have learned the tricks of lengthening an article without jeopardizing the quality but the acne case was a constant reminder that this is not always possible.

Web articles are here today, gone tomorrow

A regulatory document can last for a very long time, filed away on a dusty shelf somewhere by regulators for posterity. In comparison, web articles seem ephemeral. Science news published on the web may occupy the headlines for a few hours—sometimes for just a few minutes—before being replaced by the next breaking news. In addition, websites and web-based companies seem to have short life spans and can disappear overnight: your project can go down the drain without warning. In regulatory writing, we have timelines in terms of weeks or months. In web writing, it would be in days if you are lucky. A fast turnaround is vital as you have to get the news out quickly. I got this email one very early morning in January: *Raquel, can you do a piece on the first breast-cancer-free baby? Delivery is supposedly today in London. The same specs and rates as usual. A bonus of xx$ if you can have it ready within 2 hours, before the Americans wake up.*

I must say, I seldom have the time or the enthusiasm to do 'rush' jobs like this. But this demonstrates how 'time-sensitive' web articles can be.

Quality can be poor

When you have a low-budget, fast-turnaround project, you can't expect the results to be of the highest quality. That doesn't mean that all web writers do a sloppy job. However, not all health websites aim to have high-quality scientific content: there are health sites set up primarily to earn revenues through Google advertisements.

I believe in my accountability as a writer and really do my best to deliver something worthwhile, both on time and to budget. But financial and time constraints don't allow much room for proofreading or quality assurance, and the web editors/administrators may often not really care (or know) about grammar and punctuation. In other words, web writing is not for perfectionists!

Client interaction is very limited

If you think you have less interaction with your regulatory clients now that you are freelancing, think again. Currently, I am working for three web communications companies: one based in Canada, and two in the US. I've never spoken with

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anyone in these companies, face-to-face, or even on the phone. There are contracts and guidelines just like in regulatory writing but everything is done by email or by post. The closest thing I have to a conversation with a web-based client is a discussion using Google talk or updates via 'Twitter'. Even payments are done by email through PayPal.

This anonymity sometimes presents problems that would include scams (e.g. the client simply disappears from the web without paying) and good publication practice issues. As an example, I was contracted to write a review paper for an online, open-access journal. I only had contact with the medical communications company but not with the authors. During the three review cycles, I repeatedly emphasized the importance of acknowledging the role of the medical writer, or at least the communications company. In the publication, the authors acknowledged the graphic artist who prepared the figure but not the writer. I was a ghostwriter whether I wanted it or not.

You don't know where your work ends up

When writing science news, the writer usually does not retain the copyrights to his or her work, may not get a byline and also doesn't know where his or her articles end up. An example is a project in which I wrote medical article reviews for primary care clinicians but never saw the finished product because the website was for medical professionals only—I couldn't access it without an identification number! This loss of control after writing is also true for regulatory writing, but the catch for writing for the Internet is that the buyer of a web article can modify the piece and sell it a hundred-times over under another name under the so-called private label rights. Your article might even end up in some dubious site, altered and mangled almost beyond recognition, so that you are actually grateful for the lack of byline. Now, despite all of the aforementioned headaches of web writing, I still like doing it. The reasons why I still like it are...

They are great fillers for slack periods

This is how it all started. I wrote scientific web articles for the want of something to do. Unlike well-established medical writers who are usually working at full capacity, I experience slack times now and again. Those are the times when I ask myself whether becoming a freelance writer was such a good idea. That is when the small web-writing projects come in handy. They keep me sane until the next regulatory project comes.

They are fun

Regulatory work can be monotonous. Don't you ever feel a need for a break from the restrictions of scientific style guides, grammar rules and templates, and simply let the words flow? Maybe you are sick of writing about the same topic again and again? For example, I had one project which involved writing almost a hundred patient-safety narratives. Another required an extensive literature review on the unappetizing topic of maggot therapy. At these times even a 300-word web article on acne can be a welcome break.

What I like about web writing is the variety. During the last two years of doing web writing I've researched and written a wide range of newsworthy topics that I would probably never have encountered in regulatory writing. Just to name a few: bisphenol A, e-cigarettes and medical spas.

It is important, of course, to vary your writing style depending on the audience. I have written medical article reviews for doctors, health guides for patients and science news for the general public. The guidelines, if there are any, are not as rigid as regulatory guidance. Sometimes I even allow myself to be creative and break a few scientific writing rules. And sometimes I end up doing something different, unexpected and fun. Last March, for example, I had the chance to have a phone conference with the actress Chandra Wilson who plays the small but tough surgeon Dr Miranda Bailey in the medical soap Grey's Anatomy. Wilson is currently the spokesperson for the *Treat with Care* campaign of the Consumer Healthcare Products Association (CHPA). CHPA is an American not-for-profit association representing the makers of over-the-counter (OTC) products, including medicines and nutritional supplements. *Treat with Care* is a public service to educate parents and caregivers on the safe and correct use of OTC cough and cold medicines in children [4].

You can learn a lot

Between motherhood and freelancing, I seldom have time to glance at a newspaper or watch the evening news, much less keep up with what is going on in the scientific world. When I started science writing for the web, however, reading and being informed of the most current events became part of the job. How else could I have known about medical marijuana, Google health and pink washers[1]?

Aside from the variety of topics I've written about I've also learned to use web tools to keep me updated without wasting my time Googling (see Box). One trick, for example, is to subscribe to news updates from certain sites which are then automatically sent to your email. I've subscribed to automatic updates from the US Food and Drug Administration (FDA), the US Centers for Disease Control and Prevention (CDC) and the National Academy of Sciences. Unfortunately, there is the risk that your inbox will get flooded when there is a major regulatory or health issue going on. (Last February I received, on average, 20 emails a day from the US FDA updating me about peanut butter recalls; currently it is CDC updates on the swine flu).

In due course, I have learned to discriminate and distinguish the scams from bona fide projects, the good sites

[1] companies that purport to care about breast cancer by promoting a pink ribbon campaign, but manufacture products that are linked to the disease [5].

Writing for web-based media: Some pros and cons

from dross, and to accept only the most interesting (and hopefully the best paying) projects.

Web writing isn't for everyone. It won't make you rich. Not everybody wants to put a fresh spin on old topics or chase tight deadlines on breaking news. However, for those aiming for a career in science or health journalism, the web is the best training ground. In my case, I simply view web writing as a hobby that pays some dividends. Regulatory writing gives structure and discipline to my writing and puts food on the table. Web writing gives me some degree of artistic license and pays for latte grandes. What more can one want from life?

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4. OTCsafety.org. Treat With Care. http://otcsafety.org/Treat_With_Care.aspx. Accessed 5 April 2009.
5. Think Before You Pink, a project of Breast Cancer Action. Focus on Pinkwashers. http://www.thinkbeforeyoupink.org/Pages/FocusOnPinkwashers.html Accessed 29 April 2009

Recommended sites for getting the latest science and medical news

E! Science News	http://esciencenews.com/
Science Now Daily News	http://sciencenow.sciencemag.org/
Science Daily	http://www.sciencedaily.com/
Health Day	http://www.healthday.com/
Science Centric	http://www.sciencecentric.com/
EurekaAlert	http://www.eurekalert.org/
Medwire News	http://www.medwire-news.md/

Perhaps 'Baboons in disguise' would have been more accurate. Photo taken in South Africa by Maria Wendt.

Imitation is the sincerest form of flattery

A little while ago, I was browsing the internet looking at medical writing companies, just to see what sort of a presence my competitors have online. Imagine my surprise when I found 3 websites of medical writing companies that bore a striking resemblance to my own. In the worst cases, entire paragraphs of the text of my website had been copied verbatim on the other companies' websites.

I was a bit miffed by this. Particularly since 2 of the websites were run by fellow EMWA members. I'd always thought of EMWA members as a thoroughly decent bunch of people who wouldn't dream of doing anything as dishonest as plagiarising someone else's website, so this was a bit of a disappointment.

I e-mailed the owners of all 3 sites, and the responses were variable. One never replied at all. Another replied and apologised, saying that any similarity was purely unintentional, and that they would make some changes to their website, which they did. Their home page now no longer looks just like my home page, although elsewhere in their site the source of their 'inspiration' is still perfectly obvious. The third claimed, implausibly in my opinion, that they had never seen my website and that it was just pure coincidence that so much of their website was similar to mine.

Although I have found this episode disappointing, as I would have expected higher standards of behaviour from EMWA members (and I'd also expect that anyone advertising medical writing services really ought to have the skills to write their own website copy), I have also found a positive side. It is gratifying to know that my website is so greatly admired that not one, but 3 companies believe it to be worthy of imitating. I feel sincerely flattered.

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The much imitated www.dianthus.co.uk

Online English and American Idioms Dictionary

Ever wanted a new baby quote, safety slogan, famous humorous quotation, funny campaign slogan, famous love quotation or any other slogan or quotation? You can find these in the idioms online dictionary or you can use the dictionary to discover the meaning of an idiom.

http://www.quotations.me.uk/famous-idioms/index.htm

Information sources for medical writers[1]

by Alison Dev

In this article, I will first look at the different resources available to us, and their advantages and disadvantages. I will then focus on literature searching and internet searching. Lastly, I will discuss some internet resources for medical writers.

Our first question is: what are information sources? There are four main sources that we are most likely to use:

- Books
- Online databases
- Internet
- Verbal communication

Books

Up until a few years ago, books were our main resource for most questions. They have many advantages, including the fact that we can be fairly sure that they are accurate, we do not need anything to access them except hands and eyes and, once we have bought them, they are available to us forever. However, they do have some drawbacks. Particularly in fast-moving fields of research, they may contain out-of-date information even before they are published. Also, unless they are very well indexed, it can be difficult to find the information we are looking for. But they are still one of the best sources for a good general overview of a topic. I enthusiastically recommend keeping a copy of a good medical textbook on your desk, such as *Harrison's Principles of Internal Medicine*, or the *Merck Index*, and a medical dictionary. Also, some sort of pharmacopoeia is useful (e.g., *British Pharmacopoeia*, *United States Pharmacopeia*, *European Pharmacopoeia*, *Martindale—The Extra Pharmacopoeia* or *Physician's Desk Reference*), as these are a very useful source of information for many drugs. These can often provide a quick answer. However, for a more thorough exploration of a topic, you might want to turn to their electronic versions (either CD—ROM or online versions) or to the other sources below.

Online databases

An online database is a resource provided by a service provider. It either contains data that have been located and put together onto the database by trained professionals (e.g., the Registry of Toxic Effects of Chemical Substances [RTECS] gives actual LD50 values), or contains a link to the source (e.g., PubMed, which contains links to abstracts and scientific articles). This second type of database is sometimes referred to as an online index or a bibliographic database. Here, I will refer to both types of database as online databases.

Online databases have many advantages, including the fact that they are updated regularly to ensure they contain the latest information, and that they are of high quality. They provide access to a huge amount of information, and often have excellent search facilities. However, they do have disadvantages. They often require a subscription to the service provider in order to access them, and this can be expensive. Also, there is so much data that there is the potential to lose focus and drown in the data. Some databases require training in order to use the search functions effectively (training courses may be provided free). Also, the scope of the database is determined by the sources that the database researchers review—they may look mainly at US or European sources. It is important to know the sources for the database, so that you are aware of its potential limitations.

The Internet

This is the one we all know and love! What did we do before Google?! The internet has many advantages, including being mostly free, and the vast amount of information that is available using online search engines. However, the disadvantages include the vast amount of information available using online search engines…! It is very easy to spend long hours chasing links through an array of web pages, and not be much wiser at the end. Also, it is not always easy to determine whether the information is up-to-date (check whether there is a date of last update at the bottom of the web page). Another issue is the reliability of the information. For example, Wikipedia can be very helpful. But be aware that just about anyone can upload information into it, so it is not a 'reliable' source and should never be used as a citation!

Verbal communication

Never underestimate the value of a well-placed phone-call to someone who you know is knowledgeable in a certain area. Or even a quick chat with your colleagues. It is amazing how much information we store in that grey-matter, and colleagues may at least point you in a starting direction.

Performing literature searches

This is one of the activities that medical writers do on a regular basis. It may be a formal, structured search to support a marketing application or a safety update, or it may just be a 'let's see what's out there' search to support a

[1] Based on the EPDP foundation workshop "Information Sources for Medical Writers"

more free-form text. As mentioned above, online databases are available through service providers. Of course, we all prefer to use free databases, so the most famous, and probably most commonly used, is Medline.

Medline is available from the National Library of Medicine (NLM) and contains access to vast amounts of medical information from journals, chapters in books and symposia. It is updated several times a week, so it is up–to–date. It is available free from various service providers, including PubMed and NLM Gateway. Both service providers provide search tools that, in combination with Medline's online thesaurus (called MeSH [medical subject headings]), allow us to locate exactly the information we want (with a bit of practice!). Indeed, this database contains so much information that it is tempting to use it as a single source for our literature searches. But beware! Medline has its limitations. Although it contains information from as far back as 1950, it has a bias towards US sources, and does not cover European literature as comprehensively. Read on…

EMBASE, the Excerpta Medica database, covers biomedical and pharmaceutical fields, is updated weekly and, like Medline, has its own thesaurus (called EmTree) to aid searching (although note that MeSH and EmTree terms are often slightly different). This database is not available free, but is available by subscription through various service providers. Since it is not free, fewer of us use it. But it is important to note that approximately one third of the information that is on EMBASE is not available on Medline, and vice–versa! Although EMBASE only goes back to 1974, it has a more comprehensive coverage of European data, and has a better coverage of drug related articles, trade–names and manufacturers for drugs and devices.

So if you need to do a comprehensive worldwide literature search on a subject, you should consider searching both Medline and EMBASE (at least). To do this, you will need to sign up with a service provider such as STN, DataStar or Dialog. These are by no means the only service providers out there so, if you are planning to start up a subscription, have a look for the provider that will be most efficient for your needs (you will need to look at the databases that are available, the costs, the search facilities, and the help features that are available). Access is usually via an annual subscription, although there is the possibility of doing one-off searches with some providers. Even within service providers, there are choices as to the service package you choose, so making this decision can take some hard thinking. However, once you have chosen your provider and package, you can search any of the databases that are available and combine the results (to remove duplicates), thus streamlining your search process. Regarding costs, be aware that as well as the annual subscription there is usually a per use cost. You will pay both for the time you are 'online' using the database, and for each result that you download. And that is before you source the actual article. If cost is important to you, you will need to think out your search strategy very carefully before you go online. Having said that, your clients can be confident that the results they receive from a multiple database search are more comprehensive than those from a simple Medline search.

Of course, Medline and EMBASE are not the only useful databases for literature searching. Other databases are available through service providers that include data on life sciences, conferences, and some more specific areas.

Other information available via online databases

There are huge numbers of databases available through service providers, and any one of these could contain just the information you are looking for. Of use to regulatory writers, IMS provide databases that cover the licensing status and history of drugs in development, as well as launched products by country and date of launch, along with details of composition and pack information. Pharmaprojects provides similar information on drugs in development, launched products, and discontinued drugs, while Adis R&D Insight contains information on drugs in development.

If you are looking for an in-depth review of clinical trials in a particular therapeutic area or indication, then Adis Clinical Trials Insight could be the one for you. Key papers are evaluated and presented in a structured format to provide an evaluation of the study, the comparative treatment outcomes, key messages and results. It also provides a percentage score for clinical trials as an independent guide to the quality of the trial, design and reporting.

Selected URLS:

Database service providers:

STN:
www.stn-international.de

Dialog/Datastar:
www.dialog.com

Ovid (SilverPlatter):
http://www.ovid.com/site/products/index.jsp?top=2

Databases available free:

PubMed (Medline):
www.ncbi.nlm.nih.gov/sites/entrez

NLM Gateway:
http://gateway.nlm.nih.gov/gw/Cmd

NLM (access to all databases):
http://www.nlm.nih.gov

Medical writing:

CMA Medical Writing Centre:
http://www.cma.ca/index.cfm/ci_id/8452/la_id/1.htm

World Assembly of Medical Editors:
www.wame.org

W.Strunk "Elements of Style"
www.bartleby.com/141

ACS Style Guide
http://www.oup.com/us/samplechapters/0841234620/?view=usa

ICMJE:
http://www.icmje.org/

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There are also various databases containing information on drug toxicity, including RTECS, ToxFile, and ToxCenter. Note that several toxicology databases are also free via NLM Gateway.

If you are particularly interested in epidemiological information, you may be interested in the Incidence and Prevalence Database, which contains epidemiology, incidence, prevalence, morbidity, mortality, trends, cost, risk-factors, and disease classifications. It is biased towards US data, contains information from 1988 onwards, and is updated quarterly.

If you are interested in natural or complementary medicines, you may find the Allied and Complementary Medicine or Natural Products Alert Databases helpful.

This is only a brief taster of what is available—there are hundreds of databases out there. Take a look at some of the service provider database information and see whether any of the databases could make your life easier.

Searching the Internet

The internet is such a vast interconnecting web of information that searching it effectively is a considerable challenge. Many of us (myself included) often take the lazy option and 'Google' a keyword. And to be fair, it often works! I often use Google to find regulatory guidance that is almost impossible to find on the official regulatory site. However, there are times when we need to perform a more formal search, or where the search term is not simple, and that is where we can come unstuck. Some tips. Firstly, choose your search engine carefully. Although Google is a wonderful tool, there are other search engines (e.g., Yahoo, AltaVista). Dogpile is a search engine which searches the major search engines, so if you have a very obscure term, this may be a good place to start. Secondly, you may reduce the number of non-medical hits if you use a medical search engine (e.g., Health on the Net, Medscape, Medical World Search). Thirdly, ALWAYS look at the 'help on searching' section in the search engine you choose, and almost always use the advanced search function to help you limit the strategy. Remember that if you use several words in your search, the engine will look for each of them independently. So if you want to look for a specific multi-word term (e.g., epidermal growth factor), put it in quotation marks ("epidermal growth factor") to ensure that the engine only retrieves hits containing the entire term.

Internet resources

In this last section, I will provide information on the websites that I consider to be particularly useful to a medical writer. There are a lot more that I do not have time and space to discuss here. If you think there is a really good website that I have not cited, please let me know.

Journal articles

It is not always easy to get access to an article without having to pay a fee (and a copyright fee). However, there are some sites to help you find articles that can be accessed for free, including PubMed Central from NLM, Free Medical Journals, and BioMed Central. Of course, if you cannot access the article for free, you will have to buy it. There are various sources, including service providers (as discussed above), the British Library, and Science Direct.

Regulatory information

Each country and geographical area has its own regulatory authority website (e.g., the European Medicines Agency [EMEA] and the Food and Drug Administration [FDA]). These are a useful source for regulatory information, particularly for guidelines, format and content of specific regulatory documents, templates, etc.

Evidence-based medicine

The Cochrane library is a very useful source of information. Access is free in a lot of countries: United Kingdom (UK), US, Canada, Finland, Norway, Poland, and others. It contains various databases, including the Systematic Reviews and Protocols database, which has reviews of randomised trials (some with meta-analyses), other reviews, Methods Studies, Health Technology Assessments, and National Health Service (NHS) Economic Evaluations. There is also a link to the Health Economic Evaluations Database, as well as several online books and encyclopaedias.

Clinical trial information

Clinical trial information (both ongoing trials and results) can be accessed via the search portal of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), including the following three websites:

- ClinicalTrials.gov: A registry of federally and privately supported clinical trials conducted in the US and around the world, since February 2000.
- Current Controlled Trials: An international register of ongoing randomised controlled trials, since 1998.
- Pharmaceutical Research and Manufacturers of America (PhRMA): Clinical study results (mainly phase 3 and 4) in a standardised format, since October 2002.

Prescribing information

It can quite often be difficult to find prescribing information, particularly Summaries of Product Characteristics (SmPCs). Although I frequently revert to Google (!), there are some useful websites. For the UK, try the Medicine Guides, which includes the electronic medicines compendium (eMC), SmPCs and Patient Information Leaflets (PILs). For US-biased information, try RXList, which provides all sorts of prescribing information, including patient monographs, and also has a pill identifier and medical dictionary. However, trying to find country-specific information is still a struggle.

Medical writing

Lastly, since we are medical writers, it is probably helpful to have some medical writing resources. The Canadian Medical Association Medical Writing Center has lots of useful writing help, and contains links to all sorts of useful medical writing information. The World Assembly of Medical Editors (WAME) can also be helpful. Bartleby.com provides access to the "Elements of Style" by William Strunk, although there is debate as to the value of

some of the advice in this book (see page 89 in this issue. The American Chemical Society (ACS) book *The ACS Style Guide: A Manual for Authors and Editors* from Oxford University Press is also a useful resource. When preparing manuscripts, you will need to look at the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, which is available from International Committee of Medical Journal Editors (ICMJE).

I hope you have enjoyed our journey through the various information sources available. Hopefully, you have even found a new resource that will make your work easier. I am looking forward to hearing about all those great resources that I have missed…

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Some thoughts on medical writing

"In a nutshell then, the darkest interpretation of the story so far is that medical writing in English is often bad to the point of dreadful. Its exponents, or certainly the younger ones, have passed through an increasingly restrictive and specialized system of education in which the placental nourishment of English literature is severed at a tender age. They then find themselves required, largely without formal guidance, to furnish evidence of their abilities—though one might ask, abilities of what?—by writing and having published academic papers. The models for these great works are their colleagues' academic papers, of variable quality, many of which have not been subjected to any significant editorial process whatsoever. In words that suit the topic: there exists the potentiality for an ongoing vicious circle situation."

This paragraph appears on page 21 of our book [1]. I remember it was written by Martin and he was spot on. An added problem is that most writers simply do not care. Perhaps they know that in all likelihood no one will read what they have written, most published work remaining unread; certainly they do not really care whether anyone reads it or not, because all that matters is that it is published and can appear on a curriculum vitae. Electronic publication will not bring improvement.

I spent many years rewriting papers. In general, writers (I cannot call them authors) whose first language was not English were grateful, sometimes effusively so; writers whose first language was supposed to be English were often defensively ungrateful, sometimes obnoxiously so. This is a generalisation, although I cannot remember a non-English writer who was ungrateful rather than merely non-committal.

There is no simple answer to poor medical writing. The roots of the problem are in the system of education, and there will be no improvement while education is seen by governments simply as a means of getting the population to work. I remember some telling arguments I've had about the meanings of words. In the most extraordinary, a group of workers was describing a laryngoscope blade. This is put in the mouth to enable anaesthetists to insert tubes into the trachea, but the relation of the blade to the anatomy of the mouth and throat is complicated, and this is what the group was describing. They talked about the length of the blade, which corresponded to the blade going into the mouth. Then they talked about the width of the blade, which surely should be in the same dimension as the width of the mouth. But no! This group described the width of the blade in the same dimension as the opening of the mouth, i.e., as the blade fitted between the upper and lower teeth: what anyone with common sense and a reasonable vocabulary would call the depth. When I stood up and said this was tantamount to calling the left the right, I was informed that it couldn't be changed because they had already had a paper on the same subject using their nomenclature. Try explaining to such people the difference between affect and effect, or imply and infer.

The passive is often praised because it celebrates the 'passive observer'. All that matters is what is said, not who is saying it. I think this is complete nonsense but the passive is deeply entrenched. I still have my first year school science books. There it is: "A beaker was filled with 100 ml water and brought to the boil". Not: "I filled a beaker..."

Of all the reasons given for preferring complicated prose the most pervasive and pernicious is that ordinary prose is not serious enough. Again as appears in our book somewhere, I was at a meeting where some chap described how "Rats were haemorrhaged 5 ml..." I asked him why he didn't use the simpler (and correct, since transitive) "bled", and he replied that he thought haemorrhage was more scientific. Thus, to some, scientific is synonymous with complicated. True, some science is immensely complicated, but why that should mean its description should be similarly complicated escapes me. Remember also that for doctors knowledge is power, and telling a patient that they have erythema will impress more than telling them they have a red rash.

Why are journalists better writers than scientists? As Tim Albert says, if a journalist doesn't come up with a punchy first sentence, the reader will move on to the next story [2]. No one is forced to read a piece from a journalist, but medical scientists have to read research papers, no matter how badly written.

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Book reviews in the medical scholarly literature Part III: Targets of criticism

by Françoise Salager-Meyer

Part III of my contribution based on my studies of medical book reviews (BRs) deals with the evolution of the targets of criticisms in what I labelled 'early BRs' (i.e., those published in the mid-20th century) and 'late BRs' (i.e., those published in the closing years of the 20th century) [1,2].

But before entering into the heart of the matter, I would like to mention that 1- and 2-authored books are today outnumbered by multi-authored (edited) books. It is thus my contention that the differences between early and late BRs discussed below are in part attributable to the types of books prevailing in each period, each book type calling, it seems, for different kinds of critiques.

This is why I will first present and discuss the critical comments most commonly encountered in early BRs (i.e., those characteristic of single-authored books), then those most frequently found in late BRs (more characteristic of multi-authored works), and finally those common to both types of books.

Content-related (conceptual) criticisms

Conceptual criticisms characteristic of books (mostly found in early BRs)

In early BRs, the most frequent criticism voiced at the conceptual aspect was that related to omission (underemphasise or lack of comprehensiveness) on certain topics. These critical remarks were mostly expressed in the following terms: "*unexplored issues", "only sketchy details on", "no adequate attention has been given to", "... has received scant attention", "... fails to mention", "not enough detail on ..."* etc. Much less frequent was an excess of information (or overemphasis on certain issues) a source of criticism.

Book authors themselves were sometimes directly criticized in early BRs. It is interesting to note in this respect that the blow of the attack was then frequently softened by lukewarm epithets of politeness or praise, a rhetorical strategy called "*courtesy marker*" [3,4] or "*agreement prefaces*" (3) which provided a note of profound deference. In example 1 below, the reviewer's deep emotion is linguistically realized by means of the adverbs '*regretfully'* and '*sadly'*:

1. Dr. Danowski, an outstanding physician, experienced teacher and versalite investigator, has sought to cover a field that less brave a man might have thought too wide for one person to encompass. The reviewer feels that the author has proved the timid appraisal's correctness: Indeed, it could not be done. … Errors are too numerous to be listed. … The reviewer must regretfully conclude that the author has sadly overreached himself. (1946)

We could venture to posit that this 'good news-bad news' strategy is a reminiscence of the gentlemanly conduct so characteristic of 18th and 19th century scientific prose [5]. It is interesting to note that I have not found a single example of such a rhetorical strategy in late BRs.

The book author's lack of critical mind—mostly with respect to reference citing—was also quite frequently mentioned as a critique:

2. In our judgment the text would have considerably more value if the author did not avoid for the most part any critical judgment of the material in the literature. (1955)
3. The efforts of the author are uncritical at times in collecting the extensive and very heterogeneous assortment of data. (1957)

Book authors themselves are today rarely directly criticized and, when they are, the criticisms formulated are very matter-of-factly expressed as example 4 below illustrates. The author's lack of critical judgment on generally hotly debated issues is sometimes pointed to in today's BR. For example, the following statement was written by a reviewer about a recently published book on the treatment of the post-menopausal woman:

4. Although the discussions are unbalanced and critical, in my opinion, they are not critical enough….A critical analysis of drugs such as …. would have been instructive since these drugs are being used. (2000)

Conceptual criticisms characteristic of edited (multi-authored) works (mostly recorded in late BRs)

Although omission of information is also a source of criticism in late BRs, the most frequent critical conceptual remarks in multi-authored works are voiced at poor chapter integration, lack of consensus or of agreement from chapter to chapter, between chapter redundancy, unbalanced chapters. As one reviewer sums this up very clearly:

5. Everything is in this book, but in some ways, everything is everywhere. (2000)

The review of the second edition of an edited book on molecular biology in cancer medicine echoes this same idea as follows:

6. The book's major problems are common in multi-authored books: poor integration of chapters, redundancy and inconsistent presentation of information. (2000)

Some reviewers even find such a repetition irritating:

7. My most serious criticism is the amount of repetition between chapters. While this may be hard to edit in the context of a multi-author book, there are several vast areas that are repeated.... It becomes irritating when reading large sections of the volume. (2000)

In other words, the most frequent conceptual criticism recorded in today's BRs is not so much the omission of information as the lack of cohesion or cohesiveness.

The uneven quality of contributions (i.e. the contributors' competence and qualification) is also a common criticism in edited works. Not surprisingly, in early BRs such a critique was emphatically/emotionally expressed as the following example illustrates:

8. There is still the basic problem of the contributors not being always superbly qualified to write their chapters. (1943)

Another criticism quite frequently formulated in BRs of edited works has to do with arbitrary editing. When uttered in early BRs, such critical remarks were unsurprisingly harsh and face-threatening:

9. … the rather thoughtless and quite incomprehensible and arbitrary editing of the texts. (1948)

but are only matter-of-factly expressed in today's BRs:

10. Further editing would have improved the cohesiveness of the book. (2000)

Conceptual criticisms common to both books and edited works

Bibliographical references

Misquotation, sloppiness, 'non-supportiveness' and triviality in reference citing were frequent sources of criticism in early BRs. These, as can be expected, were expressed in a derogatory (example 11) and, at times, humorous (example 12) fashion, as can readily be appreciated with the following statements:

11. The preface admits that references have been included without verification. (1932)
12. Efforts towards exhaustive completeness which lead to the citation of trivial or discredited contributions alternate with reckless eclecticism. (1938)
13. Whatever possessed the editors to lump together almost 1,000 references contributed by 45 authors and covering a multitude of sometimes not so closely related subjects in one alphabetical list will remain a mystery forever. As it stands now, the list of references is useless and will defy all but the fiercest and most persistent investigators. (1953)

By contrast, today's book reviewers criticise either the lack of or the out-datedness (un-recency) of references, thereby corroborating Motta Roth's observation [7] that in some fields (e.g., chemistry) recency of publication is a crucial factor in book evaluation.

Audience

The concept of audience—answering the question 'whom is the book intended to' or pointing to the rather limited potential readership—was quite frequently referred to in early BRs:

14. This is a book of a necessarily limited appeal. (1943)
15. It is unclear for what audience the book is intended. (1961)

The following harsh and face-threatening audience-related question was obviously found in an early BR:

16. For whom is this expensive, Gargantuan, grotesque opus intended? The essence of a good textbook is the judicious omission of the irrelevant. This book exemplifies the opposite approach, which may be termed 'from soup to nuts'. Is it then supposed to be an encyclopedia for the practitioner of endocrinology who is no novice? (1946)

Later BRs also critically refer to the concept of audience, but when they do, they rather address the question of whether the book really attends the intended or potential readership:

17. The book is insufficiently distilled for the editor's target audience of busy clinicians and managers. (1999)
18. The limited detail of bowel movements is insufficient for surgical trainees or specialists who wish to develop an incontinence practice, as mentioned in the preface. (1999)

Errors

Errors are another source of criticism in both early and late BRs, but here too, the types of errors referred to in early BRs differ from those towards which the criticism is voiced in late BRs. Indeed, in early BRs, errors in grammar, orthography, typography, bibliographical references and errors of interpretation on figures, graphs or tables were the most frequent sources of errors mentioned. These errors underlined careless proofreading and were bluntly and face-threateningly referred to *as 'too many', 'an inexcusable collection', 'too numerous to be counted', 'countless'* and ' *glaring'*.

Few errors as such are today mentioned in BRs, and these are not linguistic or typographical, but refer to errors in web page indications or to the incorrect use of statistics. We could speculate that automatic correction with the use of computer-incorporated dictionaries and in-house editing greatly facilitate book authors' job, at least as far as orthographic correctness is concerned.

External/non-textual criticisms

The variety of external (i.e., non-content-related) criticisms is much greater in early BRs than in later ones. For example, price was quite a common target of critique in early BRs.

19. The advice to the would-be buyer who is about to hock a prized belonging to raise $60—the book's sky-high price—is very simple: Don't. (1938)
20. Since the price places the book beyond the reach of any but the most affluent medical student, it is fair to ask if it is an adequate monograph for the internist. (1958)

By contrast, we do not find a single (positive or negative) price-related remark in today's BRs.

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>>> Book reviews in the medical scholarly literature

Overall presentation was also much more of a concern yesterday than it seems to be today. Indeed, in early BRs, reviewers would complain about the fact that the "*book value is impaired by a rather disjointed presentation*", that the readers would have preferred a *"slightly smaller format*" or that the book organization was "*haphazard*."

In early BRs, visuals quality (drawings, artists' sketches and X-ray reproductions) were frequently qualified as *"mediocre", "poor"* or "*impossible to interpret*".

In today's BRs, by contrast, criticisms to non-textual materials are much less frequent and are mostly directed to the fact that plates and illustrations are in black and white, that radiological and histological images *"lack clear markers to identify the features of interest*" and that photographs (taken from digitized images) are blurred.

The examples provided above thus show that the targets of criticisms have changed a lot over time and so has the 'culprit' of the flaws mentioned[1]. Indeed, in the mid-20th century, it was the book author who was blamed for having omitted important information or for having misquoted bibliographical references. By contrast, it is the book or a book chapter that is now being criticized for being redundant or for lacking cohesion.

Overall conclusions

The examples provided in Parts I, II and III of this diachronic study of medical BRs have put forward a certain number of differences with respect to the way criticisms were formulated in the mid- and end-of-20th century BRs. The Table below summarizes the main findings.

The changes observed in the rhetorical evolution of criticism reflect changes not only in the scientific enterprise but also in the scientific society in general. Such changes should not be considered as a sign of progress or improvement but as a process of selection and adaptation to the increasing volume of scientific papers, to the needs and the increasing complexity of the context in which scientific activity develops and to the changes suffered by the scientific enterprise whose actors—who come from different linguistic and geographical horizons—must struggle to make themselves visible on the Big Science stage.

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	Early book reviews (mid-20th century)	**Late book reviews** (closing years of the 20th century)
Tone of voice	emotional, face threatening	casual matter-of-fact
Humour	quite frequent	almost non-existent
Targets of criticisms	omission of information sloppiness in reference citing book price audience	lack of cohesiveness poor editing unrecency in reference citing audience
The "**judge**" (book reviewer)	polemical arrogant aggressive passionate	Neutral detached, *efface* unemotional tries to minimize interpersonal damage
On the bench of the "accused"	an animate entity, a person: the author	an inanimate entity, an object: the book or a book chapter
Science	Polemical *"science in the making"*	harmonious cooperative, respectful concord-seeking "*science once made*"

[1] It is worthwhile mentioning here that in 19th century BRs criticisms were mostly voiced at methods and surgical procedures, especially when comparing the way these methods/procedures were performed on both sides of the Atlantic (USA vs UK). The reviewer would then go at great length to explain why, how and to what extent he disagreed with the book author. At that time, criticisms were also targeted at questions of nomenclature, definition or classification. However, the closer we get towards the year 1900, the more important do visual elements become: table presentation, illustrations and drawings were more and more frequently the targets of critical remarks. This means that it is from the end of the 19th century that scientists began to integrate the visual and the textual and to exploit the cognitive possibilities of visual elements.

Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers

by Adam Jacobs and Cindy W Hamilton

Introduction

Ghostwriting, defined as undisclosed contributions by medical writers to manuscripts for publication in medical journals, is unethical and undermines the integrity of the authorship system [1]. The International Committee of Medical Journal Editors (ICMJE) [2], American Medical Writers Association (AMWA) [3], European Medical Writers Association (EMWA) [4], and other organisations [1, 5, 6] agree that substantial contributions to manuscripts should be disclosed with either a byline (authorship or contributorship) or an acknowledgement. In addition, many organisations recommend disclosure of potential conflicts of interest by medical writers, in particular their source of funding [1, 2, 3, 4].

Ghostwriting is believed by some to be common practice [7], but the prevalence of undisclosed contributions in medical journals is unknown because of a lack of specific research [8]. Estimates are often based on the survey by Flanagin and colleagues [9] in which 11% of 809 articles published in 1996 had evidence of ghost authors. Similarly, 9% of 141 reviews published in 1999 had evidence of ghost authors [10]. Ghost authorship, however, should be distinguished from ghostwriting. Ghost authorship is defined as failure to identify all authors meeting each of the following authorship criteria: (1) conceive and design the work or analyse and interpret the data, (2) write at least part of the manuscript or revise it to make important content changes, and (3) approve the final version [2]. Medical writers and editors can make substantial contributions without meeting all 3 authorship criteria. Such contributions, if unacknowledged, constitute ghostwriting. Only 1% of the 809 articles in Flanagin's survey [9] had an undisclosed medical writer or other undisclosed individual who participated in writing the article. A paper published in 2007 by Gøtsche et al [11] has been widely cited as evidence of the prevalence of ghostwriting, but in fact looks specifically at whether statisticians are listed as authors, and provides no evidence on the role of professional medical writers. It is therefore clear that there is an important gap in the literature on how common ghostwriting is.

To evaluate the prevalence of ghostwriting among papers written by professional medical writers (ie, those whose main job is writing, as opposed to researchers who write their own papers), we conducted 2 surveys of members of AMWA and EMWA. Our primary objective was to determine the proportion of substantial contributions by medical writers that were undisclosed in submitted manuscripts (ie, ghostwriting; hereafter, undisclosed contributions). Secondary objectives were to determine the proportion of participants who request acknowledgement of their contributions and disclosure of their potential conflicts of interest, and effect of familiarity with guidelines [2, 3, 4, 5, 6] and other factors on disclosure. Our original survey was done in October 2005. To investigate changes over time, specifically after the EMWA guidelines [4] were published, we repeated the survey in November 2008.

Methods

Our first survey of AMWA and EMWA members was done from October 12 to 28, 2005, using an internet survey tool, Survey Monkey (www.surveymonkey.com). We developed the survey instrument using repeated rounds of pilot testing among groups of medical writers. All members of AMWA and EMWA were invited by e-mail to participate in the survey; 1 e-mail reminder was sent. No incentives were offered. To encourage participation, we promised that it would be anonymous and would take only 5 minutes.

The survey instrument comprised 13 multiple-choice questions and 1 open-ended question about the practices and experiences of medical writers who make substantial contributions to manuscripts intended for submission to biomedical journals. See the EMWA website [www.emwa.org] for the full version of the survey used.

We repeated the survey from 13 to 25 November, 2008. The survey was identical to the 2005 survey, apart from the addition of one question asking whether participants wrote mainly primary manuscripts, review manuscripts, or a mixture of both.

Some questions allowed for internal validation of responses. For example, participants were considered to have invalid data if they indicated that 90% or 100% of manuscripts did not disclose their substantial contributions (question 3), that they always or usually requested acknowledgement when they made substantial contributions (question 7), and that this request was always or usually granted (question 8), as if the answers to questions 7 and 8 were true, then it should also be true that most of their contributions were disclosed. Participants with invalid data were excluded from the analyses. If participants answered any parts of question 5 about familiarity with relevant guidelines, but did not answer whether or not they were familiar with any specific guideline, then we assumed that they were not familiar with that guideline. Otherwise, missing data were ignored with no attempt at imputation.

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>>> Evidence of ghostwriting in a survey of medical writers

All statistical analyses were done using Stata (StataCorp, College Station, Texas). The primary analysis was calculation of mean percentage of manuscripts containing undisclosed contributions in the last year (question 3) weighted in proportion to the number of manuscripts to which participants had made substantial contributions and that were intended for submission to biomedical journals during an average year (question 2). The response category >20 manuscripts/year was assumed to be 25 manuscripts/year. The 95% confidence interval (95% CI) was calculated assuming that responses were normally distributed. An unweighted mean and CI were also calculated similarly.

Secondary analyses were done to test the null hypothesis that familiarity with relevant guidelines (question 5) was not associated with frequency of undisclosed contributions (or, in subsequent analyses, participants' requests for acknowledgement [question 7] and disclosure of pertinent professional or financial relationships [question 9]). Linear regression analysis was used to test whether the percentage of undisclosed contributions was associated with the number of guidelines with which the participant was familiar, (maximum 5, minimum 0). Ordinal logistic regression was used for analogous analysis of frequency of request for acknowledgement or disclosure of potential conflicts of interest in the following 3 categories: always, usually, and rarely or never (including both "rarely or never, but I am not opposed to the practice" and "rarely or never, because I am opposed to the practice" in the case of request for acknowledgement).

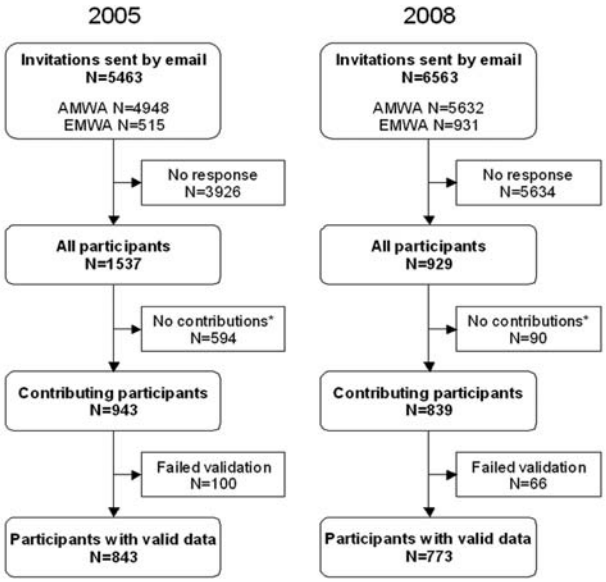
Further exploratory analyses investigated other potential predictors of these outcomes, namely percentage of manuscripts with undisclosed contributions and participants' requests for acknowledgement and disclosure. Predictor variables to be evaluated were number of manuscripts to which participants had made substantial contributions during an average year, familiarity with each of the 5 guidelines specifically, type or place of employment, number of years of experience in biomedical communication, and membership in professional organisations. These were investigated in both univariate and multivariate analyses.

Results were analysed in an identical manner for the 2005 and 2008 surveys, except that the proportion of review papers was included in the multivariate analyses as an extra independent variable in the 2008 data, and different versions of Stata were used (version 8.2 in 2005 and version 9.2 in 2008). No formal statistical comparisons were made between the 2005 and 2008 results, as this was not a prespecified objective at the time the 2005 survey was planned.

Results

The response rate was 28% in 2005 and 14% in 2008 (the invitation to the survey explained more clearly in 2008 than in 2005 that the survey was only relevant to those writers who made substantial contributions to manuscripts intended for publication). After excluding participants who did not contribute substantially to manuscripts and those who failed the internal validation check, 843 and 773 participants contributed data for analysis in 2005 and 2008 respectively (Figure 1).

Figure 1 Flowchart of respondents to survey



* No substantial contributions to writing or editing manuscripts

Characteristics of the participants are shown in Table 1, and were similar in both years. The most common type of employment in both years was freelance, followed by pharmaceutical, biotech, or medical device companies. In both years, most participants had at least 6 years of experience in medical writing. Consistent with the relative sizes of the organisations, AMWA members greatly outnumbered EMWA members in both years.

Familiarity with guidelines was greater in 2008 than in 2005. In both years, the AMWA position statement and the ICMJE guidelines were the most familiar (Table 2).

The mean, weighted percentage of manuscripts with undisclosed contributions decreased from 62% in 2005 to 42% in 2008, in other words acknowledgement of medical writers' contributions became more common over the 3 year interval. In both years, the unweighted percentage of manuscripts with undisclosed contributions was slightly lower (Table 3).

Consistent with the observed fall in the proportion of undisclosed contributions, the majority of respondents in 2008, although not in 2005, replied that the frequency of undisclosed contributions had decreased in the last 5 years in their experience (Table 4). Also consistent with the fall in the proportion of undisclosed contributions, the percentage of writers who always requested acknowledgement and the percentage of respondents reporting that their requests were always granted increased substantially from 2005 to 2008.

In both years, there was a highly significant negative correlation between the number of guidelines with which participants were familiar and the frequency of their undisclosed >>>

Evidence of ghostwriting in a survey of medical writers

Table 1 Characteristics of the participants

	Total responses		n (%)	
	2005	2008	2005	2008
Employment:	746	662		
Self-employed or freelance			289 (39%)	260 (39%)
Pharmaceutical, biotech, or medical device company			208 (28%)	154 (23%)
Medical communications, medical education, or PR			112 (15%)	131 (20%)
Hospital, university, or medical school			77 (10%)	57 (9%)
CRO			32 (4%)	32 (5%)
Other			28 (4%)	28 (4%)
Years of experience	737	657		
0–2			85 (12%)	87 (13%)
3–5			158 (21%)	157 (24%)
6–10			208 (28%)	160 (24%)
11–15			106 (14%)	115 (18%)
16–20			71 (10%)	55 (8%)
> 20			109 (15%)	83 (13%)
Number of manuscripts per year	776	691		
0–2			169 (22%)	131 (19%)
3–5			275 (35%)	229 (33%)
6–10			184 (24%)	188 (27%)
> 10			148 (19%)	143 (21%)
AMWA member	736	647	631 (86%)	500 (77%)
EMWA member	736	647	127 (17%)	166 (26%)

Table 2 Familiarity with position statements and guidelines

	n / total responses (%)	
	2005	2008
AMWA position statement [3]	317/625 (51%)	497/654 (76%)
EMWA guidelines [4]	198/735 (27%)	298/641 (46%)
GPP guidelines [6]	317/730 (43%)	377/646 (58%)
ICMJE guidelines [2]	399/735 (54%)	498/661 (75%)
PhRMA guidelines [5]	206/719 (29%)	229/632 (36%)

Table 3 Percentage of papers with undisclosed contributions

	N	Mean	95% CI
2005			
*Weighted mean**	774	62%	59–65%
Unweighted mean	750	59%	56–62%
2008			
*Weighted mean**	678	42%	39–45%
Unweighted mean	684	39%	36–42%

* The weighted mean was weighted in proportion to the number of manuscripts the respondent wrote per year

>>> Evidence of ghostwriting in a survey of medical writers

Table 4 Experience of and practice in requesting acknowledgement

	Total responses		n (%)	
	2005	2008	2005	2008
Change in last 5 years in frequency of undisclosed contributions in participants' experience	688	651		
Decreased to none			20 (3%)	72 (11%)
Decreased but still occurs			250 (36%)	340 (52%)
No change			360 (52%)	198 (30%)
Increased			58 (8%)	41 (6%)
Request acknowledgement of substantial contributions	747	665		
Always			187 (25%)	288 (43%)
Usually			183 (24%)	168 (25%)
Rarely or never, but I am not opposed to the practice			354 (47%)	194 (29%)
Rarely or never because I am opposed to the practice			23 (3%)	15 (2%)
Requests for acknowledgement granted	365	466		
Always			127 (35%)	224 (48%)
Usually			177 (48%)	185 (40%)
Rarely or never			61 (17%)	57 (12%)

contributions, in other words participants familiar with more guidelines were more likely to have their contributions acknowledged. Similarly, there was a strong positive relationship between the number of familiar guidelines and requests for acknowledgement (Table 5).

Results of univariate analyses of other potential predictors on the frequency of undisclosed contributions were mostly similar in 2005 and 2008, although there were some small differences (Table 6). In both years, familiarity with each individual guideline was associated with fewer undisclosed contributions, and participants contributing to > 10 papers a year having a greater proportion of undisclosed contributions than less prolific writers. In 2005, employees of medical communication companies were most likely to have undisclosed contributions, whereas in 2008 freelance writers had more undisclosed contributions. There appeared to be a substantial change in the practices of those working for medical communication companies between 2005 and 2008. In 2005, employees of medical communication companies were highly significantly more likely to have unacknowledged contributions than those working in academia (the reference category), whereas in 2008 this difference was small and non-significant. Although it is often assumed in the popular media that ghostwriting is driven by pharmaceutical companies, it is interesting to note that employees of pharmaceutical companies were the least likely to have unacknowledged contributions in both years. In 2008, participants who wrote review papers were more likely to have undisclosed contributions than those who wrote primary manuscripts (this question was not asked in 2005). Most of these results were similar in the stepwise multivariate analyses (data not shown), the final models in both years including the number of papers, familiarity with specific guidelines, and type of employing organisation as significant predictors. In addition, writing review papers or primary manuscripts remained a significant predictor in the 2008 model.

Similar results were obtained for predictors of requests for acknowledgement (data not shown).

Discussion

Our data, based on a survey of medical writers, fills an

Table 5 Regression analysis of effect of number of familiar guidelines

	N	Estimate*	95% CI	P value*
2005				
Proportion of undisclosed contributions	750	–6.6%	–8.5 to –4.8%	< 0.001
Frequency of request for acknowledgement	747	1.41	1.29 to 1.55	< 0.001
2008				
Proportion of undisclosed contributions	684	–7.7%	–9.6 to –5.8%	< 0.001
Frequency of request for acknowledgement	665	1.57	1.41 to 1.74	< 0.001

* Estimate is the regression coefficient (change in proportion of undisclosed contributions for each extra familiar guideline) for proportion of undisclosed contributions or odds ratio from ordinal logistic regression for increasing frequency of acknowledgement. P value tests null hypothesis of no effect, ie regression coefficient of 0 or odds ratio of 1

important gap in the literature on the extent to which medical writers are ghostwriters. It is often assumed that ghostwriting is common among professional medical writers, although there has up to now been little evidence on which to base that assumption. Ghostwriting was common practice in 2005, although the frequency decreased substantially over the following 3 years, such that our results show that acknowledged contributions were more common than ghostwriting in 2008.

The strengths of our survey are that it obtained results from a large number of professional medical writers from a variety of working environments in several countries, answering under conditions of anonymity. We used the same survey methods in both years, so comparisons between 2005 and 2008 should be valid. In addition, we included an internal validation step that allowed exclusion of participants who may not have answered the questionnaire sufficiently carefully.

Nonetheless, our survey also has important limitations that should be considered in interpreting the results. It is important to realise that our survey was aimed only at professional medical writers. Many papers are written without the aid of professional medical writers, and any conclusions from our survey cannot be extrapolated to those articles. Our survey provides information about the acknowledgement of writing assistance by professional medical writers, but the extent to which this is representative of biomedical publications in general is unknown. Our survey therefore >>>

Table 6 Regression analysis of other predictors of proportion of undisclosed contributions

	2005			2008		
	Est.	95% CI	P	Est.	95% CI	P
Specific guidelines						
AMWA	–9.0	–15.1 to –2.8	0.004	–10.4	–17.2 to –3.6	0.003
EMWA	–13.0	–19.9 to –6.1	< 0.001	–15.6	–21.8 to –9.4	< 0.001
GPP	–14.5	–20.5 to –8.5	< 0.001	–21.3	–27.3 to –15.2	< 0.001
ICMJE	–22.3	–28.1 to –16.5	< 0.001	–24.3	–30.9 to –17.6	< 0.001
PhRMA	–13.0	–19.7 to –6.3	< 0.001	–13.4	–19.9 to –6.8	< 0.001
Type of employment			< 0.001			< 0.001
Academic	Reference category					
Freelance	28.2	18.2–38.3		12.3	0.4 to 24.2	
Medcom	36.7	25.1 to 48.3		3.3	–9.6 to 16.2	
Pharma	0.0	–10.5 to 10.4		–7.0	–19.5 to 5.6	
Other	13.9	0.2 to 27.6		1.7	–13.2 to 16.7	
Number of papers/year			0.134			0.042
0–2	Reference category					
3–5	4.3	–4.0 to 12.5		–2.1	–11.2 to 6.9	
6–10	4.2	–4.8 to 13.1		–9.6	–18.9 to 0.3	
> 10	11.3	1.8 to 20.8		2.7	–7.2 to 12.6	
Experience (years)			0.425			0.407
0–2	Reference category					
3-5	11.7	0.2 to 23.1		3.0	–8.0 to 14.1	
6–10	11.4	0.4 to 22.4		1.2	–9.8 to 12.2	
11–15	10.6	–1.9 to 23.2		9.2	–2.5 to 21.0	
16–20	11.2	–2.6 to 24.9		4.3	–9.8 to 18.4	
> 20	10.1	–2.3 to 22.5		10.1	–2.7 to 22.9	
Reviews or primary manuscripts	Question not included in survey					< 0.001
Mostly primary				Reference category		
Some reviews				10.0	2.5 to 17.6	
Mostly reviews				16.0	7.1 to 24.8	

* No substantial contributions to writing or editing manuscripts

does not allow an estimate to be made of the prevalence of ghostwriting in biomedical publications in general, only in the subset of papers written with the assistance of professional medical writers. While the proportion of that subset is unknown, a study by Woolley et al published in 2005 [12] sheds some light on this question with the finding that 6% of a sample of publications in high-ranking journals declared medical writing assistance.

The most important limitation of our survey is selection bias, in that the respondents in our survey may not be representative of the entire community of medical writers. Our survey was sent only to those medical writers who belong to AMWA or EMWA, and our response rate was, while respectable for e-mailed surveys, still low enough that it is likely that our respondents are not even representative of AMWA or EMWA members. It could reasonably be hypothesised that AMWA and EMWA members are more likely to follow latest guidelines than medical writers who are not members, and also that those who take the trouble to respond to surveys about ghostwriting are more likely to take an interest in ethical practices and comply with guidelines. For those reasons, we believe it is likely that our results underestimate the prevalence of ghostwriting.

Nonetheless, although our estimate of the prevalence of medical writing may be inaccurate, we believe some conclusions can be drawn from our results with reasonable confidence. One such conclusion is that ghostwriting, while still common among medical writers, is now less common than it was 3 years ago. Another conclusion is that medical writers who are familiar with guidelines on ethical medical writing practices are less likely to have undisclosed contributions. Consistent with this is the finding that medical writers who are familiar with the guidelines are more likely to request acknowledgement, which is presumably the reason why their contributions are more likely to be acknowledged. Although the cross-sectional nature of our surveys precludes making causal inferences from that association, it seems reasonable to postulate that the publication of guidelines has had at least some effect in helping to reduce the prevalence of ghostwriting.

In conclusion, there is no room for complacency in the fight against ghostwriting, as the prevalence remains unacceptably high among EMWA and AMWA members. Nonetheless, this survey shows, for the first time, that ghostwriting became less common between 2005 and 2008, giving way to disclosure of medical writing assistance. Organisations such as AMWA and EMWA have a duty to continue their educational efforts to help ensure ghostwriting becomes ever closer to extinction. We, together with other medical writers, have recently published a checklist designed to ensure medical writers fulfil their role ethically when contributing to publications [13], and hope that that checklist will assist in those efforts.

Definitions box

Side effect

There are at least two meanings for this term. To the layman, side effects are serious, unwanted and undesirable actions of drugs or medicines, a usage especially beloved of the media. A better term for these properties of drugs or medicines is 'adverse effects'. However, because no drug can ever be specific (i.e. have only one action), all drugs have properties that lead to effects other than those for which the drug was developed or by which the drug is normally classified. These actions of the drug may be undesirable or useful—there are many drugs, for example, that are particularly useful because they have more than one pharmacological action. Side effects should not be confused with adverse events, which are events reported during a clinical study, whether or not they can be attributed to the preparation or preparations under evaluation in the study.

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Gateway to heaven: Analysis of the job postings on the EMWA website in 2007 and 2008

by Thomas M. Schindler

The idea of analysing the job market for medical communicators first occurred to me during the EMWA meeting in Lyon (2006) and then again in Vienna (2007). I wondered whether the increase in the number of attendees at the annual conferences reflects a rising demand for medical writers in Europe. Certainly, efforts of my own company to recruit medical writers have demonstrated a scarcity of good candidates. At the meetings of our American sister organisation (AMWA) the same message was spread: year after year and from conference to conference, the number of attendees increased. Are we at the beginning of a golden age for medical writing?

The search for some 'hard' numbers about job opportunities for the medical writing profession proved difficult, particularly on a European scale. Initially, I investigated internet job portals such as "monster" or "jobpilot" as a possible source of information. However, their functionality does not allow searches of all of Europe but only of individual countries or combinations thereof. Which countries should be included? Only the EU members (27 countries), this would however exclude Switzerland and Norway? Should I use the geographic definition of Europe including Belarus and Albania, but then what about Russia? Thus this route of investigation proved to be too cumbersome to deliver reliable numbers, and I turned instead to the obvious solution: the EMWA website. Surely, any company that was looking for a medical writer in Europe would want to use the internet and it seemed reasonable to assume that an analysis of job postings on the EMWA website would be a true reflection of the job market for medical writers. Any serious company ought to consider using this very affordable service provided by EMWA to recruit their medical communicators. With this in mind, I approached EMWA head office with a view to obtaining the source information I needed to perform a survey of job adverts posted on the EMWA website.

Methods

The EMWA web team (Shanida Nataraja and Crispin Hodges) provided me with PDF copies of the job adverts posted in 2007 and 2008 (one PDF file for each year). In addition, they supplied Excel lists with the names of the companies posting the adverts. The file of the adverts for the year 2008 contained 1 advert that had been placed in 2007; in the analysis, this advert was analysed for the year 2007.

An initial assessment revealed that the adverts varied widely with regard to amount and type of information provided. Therefore the analysis was limited to the following categories of information: date of appearance, name of company, type of company, qualification sought, salary mentioned, type of work advertised, editing mentioned, location, temporary or permanent. All adverts were analysed and categorised, and the data was entered into an Excel file which was then used to derive the summary data.

In the process of catergorising the adverts, a number of problems were encountered due to ambiguities. When the number of open positions in an advert could not be determined, e.g. because 'several positions' were offered, it was assumed for the purposes of the analysis that there were at least 2 open positions. When 2 or more different positions were advertised in one posting, i.e. a medical writer and an editor were sought; all positions were entered separately. When the advert was placed by a recruitment agency and the name of the originating company was provided, this name was used for the analysis; if the originating company was not evident, the name of the placement company was used instead (2007: 5 recruitment companies offering 8 positions in undisclosed companies; 2008: 3 recruitment companies offering 8 positions in undisclosed companies). However, all adverts of recruitment agencies provided the type of company (i.e. biotech, pharma, medcom, etc) for which they recruited. The categorisation of the type of company was based mainly on self-reporting, i.e. if a company advertised itself as a 'medical communication agency', this was used. However, the big international pharmaceutical companies were categorised as 'pharma', even if sometimes their self-presentation used the term 'biotechnology company'. A company was considered a CRO if it also offered clinical research services other than writing. 'Editing' as a job function was only entered into the database when the word was actually mentioned in the text of the advert. 'Temporary' employment was only entered if this was explicitly stated in the advert. Data analysis, quality control, and writing of this article were performed exclusively by the author.

Results

The job postings in 2007 and 2008

In 2007, 39 companies placed 57 adverts offering at least 67 positions; in 2008, 50 companies made 68 postings with at least 88 open positions (the exact number of open positions was not provided in 3 adverts in 2007 and 5 adverts

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in 2008). This represents an increase of 28% in the number of companies placing adverts. In both years, most companies placed only 1 advert in the course of a year (2007: 74%, 2008: 78%). Nevertheless, a substantial proportion of companies placed 2 or more adverts in the course of a year (2007: 26%, 2008: 22%). One company in 2007 and another company in 2008 placed 5 adverts on the EMWA website. January was the month with the highest number of postings in both years. Late spring (April and May) and autumn (August to October) were also periods with high activity. June and December marked the troughs in terms of postings (see Figure 1).

Type of employer placing the adverts

In both years, most of the adverts came from pharmaceutical companies and medical communication agencies. Together they accounted for 77% of adverts posted in 2007 and 70% posted in 2008 (see Table 1). In 2007, the group of advertisers was almost exclusively pharma, medical communication, and CROs. In 2008, some biotechnology companies, scientific publishers, and regulatory agencies also used the EMWA website to recruit new personnel.

Qualifications required, types of work advertised, salary sums mentioned

In both years, about two thirds of the adverts specified that their future employee should have a background in the life sciences. About one third of the adverts did not specify a required qualification but mentioned that the applicant needed to have 'relevant experience' (which could be as short as 6 months). The largest proportion of the postings were for positions in medical communication (2007: 49%; 2008: 38%), followed by positions in regulatory writing (2007: 30%; 2008: 28%). Proficiency in both areas was required in 16% of adverts in 2007 and 18% of adverts in 2008. In about one third of all job descriptions, editing was explicitly mentioned as one of the tasks (2007: 33%, 2008: 41%). No advert in 2007 but 3 adverts in 2008 mentioned editing as the major task of the position.

The adverts posted were almost exclusively for permanent positions (2007: 96%, 2008: 80%). Only 4% of positions in 2007 and 10% of positions in 2008 were advertised as temporary positions (in 2008, some 11% of adverts were unclear with regard to intended duration of employment). Proposed salaries were advertised only in rare cases in the job postings (3 adverts each year). The sums mentioned in 2007 were in the range of GBP 25000 to 50000; the 2008 postings offered GBP 23000 to 32000.

Location

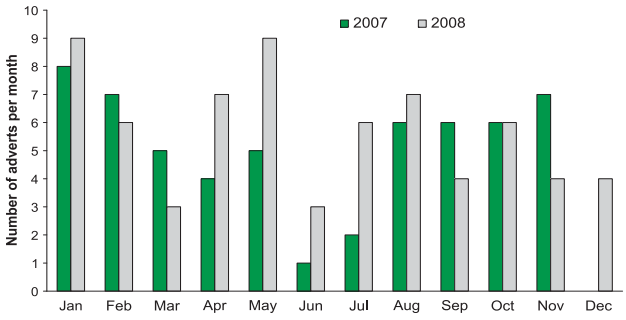
Eight different countries were offered as work locations in 2007 and 10 different countries in 2008. Most positions were located in the United Kingdom, followed by Switzerland, Germany and France. Some job postings either offered several locations or the location of the work place could not be identified from the advert. Only very few postings mentioned home-based work.

Table 1 Analysis of the job postings on the EMWA website in 2007 and 2008*

	2007	2008
Type of company		
MedCom	33%	46%
Pharma	44%	24%
CRO	12%	10%
Academic	4%	1%
Publisher	0	4%
Biotech	2%	8%
Regulatory agency	2%	3%
Other / unclear	4%	5%
Qualification required		
Life sciences	65%	70%
Unspecified	33%	29%
Language / translation	2%	1%
Types of work		
Communication	49%	38%
Regulatory	30%	28%
Mixed	16%	18%
Editorial	0	4%
Safety writing	0	2%
Technical writing	0	2%
Unclear / other	5%	8%
Locations**		
United Kingdom	55%	52%
Switzerland	9%	18%
Germany	9%	13%
France	13%	3%
Austria	0	4%
Ireland	0	4%
India	5%	0
Unclear / several	5%	1%
Other (<2 or home-based)	4%	6%

* All percentages were calculated using the total number of job postings in each year as denominator (2007: 57 postings, 2008: 68 postings).
** Including only countries with at least 2 positions in any year

Figure 1 Monthly distribution of job postings on the EMWA website in 2007 and 2008



Summary and Interpretation

A certain amount of caution is needed when interpreting the results of this analysis. The main question that should be addressed is the representativeness of the EMWA website with regard to the European job market for medical writers. It might be that the postings on the EMWA website represent predominantly those jobs which have in some aspect an international scope. It appears unlikely that for example a Lithuanian company that is looking for a medical writer to write Lithuanian regulatory documents would post the position on the EMWA website. Thus, positions with a national focus which require excellent knowledge of a language that is not English are unlikely to appear on the EMWA website. Thus, companies from mainland Europe are likely to post their international positions at EMWA, while for British companies this is an inexpensive way to recruit within their homeland. This could be a confounding factor in respect to the representativeness of the EMWA web adverts for the European market. The apparent dominance of UK-based positions might be a simple reflection of different recruitment behaviours, the British companies might also post their vacancies with a national focus while the companies from mainland Europe restricted their postings to positions with an international scope.

In summary, the job market for medical communicators is almost certainly bigger than reflected by the postings on the EMWA website. Bearing this in mind, it is however quite likely that the postings on the EMWA website provide a good indicator for the international positions in Europe (including Britain) within the field of medical communications.

The EMWA website appears to have become more popular for the recruitment of medical communicators or more employers who knew about it have chosen to actually use it. The diversity of companies recruiting increased from 2007 to 2008 and now includes regulatory agencies and small and medium-sized biotechnology companies besides the 'classical' medical communication and pharma companies. This might indicate that medical writing has become more recognised in the biopharmaceutical sector. However, given the comparison over just 2 years, this really is very speculative. The good news is for science graduates because almost two thirds of all postings required a life science background 'preferably at PhD level' to secure a position. However, there is hope for other qualifications: once you have accumulated a certain amount of experience, your chances are getting better. In some adverts, relevant experience required was as short as 6 months. However the proportion of medical writing jobs not requiring a life science degree has dropped slightly from 2007 to 2008.

The quality of the adverts posted on the EMWA website varied substantially. For some adverts, it is very apparent that actually the human resources department is in need of a writer. It is quite common that the employers post long lists of qualifications needed but fail to provide any information on their company or the department concerned. The use of the words 'self-starter', 'enthusiastic', 'hard-working', 'detail-oriented', 'excellent writing skills' is epidemic. However, some companies do not even mention the tasks of their newly recruited writer. Since small companies try hard to be attractive, they sometimes highlight remarkable features. One company located in Switzerland mentioned '6 weeks of vacation' as the main bait, another company in Ireland claimed that 'concern for our employees' quality of life affects all our business decisions'. The company claimed that even their location has been chosen because of this (and not because of the tax relief offered in this country, as some more sinister minds might suspect).

This analysis of the EMWA website postings is a first attempt to obtain reliable figures about the job market for medical communicators in Europe. Although limited to 2 years, it gives an impression of the job market for medical writers in Europe. To gain a more complete picture, further sources need to be incorporated into the analysis, e.g. the number of freelance medical writers in Europe and an analysis of the job adverts in journals such as New Scientist or BMJ. For many aspects of an organisation such as EMWA it is of great importance to monitor the developments in the job market, not only will this impact on the development of membership but also on the educational and developmental needs of the medical writers in Europe.

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An entertaining spelling game

James Harding, *The Times* editor, in his introduction to the spelling bee website[1] set up by his newspaper says "English is the country's gift to the world and its home-grown headache." But the games on the website are certainly a good cure for the spelling headache. *The Times* created the site to help young people learn to spell, but the tests are open to all comers. Shortly after arriving at the website an animated bee whooshes on screen to moderate your game. If kept waiting the bee produces a copy of *The Times* which he proceeds to read. But the bee's full attention returns as soon as you start a game. In the main game the bee pronounces a word that you should type into a box as quickly as possible. The quicker you spell the more points you will score. Each test consists of 15 words. There is also a multiple choice test where 3 words are presented, one of which is a misspelling. In another test a definition is given and you have to guess the word.

Happy spelling!

Thanks to **Ursula Schoenberg** u.schoenberg@t-online.de for alerting *TWS* to this URL.

1 http://www.timesspellingbee.co.uk/

Writing protocols: Collaboration and compromise or conflict and confusion? ICR-EMWA Joint Symposium[1]

by Alex Dedman and Andrew Smith

The challenges of developing clinical trial protocols were the topic of the second annual symposium jointly hosted by the European Medical Writers' Association (EMWA) and The Institute of Clinical Research (ICR) on 24 February 2009. Around 60 delegates discussed the difficulties associated with developing protocols that both meet sponsors' scientific and regulatory requirements, and facilitate the practical conduct of the study.

Medical writing for protocols: Details and diplomacy

Debbie Reynolds, Senior Medical Writer, Dianthus Medical Ltd

Wendy Kingdom, a long-standing member of ICR and the then Treasurer of EMWA, opened the meeting and handed over to Debbie Reynolds, who gave an overview of developing a study protocol.

Debbie noted that the protocol development team includes:

- a medical writer,
- a statistician,
- an investigator (internal and/or external),
- the sponsor, and
- a monitor to advise on practicality.

She highlighted the medical writer's role in integrating inputs, making the complex document easy to understand and implement, and resolving disagreements between contributors. Debbie discussed problems that commonly arise in agreeing a detailed synopsis, coordinating the team, resolving disagreements, coordinating comments, and version control. She gave examples of pitfalls, such as team members missing deadlines, changing their minds, or confusing different versions. To improve the process, she advised using a specialist medical writer, being strict on version control and on deadlines, and then trusting to the writer's skills.

In closing, Debbie mentioned the CDISC protocol standard that facilities the development of machine-readable protocols. This assists the generation of case report forms (CRFs) and study databases. Each data field is used only once, so any change can flow through every occurrence in the document.

A pharmaceutical company view of protocols

Sandra Waechter, Senior Project Manager, Janssen-Cilag

Sandra Waechter gave the pharma view, outlining the overall development process from global and regional product strategies, through research concepts and development plans, to individual studies. The development plan, with input from various stakeholders (e.g. medical, regulatory, health economics), is used to decide what studies are necessary. A research concept is sometimes developed, without a specialist medical writer, but always includes, for example, the primary and secondary objectives, and scientific rationale. The review of the concept within the company may be complex because of the range of stakeholders and the need for alignment with global strategy.

Subsequent protocol development always involves medical writers. A physician is responsible for the study, for discussing features with key stakeholders, and for preparing the synopsis for the medical writer using a standard template. Sections are assigned to other specialists. Appropriate pharmacovigilance requirements should be met, and consistent terminology and structure used. The medical writer distributes the draft protocol for review (including to local operations teams), specifying timelines for response. Comments are consolidated and reviewed, with the medical writer arbitrating changes if necessary. Sandra manages the development process, developing a budget, creating a realistic timetable, ensuring appropriate quality processes are followed, and driving execution to time and budget.

She expects medical writers to develop well-written protocols that clearly describe the research question and study objective. The introduction is vital, positioning the research question in the current context with appropriate citations. The protocol must contain enough detail to enable investigators to conduct the study. The medical writer should actively approach stakeholders to collect information, organise study-related materials to be included before submission, and ensure that the document complies with any relevant guidelines. Sandra considered that the whole process should take around 3 months.

It's never too early to ask a statistician

Adam Jacobs, Director, Dianthus Medical Ltd

Adam Jacobs, who has a background in medical writing, but is also a statistician and sits on an ethics committee, emphasised that it's never too early to ask a statistician.

For ease of implementation, a protocol should be as simple as it can be and still achieve its objectives. Once objectives

[1] This report of the joint ICR-EMWA conference will also be published in the ICR members' journal, *Clinical Research Focus*

are selected, they must be maintained, with anything else being omitted. Key stakeholders must be kept fully informed, so that problems can be identified early.

Adam discussed communication with statisticians (who may seem to speak another language). There is no substitute for face-to-face meetings, and statisticians are used to explaining again if you tell them what you haven't understood.

Adam described the statistician's role in specifying the objectives, trial design, analysis method, timing and choice of outcome methods, and sample size. Objectives should be agreed early, particularly in later phase studies, and must be in a form that can be tested statistically. Study design may be dictated by these objectives, but other elements need to be considered. Methods must avoid bias, though practical or ethical constraints may necessitate compromises.

Even in sample size, the many non-statistical inputs include consideration of a 'clinically relevant difference', which significantly affects the sample size and should be more widely discussed. Sample sizes may need to be significantly greater than anticipated by non-statisticians, which may raise budgetary issues.

Considering protocols from his perspective as an ethics committee statistician, Adam highlighted the importance of completing the application form correctly, and giving the committee the information it needs. In this case, the application form is the primary document, rather than the protocol, which may not be read.

On the subject of sample size, too large is unethical (but rare, because of cost), and too small is unethical because the study won't answer the question. The committee needs to decide whether the balance between the risks and benefits of the study is acceptable. This depends on the scientific validity of the study and thus an appropriate sample size.

Putting the square peg into the round hole

Sue Mackay, Research Nursing Team Manager, CDSS Ltd

Sue Mackay leads a team of field-based study nurses, who use protocols on a practical level. The problem for her is trying to fit the square peg of a protocol into the round hole of practicality, and she regrets that practical issues are not properly considered earlier.

A well-written and consistent protocol facilitates implementation. She advocated feedback into protocol development on how patient selection and study procedures are done in the field. For example, timelines for study procedures and frequency of patient visits might not be feasible or acceptable for patients. Sue suggested that protocol developers should consider these aspects from the patient's viewpoint bearing in mind whether timings will fit easily with family and work commitments. Also, hospital departments might not be flexible enough to meet protocol timelines, given their primary role in general patient care.

Sue suggested that more communication is vital, although the route between nurses and medical writers is less clear. Similarly, involvement of other site staff (e.g. laboratory, radiography, physiotherapy) in protocol development would be beneficial.

A project manager in the audience, who sends draft protocols to investigators, was surprised to find that the drafts are not circulated to the site study team at that stage. Perhaps research nurses could help educate their investigators on consulting more widely at the draft stage.

Panel discussion

Discussing the inclusion of summary lists and flowcharts in protocols, Sue Mackay agreed that they would be useful, though some sponsors prefer to avoid duplication. A delegate asked how site staff schedule visits and activities. This depends on the type of study but Sue tries to create a schedule whenever possible.

Adam Jacobs stressed the importance of allowing time to do the job properly: although writing the protocol may take as little as 3 days, 3 months would be more appropriate for discussion, reviewing and negotiation.

Protocols: A monitor's wish list

Laura Parkes, Clinical Trial Monitor, Merck-Serono

Laura Parkes defined a good protocol from the viewpoint of a clinical trial monitor. She emphasised that the protocol is a 'monitor's bible', used extensively as a first point of reference. As Laura put it, "If it is written in the protocol, then it has to be done–this is a great help for a Monitor!". Laura explained how best to present the sections of the protocol of special interest to her. Clearly defined inclusion and exclusion criteria, for example, are paramount, because of the large numbers of related site queries that arise.

Laura emphasised that detailed information is the key to making her task easier, especially for feasibility studies, site training, blinding requirements, concomitant medication lists, and acceptable patient compliance levels. Detail is especially important in the study drug and safety monitoring sections, which are often used as stand-alone sections by pharmacists, investigators, and other protocol users. Laura commented on the need for user-friendly timetables and flowcharts, noting that monitors often have to generate task sheets and tick lists based on the protocol.

Despite the need for a huge volume of information, Laura favoured a concise protocol, with supplementary information (i.e. declaration of Helsinki, study questionnaires, and specific assessment schedules) in appendices. She mentioned the importance of protocol formatting and of strict version control, a common theme of the session. Finally, Laura presented the monitor's protocol wish list. In summary, from the monitor's viewpoint, protocol developers should consider all those who will use the protocol and

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>>> ICR-EMWA Joint Symposium

write suitably specific requirements in a clear, succinct, and precise format.

Laura's presentation prompted discussions on the need to balance the level of detail in a protocol against the increased likelihood of amendments, and on the need for frequent communication to ensure that the protocol is helpful to all users.

Recruiting patients: Trials and tribulations

Abhijit Chaudhuri, Consultant Neurologist, Queens Hospital, London

Abhijit Chaudhuri discussed clinical trial design and patient recruitment. He explained that the most important issues for investigators and patients considering participating in a trial are whether the trial is asking a relevant and scientifically sound question, and the risk to benefit ratio of taking part.

Abhijit pointed out that 90% of clinical trials fail to enrol on time, and more than half are delayed by at least 6 months, suggesting that potential delay should be factored into timelines. The protocol, one of the 'seven Ps' (product, protocol, place, people, participants, price, and promotion) essential for a successful trial, must be flexible and have well-designed inclusion and exclusion criteria. Abhijit illustrated this point with 'Lasagna's Law', which demonstrates that a pool of eligible patients can shrink by 70% after applying stringent inclusion and exclusion criteria, and taking account of patient drop-out rates and lack of trial promotion. Abhijit, like other speakers, considered communication to be the key to a successful trial, especially communication with the patient.

Abhijit predicted that the ever-changing economic landscape would influence future clinical research priorities, especially in the UK and the USA. He wondered whether the exciting prospects of pharmacogenomics and personalised medicine might shape a new era in which 'patient minorities' are recruited into smaller clinical trials.

Abhijit's talk led to a discussion of patient information leaflets, which many delegates agreed have become cumbersome. The consensus view was that patient information should be presented in a clear and simple format.

Top team tactics

Dr Martin Robinson, Principal Training Consultant, Institute of Clinical Research

The final talk of the day was a light-hearted and informative presentation about team dynamics from Martin Robinson, who illustrated his points with references to sporting teams, contrasting, for example, the successful Manchester United football club with the not-so-successful Newcastle United. Martin showed that flexibility, mutual dependence and reliability, and a common drive to succeed are essential when working together. Drawing on his examples, he showed that the common traits of successful teams include good training, strong lines of communication, stable and continuous leadership, a clear sense of collective purpose, and good resources.

Martin discussed the four different team development stages. The first stage represents team creation, when individuals with specific skills are first brought together. Next comes a developmental phase, when the team becomes 'experimental'. During this, the most difficult stage, roles and responsibilities are uncertain and power struggles may develop. In a third 'consolidation' phase the team finally starts to work well as a single unit. Eventually, in the fourth and final stage, the team develops into a mature and productive working unit. Martin emphasised the need for definite and flexible leadership throughout.

To conclude Martin listed twelve 'top team tips', the first of which was great leadership. Discussion of the role of medical writers in a multidisciplinary clinical research team followed. Delegates pointed out that many medical writers do not feel they have a leadership role, although their coordination skills are often called upon to drive the project forward, sometimes within the difficult paradigm of working for a client who is technically 'in charge'. Martin clarified that leadership is behavioural; a 'team leader' can be someone who acts to coordinate members and facilitate team success irrespective of whether they have been assigned a formal leadership role.

Concluding thoughts

This panel of speakers, with diverse perspectives on the development and use of clinical study protocols, gave an interesting and informed overview of the challenges of protocol development.

Potential sources of conflict during protocol development were highlighted. For example, having an accurate and finalised protocol synopsis at the start of the project seemed to be a higher priority for medical writers than for project managers. It was agreed that more feedback was needed from protocol end-users and that perhaps clinical research nurses and clinical trial monitors should be more actively involved in protocol development. Concern was, however, expressed that having too many reviewers can lead to confusing differences and difficult management issues.

Alongside the small differences, were many areas of consensus, including the need for clear version control, for inclusion of simple checklists and user-friendly schematics in the protocol, and for clear and more concise patient information leaflets. Above all, the value of broad and consistent communication throughout the protocol development process was repeatedly emphasised.

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In the Bookstores...

Useful help and advice for writing regulatory documents

Linda Fossati Wood and MaryAnn Foote, editors: Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics. Birkhauser, 2008. ISBN 978-3-7643-8361-9. 39.99 GBP, approximately 45.00 euro. 237 pages.

Quite often, in the dialogue section of the EMWA website, people new to regulatory writing ask whether they can access examples of clinical study reports (CSRs) or protocols. Although International Conference on Harmonisation guidelines are available for the content and structure they don't really provide a flavour of what information/data the finished document might contain or what it will actually look like. It is difficult to gain open access to examples of these types of document because, unsurprisingly, they are confidential and not freely available.

This book, which is primarily aimed at the novice medical writer, provides what could be considered the next best thing. Individual chapters deal in detail with protocols, CSRs and investigator brochures (IBs). In each of the dedicated chapters the author provides a suggested outline of sections, describes what the purpose of each individual section is in the document, and the type of data you would expect to find in the section. This information is presented together with examples of in-text table formats. For example, the CSR chapter includes in-text tables for adverse events and serious adverse events and an example table for structuring patient narratives. Other chapters of the book describe the role of integrated summaries of efficacy and safety (ISE and ISS) and the common technical document (CTD). There is also a very useful glossary and list of abbreviations that new writers might be unfamiliar with.

The authors provide the new writer with an introduction to everything they might be unfamiliar with when it comes to being a regulatory medical writer. They set the scene by providing an insight into the regulatory aspect of medical writing and the drug development process. They introduce the concept of source documents (protocols and CSRs) and integrated documents (IB, ISS, ISE, CTD etc) and how they come together to form the clinical submission. The authors also highlight the differences/similarities between the submission requirements of the three main regions: the European Union, Japan and the United States. Strategies for organising and writing the documents to maximise efficiency and consistency are presented and discussed.

They also attempt to provide an insight into best practice for regulatory medical writing. Examples of templates, and style guides as well as check lists for performing quality control on protocols and CSRs are presented in a series of appendices. There are very helpful regulatory writing tips together with insights into the review process and the role of the medical writer in this process. For those working in a larger company, templates and standard operating procedures will be well established, however this may not be the case for smaller companies or writers setting out on the freelance road. This book could provide you with a very useful starting point if you find yourself in this position.

I liked this book a lot, with the lay out suited to my own style of learning. It is well organised with each chapter building into the bigger picture of the regulatory submission. You can read it from beginning to end, or use it as a reference book to look up specific topics relating to particular documents. Although I think the book is well suited to the novice writer, it would also make a useful reference book for more experienced medical writers who find themselves in need of a quick tutorial, or an equally useful addition to a departmental library if such things still exist!

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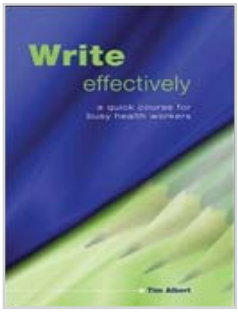
A great overview for the uninitiated medical writer



Tim Albert: Write effectively—a quick course for busy health workers. Radcliffe Publishing, 2008. ISBN 978-1-846191350 (paperback) 21.95 GBP, approximately 25.00 euro. pages 140.

Being relatively new to medical writing, *Write effectively* gave me a fantastic overview on what makes an effective healthcare writer; having said this, I think it could apply equally to most types of writing as the basic rules given follow a common sense approach. The book describes the kind of logical things that seem quite obvious for a writer to know, yet could so often get overlooked when starting a piece of writing from fresh.

The book is divided into 10 'sessions' that aim to teach effective writing of any sort of document relating to health such as articles, reports, applications, protocols, policy statements and even e-mails. Examples of the session titles are *putting together a plan, writing the first draft—and enjoying it!, rewriting—ask the big five questions, and getting others to help (not hinder)*. An exercise is given at the end of each session to help cement the learning. This allows readers to put what they have learnt into practice by focusing on a piece of writing they are currently working on and applying the rules to this. Thus the interactive element ensures that this book does not simply involve masses of reading, and so holds the reader's interest.

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>>> In the Bookstores...

Then there is an 'after-sales service' that acts a little like revision notes that you can come back to after a month or so. These notes address the same initial questions to ensure you have not deviated too far from the basic writing rules. There is a section at the end with very handy lists such as commonly misspelt words, useful grammatical terms and avoiding clichés. This makes *Write effectively* a useful reference book that is handy to keep close by for those moments when you simply can't think of a non-cheesy alternative version for something.

There is a very informative section on what effective writing actually is. Little did I know, but this is not about how well a piece flows or how interesting it is. Nor is it about how concisely it has been written or if it contains all the correct information. Effective writing is, quite simply, about getting your message across to your target audience. Get this right and the rest will follow; and this is precisely what this book aims to teach.

Of course everybody has their own preferred style of writing and long-standing, seasoned professional writers will no doubt have their own tried-and-tested methods. But I think this book offers a very comprehensive overview for newcomers such as myself. Hatching a thorough plan before commencing the writing process is an invaluable tip that could save a great deal of time. It forces you to think about the overall structure of the piece and who the message is directed towards.

Once a plan has been written and the background research done, a suggested, yet somewhat daunting writing method is to hide all materials far out of reach, not to refer to them again, and simply write, write, write for 10 minutes solid without reading anything back until the following day. The idea behind this is not to be seduced by adding superfluous information just because it is sat there in front of you–the things you remember will be the really important points.

One part I found of particular relevance was the author's views on political correctness. Albert's advice, when writing a first draft, is not to worry too much about political correctness, but instead to write a 'private' draft and then rewrite it by removing/rewording anything that could needlessly offend your audience. The danger with thinking about this too thoroughly before beginning a piece is that we often worry unnecessarily about offending people and end up saying too little. I rather like the thought of taking this more relaxed approach!

There is an adequate but not exhaustive index. With136 pages the book is a good length for busy health workers as the title suggests. All in all, I would recommend *Write effectively* as a great kick-off point for the uninitiated medical writer.

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Acknowledgements then and now

Acknowledgements have existed for over 500 years, but as Roberts (2003)[1] interestingly reports, the common practice of acknowledging among 16th and 17th century authors was not to recognize any intellectual contribution (as is most frequently the case today), but to thank financial benefactors or to endear authors to potential patrons. This form of acknowledgments was called an "impensis" which, in Latin, mans 'at the expense of.'

Another type of acknowledgement these early authors quite frequently resorted to was what Roberts calls a 'a prudent bow' to the official body, religious or secular, that licensed the printing of the book. That form was known as 'imprimatur', Latin for 'let it be printed'. Later, for strategic reasons and for underlining academic network dependence and belonging, Acknowledgements started flourishing in academic writing and publishing, from doctoral dissertations to scientific research articles.

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1 Roberts, S. (2003) On acknowledgments, the Inquisition was easier. *New York Times*, November 27th

Definitions box

Strong/weak

These adjectives are often applied to drugs or their effects, but are effectively worthless in this sense as they cannot be expressed numerically. A more useful term is *potency*, which expresses the amount of drug needed to produce a given effect—a potent drug produces its effects at low doses (or concentrations), whereas an *impotent* drug produces the same effects at high doses (or concentrations). Sometimes the term *strong* is used in a way that implies that the drug in question has a high propensity to cause unwanted effects (*side effects* or *adverse effects*). There is no place in science for terms which imply properties but which cannot be measured or expressed numerically. For such drugs the term *non-selective* may be more useful, although low selectivity does not necessarily mean that the side effects of the drug are undesirable or adverse.

However, the adjective *strong* can be usefully applied to some properties of drugs, notably *affinity*. It is perfectly reasonable to describe a drug as having *strong* affinity for a particular receptor, although it would probably be better to write *high* affinity. This is because it is possible to express affinity numerically.

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Webscout:

Drug-induced injuries —a growing concern by health authorities

by Joeyn Flauaus

The world population is continuously growing older because of an increased life expectancy and is thus using more and more drugs, whether prescription or over-the-counter drugs. Therefore, chances of drug-induced injuries are rising.

Over the years, a number of postmarketing labelling changes or drug withdrawals from the market due to postmarketing discoveries have occurred. Even the best planned and carefully designed clinical studies have limitations. To detect all potential adverse drug reactions, you need quite a large number of subjects exposed to the drug and the number of subjects participating in the clinical studies might not be large enough to detect especially rare adverse drug reactions. To minimise the risk of postmarketing discoveries such as unrecognised adverse drug reactions, certain risk factors, e.g. laboratory or ECG abnormalities, are subject of increased regulatory review.

The most frequent cause of safety-related withdrawal of medications (e.g. bromfenac, troglitazone) from the market and for FDA non-approval is the drug-induced liver injury (DILI). Different degrees of liver enzyme elevations after drug intake can result in hepatotoxicity, which can be fatal due to the irreversible damage to the liver. Since animal models cannot always predict human toxicity, drug-induced hepatotoxicity is often detected after market approval. In the United States, DILI is contributing to more than 50% of acute liver failure cases (data from WM Lee and colleagues from the Acute Liver Failure Study Group).

The second leading cause for withdrawing approved drugs from the market is QT interval prolongation, which can be measured during electrocardiogram (ECG). Some non-cardiovascular drugs (e.g. terfenadine) have the potential to delay cardiac repolarisation and to induce potentially fatal ventricular tachyarrhythmias such as Torsades de Pointes.

Drug toxicity is also a common cause of acute or chronic kidney injury and can be minimised or prevented by vigilance and early treatment. NSAIDs, aminoglycosides, and calcineurin inhibitors are for example some drugs that are known to induce kidney dysfunction. Most events are reversible, with kidney function returning to normal when the drug is discontinued.

Consequently, the pharmaceutical industry has a strong interest to identify drugs bearing the risk of causing adverse drug reactions as early as possible in order to improve the drug development programme. I have put together a selection of websites providing you with more insights about certain drug-induced injuries and their impact.

Drug-induced liver injury:
http://www.fda.gov/Cder/guidance/7507dft.pdf
Draft Guidance for Industry—drug-induced liver injury (Premarketing Clinical Evaluation): this guidance outlines how laboratory measurements that signal the potential for DILI can be obtained and evaluated and introduces an approach to identify drugs that are likely to cause significant hepatotoxicity (Hy's law).

Drug-induced QT/QTc interval prolongation:
http://www.fda.gov/CDER/GUIDANCE/6922fnl.pdf
Guidance for Industry E14—Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs: this guidance provides background information on the impact of QT prolongation and describes methods to assess the potential of a drug to delay cardiac repolarisation.

Drug-induced kidney injury:
http://www.ifcc.org/PDF/20010908.pdf
This article [1] of the International Federation of Clinical Chemistry and Laboratory Medicine (JIFCC) provides an overview on drug-induced kidney injuries. Several mechanisms of drug-induced renal dysfunction including hemodynamic and intrinsic kidney injuries and intrarenal obstruction are described.

Data on drug approvals, safety-based withdrawals and boxed warnings are also publicly available on the internet, as follows:

USA
Recalls, Market Withdrawals and Safety Alerts:
http://www.fda.gov/opacom/7alerts.html

Black Box Warning information:
http://formularyproductions.com/blackbox
List of drugs on the market that have a warning that appears on the package insert indicating they carry a significant risk of serious or even life-threatening adverse effects. These drugs are listed by their generic names.

Europe
EMEA Marketing Authorisation (MA) Withdrawals and Suspensions—Medicinal Products for Human Use: http://www.emea.europa.eu/htms/human/withdraw/withdraw.htm

EMEA Human Medicines—Product Safety Announcements:
http://www.emea.europa.eu/htms/human/drugalert/drugalert.htm

If you find a website that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at: Joeyn.Flauaus@sanofi-aventis.com.

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Sanofi Aventis Deutschland GmbH
Frankfurt am Main, Germany

Reference:
1. Drug-Induced Kidney Injury - eJIFCC 20/01 2009 http://www.ifcc.org

Journal watch:

Publication practices survey, advice on using medical writers, advertorials, new GPP guidelines, and ghost management of medical publications

by Nancy Milligan

Authorship, writing, and publication planning practices survey

Surveys on publication practices tend to be based on author responses or acknowledgements in published articles; Stephanie Phillips has carried out a survey with a different approach: of writers within healthcare companies [1]. A 16-item questionnaire was emailed to over 700 American Medical Writers Association (AMWA) members involved in, or knowledgeable about, their company's authorship, writing, and publication planning practices. 61 members responded (53% worked for a pharmaceutical company and 28% worked for service companies, e.g. medical communications agencies, contract research organisations). The major findings of the survey were:

- Use of medical writers: research articles were more likely to be drafted by medical writers than review articles; a third of responders said that their companies were more likely to use medical writers now than 5 years ago, although 63% felt that there had been no change; speed and quality were the main reasons for companies using medical writers
- Publication planning: 66% said that their company developed publication planning strategies (21% suggested they sometimes did), this was higher for pharmaceutical company employees (75% yes, 19% sometimes)
- Role of author and writer: for research articles, 70% said that authors were not involved until after data tables were developed, 5% said authors were not involved until a first draft of the article had been prepared; for review articles, 75% said that authors were involved before an outline was written; responders estimated that when drafting an article, 51% of content was controlled by the author, 32% by the writer, and 19% by the company
- Acknowledgement of medical writers: 49% said that their company always acknowledges medical writers (this was less common in medical communications companies [18%] than in pharmaceutical companies [67%]); 64% felt that writers are more likely to be acknowledged now than 5 years ago (35% felt that there was no change); 88% did not feel that acknowledgement made acceptance less likely

The author commented that the survey seems to suggest that companies are using medical writers more, involving authors earlier in the writing process, and are more likely now than previously to acknowledge medical writers, which helps to make the process more transparent.

Advice for authors using professional writers

Writing recently in the *Clinical Journal of Oncology Nursing* (*CJON*), Mayer et al suggest that the journal "needs to provide more guidance to authors to ensure *CJON* articles are unbiased as well as to help develop the publication skills of oncology nurses" [2]. To avoid ghostwriting, *CJON* previously had an editorial policy banning articles written by medical writers; however, in this article Mayer et al recognise that ghostwriting does not occur if writing support is clearly described in published articles. Mayer et al suggest that authors should think about several key points when considering hiring a professional writer; these were, in brief: ask questions about how and why a potential author is approached to write the paper, retain ownership of the work by determining the flow and direction of the paper, review and approve the amount and type of editing before submission, and upload the article files or request a copy of the final uploaded version if the writer/company submits to ensure version control (they suggest the author should also be in charge of editing queries and review of the final proofs). Mayer et al argue that transparency is essential to maintain editorial integrity and therefore the published article must honestly acknowledge the use of a professional writer, the funding source of the support, and the extent to which the author claims ownership of the paper.

Journals and 'advertorials'

In a series of letters to *The Lancet*, the topic of journals publishing 'advertorials' (advertisements disguised as editorial content) was discussed [3]. In the first letter, Meilof and Hylkema criticised a *Lancet*-published research article by Ho et al [4], which they considered an advertorial because 8 of the 12 authors (including the first and corresponding author) were employed by Merck, the funding sponsor of the study. They also pointed out that data were analysed and the process supervised by employees of Merck, and that 3 employees drafted the first version of the paper. Meilof and Hylkema argued that this raises the question of who, independent of the sponsor, can vouch for the integrity of the data and the presentation of the results. They went on to suggest that a paper should not be accepted for publication if the first and last authors are employees

of the funding sponsor. In response letters, academic authors (Ferrari, Dodick, Winner, and Koppen) and industry authors (Ho, Michelson, and Gertz) agreed that whether conflicts of interest should disqualify researchers from participating in scientific discourse was an important issue, but suggested that they had been completely transparent and honest about the people involved in the design, conduct, analysis, and interpretation of the study in full compliance with the guidelines for authorship (which they suggest is a good deal better than using ghostwriters and fake first authors). They went on to argue that just because a researcher works for a pharmaceutical company doesn't mean that they don't have adequate professional training and an allegiance to scientific principles, as do other researchers. They also pointed out that many journals, including *The Lancet*, have developed policies and practices to reduce bias from potential conflicts (i.e. by requesting to see the protocol or analysis plan that was finalised before unblinding data). They suggested that "rather than simply criticising pharmaceutical industry involvement, the real challenge should be to come up with a realistic solution to prevent industry-biased publications".

GPP guidelines for medical communications agencies

Published guidelines and recommendations for publication practices are available to strengthen and uphold ethical standards in biomedical communications. Various guidelines have been developed that reflect the perspective of medical journals, medical writers, publishing professionals, and the pharmaceutical/biotechnology industry. A recent article provides the first publication of good publication practice (GPP) guidelines specifically focusing on the perspective of a medical communication agency [5]. A task force of staff members from the AXIS group of companies in the US reviewed current guidelines and agreed that a GPP document specific to medical communications agencies was needed. Accordingly, the guidelines, provided in full in the article, were developed collaboratively over the course of a year by a working group of employees within the AXIS group of medical communications agencies. The goal of the guidelines is "to provide guidance for medical communications agencies supporting the development of medical publications in collaboration with both the research sponsors and the authors/researchers responsible for the design of the study and the collection of the data". The resulting guidelines are aligned with existing publication guidelines and cover several key issues such as authorship, transparency and acknowledgements, potential conflicts of interest, and financial disclosures. They also provide guidance on topics perhaps unique to agencies, such as interactions among medical writers and editors as part of an agency, authors, journals/congresses, and the sponsoring company; submission processes; data security and confidentiality; and training. The guidelines were developed for the use of agencies in the US, but should be of interest to agencies in other countries as well.

Publication planning: ghosts in the machine

And finally, in a recent article in *Social Studies of Science*, Sergio Sismondo, associate professor of philosophy at Queen's University in Canada, discusses pharmaceutical company publication planning [6]. In general, Sismondo is quite critical of publication plans saying they "extract the maximum amount of scientific and commercial value of data and analyses through carefully constructed and placed papers" and argues that it reflects "a new kind of corporate science, designed to look like traditional academic work, but performed largely to market products". He suggests that most pharmaceutical company-sponsored research is now carried out by contract research organisations (CROs), analysed by pharmaceutical company statisticians, written up by medical writers, approved and edited by academic researchers who then serve as authors, and the whole process is guided by publication planners. He argues the work of these people behind the scenes is rarely acknowledged, and for this reason suggests we should see publication planning as the "ghost management" of medical research and publication. The bulk of the article reports on a conference of an international association of publication planners (the third annual meeting of the International Society of Medical Planning Professionals, the ISMPP), during which Sismondo relays some of the main points made by speakers during the conference and uses examples to liken publication planning to marketing and public relations. There is also a section on authorship and ghostwriting, which was also a topic covered at the conference, in which the author talks about the role of key opinion leaders as authors and the distinction between ghostwriting and medical writing. He acknowledges that both publication planners and pharmaceutical companies want formal guidelines and standardised procedures and formats for clinical trials and journal papers, even though, he points out, that publication planning "runs directly against the goals behind those guidelines and standards".

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Out on our own

We had another record turnout at the Freelance Business Forum in Ljubljana this year—more than 60 people attended—and we have already asked for a room for at least this number at Frankfurt later this year. The topics discussed are summarized in the report in this issue, and I pick out one to mention here: we have set up a Freelance User Group for EMWA with 6 volunteers in different countries because freelance members now account for more than 15% of the total membership. The first meeting of the group is in July, and you will be hearing more about it in the September issue. If anyone has issues they would like the User Group to discuss or feels there are issues that should be drawn to the attention of Head Office or the EC, please let Sam or me know.

Linda Liem tells us about a week in her life as a freelance writer after moving from the Netherlands to Norway with her family, and Phil Leventhal reports on two lunchtime discussion tables at the Ljubljana conference where freelancers and salaried colleagues considered which status is best, brought together with some thoughts of his own.

Our cost-trackers were active again at the Ljubljana conference. All agreed it was a great place to visit and that the conference content was as worthwhile as ever, but they were not unanimous in their opinion of the costs of attending this conference and EMWA conferences in general and had several suggestions for decreasing the cost. Read on!

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Report on the Ljubljana Freelance Business Forum, May 2009

More than 60 people attended the Freelance Business Forum (FBF) at the Ljubljana Conference on Wednesday 27 May 2009. The highest turnout yet, and we were pleased to see a lot of new faces. The topics discussed are summarised below.

1. Website

The format of the Freelance Listing on the EMWA website has now been revised. Thanks to Jo Whelan for co-ordinating this activity. Some requested changes still have to be made. Changing to an alphabetical listing will be done in the near future. Some requests for changes cannot be done because of software constraints. Additional comments or suggestions are welcome.

2. User group established

Currently, more than 15% of EMWA members are freelancers. The exact number is not known, but 25% of the respondents to the recent member survey were freelancers. To support the EC in better understanding how freelance members can be served by EMWA, a User Group was established at the meeting to represent the views of freelancers. The group will meet by telephone conference every 3 months to discuss freelance membership-related issues. Alistair Reeves or Sam Hamilton will then feed back to the EC with a short written summary. The following people volunteered to be in the User Group: Ingrid Edsman, Neil Fisher, Claudia Frumento, Debbie Jordan, Elaine O'Prey, Diana Raffelsbauer. A report from the first meeting of the User Group will be published in *TWS* in September.

3. Training and training records

Freelancers do not always enjoy the intensive training offered by employers. Alistair Reeves suggested that freelancers can ask a client if they can join in-house training events. Within teaching hospitals, training events can be as cheap as €20 per day.

The importance of maintaining training records was stressed, as these are asked for during inspections. Jo Whelan reminded all that Certificates of Attendance are supplied at each workshop for training records. It was also suggested that a description of a workshop or its 'Abstract' could be attached to the Certificate of Attendance, since inspectors are interested in the contents of training events. Sam Hamilton reminded all that the onus was on us all to maintain our training record.

Robert Kahn was not happy with the 'artificial restriction to 4 credit workshops' at one conference and made several suggestions: decrease the workshop fee, increase the number of attendees per workshop, raise the number of credit workshops it is possible to attend at each conference to 5. John Carpenter (as a member of the Education Committee) offered to consider the issue again, but Rosie Bischoff (an ex-Education Committee member) felt that this was unlikely to be changed.

GCP training for freelancers is now a regular event at each EMWA conference, primarily aimed at the freelance membership. Self-marketing was suggested as a further area for which freelancer-specific training could be offered at future EMWA events. Members were asked to submit further suggestions.

4. The FDF on the website

The FDF is clearly not being used, and not only the freelance area. One of the first tasks of the EMWA Freelance User Group will be to explore more attractive possibilities for an electronic discussion forum. The Freelance Email Discussion Forum (FEDF) may be temporarily resurrected to bridge the gap.

5. Accreditation

A few members have included the statement 'accredited' by EMWA on their promotional materials. Members are not permitted by the EC to claim that they are 'accredited' by EMWA because the term 'accredit' implies 'endorsement'. A member can state, however, that they have an 'EPDP Certificate' at foundation or advanced level, once this has been obtained.

6. Credit transfer between EMWA and AMWA

Robert Kahn asked that the EC consider the transfer of AMWA foundation credits. AMWA to EMWA transfers are accepted but the reverse does not happen. The 'reverse issue' has been discussed by the Education Committee but no statement has been issued. It was noted that an 'Advanced EPDP Certificate' can be pursued without doing the 'Foundation Certificate'.

7. Information accessibility

Ingrid Edsman would like a platform created for discussion of items raised at previous FBFs, for example: sharing hands-on experience such as content of QC checklists, time estimates for standard documents, useful software tools. Good freelance advice has been generated so far in previous FBF, FEDF and FDF discussions (and in *TWS*, added Alistair Reeves). *TWS* articles and other materials could easily be placed on a members' blog on the EMWA website. Ingrid offered to do this. Sam Hamilton noted that we now have more than 2 years of 'Out On Our Own' articles. She wants to make these readily accessible, and also information generated by the FEDF. The latter would have to be reviewed for confidentiality issues, as some contributors wanted to remain anonymous.

8. Economic climate

Both Neil Fisher and Ingrid Edsman were concerned about the effects of health spending cuts in the USA and the general economic situation. Susan Bairnsfather (from the USA) responded that the spending cuts are to be over several years, implying that there is no immediate concern. Alistair Reeves added that although alerted to this information, there is little we can do about it. John Carpenter's experience of 2 recessions is that as work from 'pharma' reduced, agency work expanded, and more freelance work was available.

9. Unreliable clients

EC members present confirmed that EMWA cannot support the provision of information on unreliable clients. In the case of late payment, informing the client that you intend to 'seek legal opinion" usually produces a rapid response. Sam Hamilton stated that with clients who are persistently a few days late with payment, she calls them to suggest 2 options: a charge of 1% of contract fee per day late, or payment within 14 days instead of her usual 28 days. Margaret Gray believed that there is an EC or UK law stating one can charge interest for late payment (note: late payment legislation exists in the UK and most, though not all, EU member states).

10. Headhunters

Nelly Thomas stated that she receives weekly calls from 'headhunters' and wanted to know if this is usual. Many members stated that it is. Rosie Bischoff replied that she receives calls for short-term fill-in positions from 'manpower agencies'; she has prepared 3 proposals to fill interim positions but is not convinced that it is the right approach to finding work because fees are pushed downwards with having a 'middle man'.

11. Google analytics

Sam Hamilton explained using 'Google Analytics' to see who looks at her website, how long they spend, and what search term(s) are used to find her. These help her to understand the profile and geographic spread of those searching for her.

12. Online training

Claudia Frumento asked about the possibility of online training. Susan Bairnsfather replied that she thinks that online training is possible for any subject. Several other members doubted this very much. Wendy Kingdom added a note of caution: someone would have to design online training sessions; this would be very time consuming and would exceed what can be expected of volunteers. Face-to-face training is the optimum medium, although online training can be used as a means of becoming familiar with a subject.

13. Contributions for *TWS* Out On Our Own

Contributions are planned for the Out On Our Own section of the September issue of *TWS*. Contributions are always needed, and a call was made for articles and boxes relevant to freelancing, and also for ideas, even if the proposer did not feel they could write on the subject themselves.

Thanks to: all those who attended, Alistair Reeves and Sam Hamilton for chairing the meeting, and Barbara Grossman for doing the minutes.

Freelance or employee: Which is better?

by Phillip S. Leventhal

Have you dreamed of being a freelance medical writer? When you are an employee, the independence of a freelance life can sound liberating and adventurous, but is it a siren song? On the other hand, employee life has real benefits, such as regular hours, steady work and vacation, but does it imply living with a lot of limitations and aggravations? Many writers have struggled with these questions and tried to find an answer to the question "Which is better: freelance or employee?" Answering this question was the goal of two lunch table discussions at the recent 28th EMWA Conference in Ljubljana.

Life as a freelancer

To begin with, freelancing offers the possibility of great independence—the romance of being your own boss, captain of your own ship. Key benefits include setting your own hours and choosing where and how you work. Also, freelancers spend more time writing, more often get the credit for the work, frequently get more interesting projects, and more often are asked to give scientific input. One very pleasing aspect of freelancing is a lack of meetings (which we all known can be a big time-waster) and a lack of administrative issues. Also, unlike employees, freelancers have the freedom to reject projects or clients they don't like.

Most of these benefits could be considered emotional rather than practical. A practical benefit is lack of a cap on earnings. However, on average, this argument is less important and probably should not be a key factor in deciding which path to take. A 2007 salary survey by the American Medical Writers Association (AMWA) found that the mean salary was $82,232 for employees and that the mean net income was $93,306 for freelancers, even though both worked roughly the same number of hours per week [1]. (Ed. – the EMWA Freelance Earnings Survey is due to be repeated in 2010; for details of the 2007 survey, see reference [2].) Of course, the slightly higher income of freelancers could reflect a higher level of experience, and the salary for employees did not include benefits such as retirement, sick leave, insurance, and other perks.

Just as there is no cap to freelance earnings, there is no *bottom*; being able to get work is not guaranteed and can be difficult, especially for a less experienced writer. Even if you get work, it can often be difficult to collect payment for work already completed. In fact, one freelancer made the surprising claim that "there are always billing problems." Although this is less of a problem when freelancing for pharmaceutical companies, it can be a serious problem when working for small-to-medium sized companies or academic institutions.

Also, although attractive, being your own boss can have disadvantages. Freelancers generally work alone from a home office, and the result can be a lack of colleagues to consult with and very real social isolation. In addition, it can be difficult to separate your work and personal life, especially with a work flow that has the potential to vary between extremes of too much and too little. The downtimes can also lead to anxiety about future earnings, an important concern for less experienced writers with fewer contacts. Another potential problem is getting pigeonholed into a single type of work—for example manuscript writing—and it is usually difficult to find clients willing to take the risk of letting a freelance writer learn on the job.

Life as an employee

What about life as an employee? Being an employee may lack the romance of freelancing, but it has very attractive and substantial benefits. One key point is stability. This includes having a fixed monthly income and a steady stream of work. Another important benefit of being an employee is working on a variety of different documents and in new scientific domains. Furthermore, many employees consider life as an employee to be less stressful than freelancing: employees enjoy regular hours, a separation between work and home, and having support staff to deal with billing, business development, and miscellaneous administrative tasks. A further important advantage of being an employee is the possibility of receiving professional training in new areas, something generally unavailable to or often too expensive for freelancers. Also, freelancers have no colleagues for backup or quality control. Finally, there are a variety of other pleasant benefits of being an employee, including paid vacation and sick leave, health insurance, retirement, and various perks only available in a company setting. As for the disadvantages, those who have been employees know them well: bad management, the aggravation of managing others, mind-numbing meetings and administrative tasks, office and company politics, the feeling of being on a treadmill, and a general lack of independence.

Three stories

Three stories may help those thinking about starting a freelance career. One medical writer described his life bouncing back and forth between freelance and employee: he had worked in pharma, then as a freelancer, is soon taking a full-time job in pharma, and eventually plans to go back to being a freelancer. He said that he is specifically going back to work in pharma because he wants additional experience that he can't get as a freelancer. He concluded that the benefits of the additional in-depth experience outweigh the negatives of temporarily giving up his independence.

A second participant was a medical writer now freelancing after many years of working in academia and pharma. He said that his extensive experience, combined with his personal network and knowledge of the marketplace gained when he was an employee made it possible for him to find clients and generate a steady work flow. He emphasized the importance of working first as an employee for several years before launching a freelance career. He pointed out that one of the worst things a freelancer can do is to take on unfamiliar work and not do a good job; the result is that you will lose the client and will gain a bad reputation. Making a good name for yourself is essential, and it generally requires in-depth experience gained over several years of working as a medical writer.

The third story is my own. Until 2003, I was a research scientist in biotech. However, like other medical writers, I always felt most comfortable in the communication of science, and I was looking for a way out of the laboratory. Getting a job as a writer directly from the laboratory was challenging, and I had become averse to working in an office. I did what a lot of scientists think of but are rarely crazy enough to try: I jumped directly from the laboratory to freelance writing. I got my first break by answering an ad on the AMWA jobs website for a manuscript editor. The pay was low, but it was a start, and the work greatly improved my writing skills. I also placed ads on the AMWA and EMWA freelance pages, which eventually generated a small trickle of editing and writing work. Over time, through networking, I managed to get a steady flow of work; however, I did succumb to the danger of losing clients because of taking on work I was unfamiliar with. Also, not knowing the marketplace, how companies work with freelancers, or how to protect myself with a good contract created a lot of stress. In the end, I was working very hard, and although independent, I felt isolated, mistreated, and typecast as a manuscript writer.

The result was that I started considering life as an employee, but I was concerned about the prospect of giving up my independence. With this in mind, I started looking around very carefully for a creative solution. One year ago, I managed to find it. I took a full-time job with 4Clinics, a CRO with a total of about a dozen writers and a branch office in Paris. So far, working for 4Clinics has been an optimal middle path and a positive experience: I have many of the freedoms of a freelancer combined with the stability and all of the benefits of a full-time job. For example, I have been able to help develop new clients and expand the company into new areas of writing, such as medical communications. I also have had the chance to learn new areas of writing and medicine that I would not have been exposed to as a freelancer. Perhaps my job is unusual, but it seems that this kind of small communications company is a good fit for someone who does not want to deal with the downside of freelancing but also wants to avoid the headaches of a big company.

Conclusion

So, which is better: freelance or employee? Freelancing is a great career path for those with experience and the ability to work alone. Surprisingly, for those already working as medical writers, life as an employee is favoured over life as a freelancer. Although the independence of freelancing is seductive, the concrete and emotional benefits of life as an employee are just as attractive, especially for less experienced writers, and they should be considered carefully.

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Battles over opinions as to superiority of products should take place in journal pages not in court

So said the Indiana federal judges in a defamation case brought by a product manufacturer against the American Society of Health Systems Pharmacists (ASHP) and the authors of an article published in the *American Journal of Health-System Pharmacy*[1]. The device manufactured by the claimant had compared unfavourably in the article which compared five devices. The manufacturer failed in their action because they were unable to prove malice, knowledge of falsity or recklessness as to the truth or falsity of statements in the article. During the court case the journal had to produce the peer reviewers' comments but were not forced to reveal the names of the peer reviewers. This was a critical case because if the manufacturers had won the case scientists would not have been able to state opinions about products without fear of legal action. The journal had also feared that the reviewers would be drawn into the case as defendants which would have had a detrimental effect on the time-honoured peer review system.

[1] Talley CR. Victory for science and peer-review publishing. *American Journal of Health-System Pharmacy* 2009;66:e1. Available at: http://www.ashp.org/DocLibrary/News/VictoryforPeerReviewPublishing.aspx.

Cost of attending the Ljubljana Conference

by Alistair Reeves, with thanks to Mary Smith, Almudena Pardo, Neil Fisher, Diana Raffelsbauer and Ingrid Edsman

'Ljubla…where?' was in the minds of many of those who came to the most recent EMWA Conference in Ljubljana. It may be a little off the beaten conference track (which doesn't necessarily mean that it was expensive to get to, as we shall see), but after making the effort, I hope all those who attended were as charmed by Ljubljana and Slovenia as I have been over the past 10 years. Our five freelance cost-trackers from different countries were obviously pleased to have visited Ljubljana and Slovenia, although their opinions on whether the conference offered value for money differ. Here they tell us about what they spent to attend the conference.

All agree that EMWA events should not be missed because of the valuable content of the high quality educational programme; themed seminars; plenary lectures; other professional development events; and the unique networking possibilities. But they do have some interesting suggestions for reducing costs—and not only for freelancers. As for the London conference, some considered the registration fee is too high, but most felt that the workshop fees offered good value.

Their expenditure is summarised in Table 1 and excludes 'lost work' costs, because opinions are divided: some colleagues do not regard the time spent at training events as 'lost' and say it is calculated into their rates (like holiday), while others cannot help thinking about what they might have been earning had they not attended!

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My journey started at the 27th EMWA conference held in London in November 2008. As I live in West London, only 4 tube stops from the venue in Kensington, how could I not attend? I paid for attendance, EPDP enrolment, and 3 workshops, and thought no more about it. Little did I realise that I would become hooked and find myself attending conferences much farther afield.

As a freelance editor and writer, I have to pay my own costs. This was fine for the London conference, where my greatest expense after the conference fees was my tube fare to the venue, but was somewhat different for Ljubljana.

My first step was to find the cheapest flight—not British Airways but EasyJet, not Heathrow (my 'local' airport) but Stansted. This may have been a false economy, as I hadn't factored in the additional costs of travel to the airport, placing a bag into the hold, and excess baggage on the return journey (yes, I went shopping).

As I couldn't justify the cost of staying at the conference hotel, despite the preferential rate, my next step was to source a hotel. My requirements were for a cheap and cheerful hotel with clean rooms in a central location. Having spent a large part of my misspent youth roaming around Asia, I am used to finding the best value options. My preferred source of travel information, Lonely Planet, came up trumps with Hotel Emonec, which did exactly what it said on the tin. Situated just off Presernov trg, the hotel couldn't have been more convenient for the conference venue, or for sightseeing (and shopping) when not attending workshops.

Food was largely taken care of with breakfast at the hotel and lunch at the conference venue. Dinner was easy to find and relatively cheap at the cafes by the river.

Even with these savings, it was an expensive trip, particularly with the £/€ exchange rate this year.

Do I think it was worth the cost, even taking into account lost earnings? The answer has to be 'Yes'. To have continuing professional development resulting in certification, while meeting some great people and staying in a beautiful city is not to be sneezed at. The workshops were all excellent, well thought out, and well presented. I learned a lot and enjoyed myself.

That said, the EPDP is an expensive exercise due to the amount of conference attendance needed to earn the certificate, and I have now realised the true cost of the programme. I attended 3 workshops at the London conference and 4 workshops in Ljubljana (the maximum for each conference). This means that, assuming all goes well with the post-workshop assignments, I will only need 1 more workshop credit from the next conference. It will be an expensive workshop, unless I decide to re-enrol in the EPDP, in which case the cycle of conference attendance, with the associated expenses, starts all over again. Perhaps the Education Committee could look at this issue so that those of us who pay for ourselves can complete the programme across 2 consecutive conferences, thus providing better value for our money.

Cost of attending the Ljubljana Conference

I have started to save for the next meeting, although having just tallied the cost of attending the Ljubljana conference, I may have to wait for another one in London. As you will see from the attached photograph, I have been on short rations since my return!

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I am a freelance medical writer, with a focus on manuscripts, based in Madrid. This was my second EMWA annual conference. I do think registration is very expensive at €550. It includes the opening lecture and welcome buffet, neither of which I attended, and brunch for the days of the conference, in which, again, I was not interested. A 'no-meal' option could be offered to provide a better price for people who, like me, are only interested in the workshops. Thus, if I was going to spend all that money, there had to be some 'extra appeal' to attend. I searched Ljubljana on the Internet and it looked like a beautiful city in a "mysterious" country (at least from my point of view) and not too touristy; the perfect vacation spot for my husband and me. Therefore, I took the conference as a chance to get to know this new and interesting place. I am enrolled on the advanced EMWA Professional Development Programme (EPDP), which requires credit for any eight advanced workshops to obtain the EPDP certificate. One can only take four of these workshops per conference and last year I only took three, since by the time I registered all others were full. Knowing that I would have to register for a third conference, this time I again took only three morning workshops to have the afternoons off, and one extra day to spend with my husband.

My trip started by taking the metro to Madrid airport and then a flight to Ljubljana via Prague. From Ljubljana airport I took a shuttle bus to the hotel. I did not stay at the conference hotel but at another very close by which, at €104 per night (including an incredibly huge and varied buffet breakfast) had the best cost-value rate I could find. This was a non-refundable rate, which was the same for one or two people. I ate lunch and dinner at different restaurants in the city, which I enjoyed very much. Since dinner was the only meal I actually ought to have been paying for, I have to say it was not expensive at €12–15. I tried to book the EMWA excursion, which included dinner, to the Postojna caves but 'fortunately' it was already full. Instead, I ended up taking the regular bus from Ljubljana bus station to Postojna (€6 each way) and from there, I had only a short walk to the caves (entrance ticket €20). The bus ride was beautiful and it was exciting to go the "local" way, and the caves were very impressive; it would have been a shame not to visit them when in Ljubljana. Of course, having my husband there made all these things much more enjoyable.

Even though I complained about the registration fee, I do think that the cost-value of the workshops is about right. I learned something in all of them and was so into them that time flew by and they seemed really short. The pre-workshop assignments not only ensured that I prepared properly for the workshops, but were also a way to start learning on the corresponding subject, and I'm sure that the post-workshop assignments will help me to use and retain what I learned. I attended the Mediterranean Editors and Translators Association 2007 Meeting in Madrid, and although it was much more reasonably priced, for the most part, the workshops suited editors' and translators' needs and not those of writers (except for one statistics workshop similar to the one offered by EMWA). Overall, I find EMWA workshops more focused on what we writers do. As a conference venue, Ljubljana was probably convenient for company employees whose expenses are paid, but for freelancers it was a hard place to reach (not too many flights and none of them direct). However, I found a good compromise by making it a vacation spot as well.

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"You're always like this after a conference," my wife said after I'd been yapping happily to her for an hour. "You always come back buzzing!"

And it's true. I've been going to EMWA conferences on and off—I'll get back to that later—since 1996, and at every one I've learned a lot, met great people and loved the social events. For me, as I suspect for most freelancers, EMWA conferences have clear therapeutic benefit. Don't get me wrong! I enjoy my work, which is frequently stimulating and rewarding, and for me the benefits of freelancing far outweigh the drawbacks; but deadlines are often tight, the days long and weekends short, there's no career progression as such, and no-one to chat to at the water cooler. In most cases we don't have a water cooler either.

EMWA is the clear antidote. Most obviously, the training program can help us expand what we do or point our careers in new directions, but the conference itself provides more: a supportive network of enthusiastic and knowledgeable peers you learn from, share experiences with, and make you proud to be a medical writer. How do you put a price on that?

My journey to this year's spring conference started in London, with the cheapest air option, from Stansted, UK: unassigned seating and non-reclinable seats, but I figured that I could cope with that for a short flight. I booked a minivan shuttle from my home in west London, the most convenient option, and arrived at Stansted in plenty of time. What I had overlooked, and this may get some heads nodding, is that the airline I used charges extra for

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>>> Cost of attending the Ljubljana Conference

checked-in luggage. This increased the cost of my return flight by around 20%. Nevertheless—including the costs of a minivan shuttle from Ljubljana airport to my hotel and back, and the return train to central London from Stansted—what I spent on transport was very reasonable and a relatively small fraction of what I spent overall.

For accommodation I stayed at the less expensive branch of the conference hotel. The advantages in using conference accommodation, of course, are that you are close to the meeting and likely to meet other writers. At the Vienna conference I stayed at a cheap place 20 minutes' march from the venue and felt rather cut off from the herd; but a four-star hotel is certainly a luxury for me and took a considerable bite out of my wallet this time round. When I booked the Ljubljana conference I was working 12-hour days and didn't have the time to scavenge lunch let alone research Slovenian hotels. I am sure that many freelancers would appreciate being offered the choice of discounted rates at a cheaper hotel in future. For the next conference, though, I'll make sure I'm organised well ahead of time. I will miss the four-star breakfasts though…

Accommodation, however, was only half the cost of the training I booked. Workshops are the *raison d'être* of EMWA conferences, and I figured that since I was going I may as well attend as many as possible. As usual, they varied in quality from excellent to outstanding; all were delivered with enthusiasm and passion – but are they good value? To decide that, I need to make some sort of comparison. The closest competitor to EMWA, in terms of training, is the American Medical Writers Association (AMWA). There are certainly all kinds of confounders, but at last year's AMWA annual conference (held in October in Louisville, Kentucky), the cost of a workshop was in the approximate range of €39 to €84. This was substantially cheaper than seminars and workshops at EMWA this year, which ranged from €50 to €210. AMWA registration costs were also less than half EMWA's (€259 vs. €600 for regular member rates).

There are all kinds of problems with a comparison like this. Here are just a few. It may be unfair to compare US and European costs. I haven't been to an AMWA workshop, so I've no experience of their quality (although I have been told that they are good), and have no idea if AMWA workshops provide for non-native English speakers, European guidelines, and so on[1]. I would also add that even though flights to the States are fairly reasonable at the moment it's still a long haul for just three days of workshops. However, if we are simply comparing workshop and registration costs, I would have to conclude that AMWA are providing better value. That, together with the lack of a more affordable hotel option, led me to decide, if only to play devil's advocate, that EMWA conferences don't provide value for money.

As an independent delegate, money, or the shortage of it, was the main reason why I didn't attend EMWA between the Henley conference in 1999 and Vienna in 2007. The costs, not forgetting lost earnings, are considerable. This raises all kinds of questions of how—or if—EMWA could be made cheaper. Although this is not the place to discuss them, I will mention that last year I attended a one-day workshop on publication planning, organised by NetworkPharma, which cost me exactly nothing. This was managed through sponsorship.

However, as I said before, an EMWA conference isn't just about the training, it's also the interaction with other medical writers during workshops, over lunch, and at the excellent and value-for-money social events. It's the networking opportunities with potential collaborators and clients. It's the reconnection with fellow freelancers, the meeting with friends, the infectious enthusiasm you pick up from the atmosphere around you—and you simply can't put a value on that.

See you in Frankfurt!

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I am in the third year of my freelance medical writer career, and this was my second EMWA conference. I live in a small town called Giebelstadt in Northern Bavaria, Germany, not far from Frankfurt am Main. The German railway (DB) offers very cheap train tickets to certain European countries. After having compared the price of the 'DB Europa-Spezial Slowenien Ticket' (€78 for the round trip) with a Lufthansa flight (approx. €700), I decided to go by train.

I took the night train from Würzburg to Ljubljana, which allowed me to save two nights at the hotel. I usually fly to meetings and had never travelled on a night train in my life, so I was very excited about this new experience. As the train got stuck 100 km away from Ljubljana for 4 hours, I enjoyed some extra hours of sleep. I also slept away the two-hour delay on the trip back, and woke up right near Munich.

I did not stay at the conference hotel. By booking a single room for two nights at a three-star hotel, I not only saved €80 per night, but also used the 15-minute walk for additional sightseeing along the beautiful river promenade. I went on the guided walking tour and had dinner in the Poet Presern room at the Restaurant Sestica. However, I resisted the temptation of the banquet: "Why spend money to 'see'

[1] AR: AMWA Workshops have a pre-workshop assignment, but no post-workshop assignment .The accent is clearly on the needs of those working in North America. Advanced workshops are open only to those who have earned AMWA core certificates or have a minimum of 5 years of experience in the topic covered by the workshop (parallel foundation and advanced certification is possible with EMWA). Each AMWA registrant may take a maximum of 3 credit workshops per conference, 2 of which can be advanced workshops (with EMWA, 4 can be taken per conference, with no restriction on the type).

Cost of attending the Ljubljana Conference

Table 1 Cost of attending 28th EMWA Conference, Ljubljana, Slovenia, May 2009

Cost item	€[a]									
	Mary		Almudena		Neil		Diana		Ingrid	
	England		Spain		England		Germany		Sweden	
Travel	Taxi/train to + from Stansted airport, flight, taxi share to LJ, taxi from LJ, hold luggage charge	370	Subway to + from Madrid airport, flight, shuttle to and from LJ airport	290	Shuttle to Stansted airport, flight, shuttle to + from LJ, hold luggage charge, train home	260	Train to + from LJ, couchette, taxi in LJ	125	Bus to + from Stockholm airport, flight, taxi to + from LJ airport	400
Accommodation	Not CH, 4 nights	255	Not CH, 4 nights	420	CHL, 4 nights	450	Not CH, 2 nights	150	CH, 4 nights	625
Conference and workshops[b]	4 F	1090	3 A	1180	4 F, 2 A	1420	4 F (1 UA)	1045	4 A, 3 S	1620
Meals and refreshments	Did not attend CB	85	Did not attend CB	80	Attended CB	120	Did not attend CB	30	Attended CB	110
Social events	None	0	None	0	2 events	80	2 events	45	2 events	145
Total	**1800**		**1970**		**2330**		**1395**		**2900**	

[a] Amounts are rounded to the nearest €5.
[b] Includes the registration fee of €550 paid by all.
LJ = Ljubljana; CH = conference hotel; CHL = less expensive branch of conference hotel; F = foundation; A = advanced; UA = under assessment; S = seminar; CB = conference banquet

all those delicious dishes that you are not allowed to eat while you are on a diet?", I thought.

I spent three days (May 27–29) in Ljubljana and attended four workshops. Three of them were very good, but the fourth was rather disappointing. I raised my 'yes/no' cards during the annual general meeting, although I unfortunately did not have the time to read the last report with the attention it deserved. I attended the freelance business forum led by Alistair Reeves and Sam Hamilton, where some new ideas on how to better achieve our goals as freelancers were suggested. All in all, I spent approx. €1,400 on the conference. If I had taken the Lufthansa flight and had stayed at the conference hotel for 3 days, I would have paid approx. €2,300, which is a high sum for freelancers.

Does EMWA offer good value for money? I think the registration fee is high, but the price for foundation workshops is reasonable, for instance in comparison with offers from a private academy in Germany that charges €800 for one workshop of 8 hours. The EMWA conference offers a unique opportunity to meet freelance medical writers from all over Europe and overseas, to establish new contacts with potential clients from the pharmaceutical industry and the contract research organisation environment, and to build your own network. For these reasons, as well as for the high-quality training offered, it is beyond doubt worth attending. Therefore, I look forward to continuing to widen my network in November 2009 in Frankfurt, where I intend to complete the credits required for obtaining my foundation EPDP certificate.

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My conference expense account started ticking on January 30 when the spring conference registration opened. Since I started attending EMWA conferences in 2007, I've opted for an all-inclusive approach and I decided to follow that approach for the Ljubljana meeting as well. That meant registering for four workshops, three seminars and three social events with the choice of workshops based on interest rather than credits, even though I'm aiming for a certificate. The workshops that particularly appealed to me at this conference were all on the advanced level, so I incurred the maximum workshop cost. I also signed up for a number of free-of-charge events: the Annual General Meeting, the Freelance Business Forum, plenary lectures, and the Welcome Buffet. A full educational and social schedule indeed!

In early February, I made arrangements for transportation and accommodation. I booked a reasonably priced air ticket on the Internet and for convenience I decided to stay at the conference hotel. I had e-mail correspondence with the hotel and booked a room at the Grand Union Executive. I also arranged for a taxi pick-up at Brnik Airport. After all these registrations and reservations, my bank account was slightly strained, but it recovered after a couple of transfer payments. With such an extensive schedule, at least I knew

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>>> Cost of attending the Ljubljana Conference

that I wouldn't have the time to spend more money in Ljubljana.

March and April passed. In May I busied myself with the pre-workshop assignments. On May 26, I boarded the airport coach, which stops one block from where I live, and at Arlanda airport I got on a direct flight to Ljubljana. Once there I had five wonderful and intense days at the conference with interesting workshops and seminars, enjoyable social activities, stimulating meetings with old and new friends and colleagues, some minor food shopping at the market (I managed to squeeze it in!), and all this in a lovely and picturesque setting.

I think EMWA combines the best of two worlds: training tailored to the needs of medical writers and great networking opportunities. With this in mind and considering comparable educational costs in Sweden (between €400 and €900 a day), I definitely think that the spring conference offered good value for money. It certainly made an imprint on my bank account, but I got 'bang for the buck'! I'll be going to EMWA events in the future and, my financial situation permitting, I'll continue on the all-inclusive track. As I am an early planner, I'm eagerly awaiting the information about the autumn conference in Frankfurt. See you there!

Suggestions for cost reduction that the EC might consider

- A 'no reception, no meal' option to keep registration costs down.
- Relaxation of the rules for the EPDP certificates so that they can be completed in a shorter time.
- Negotiation of cheaper conference rates at cheaper hotels than the conference hotel.
- Sponsorship of workshops.

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Confused about open access?

Peter Suber has just published an informative article titled 'A field guide to misunderstandings about open access'[1] in which he sets out and explains 25 misunderstandings about open access. One of the most common misunderstandings even has a name 'gold fever': to overlook green open access, which is open access through repositories. Gold open access is open access through journals, regardless of the journal's business model. Other misunderstandings relate to a view that top quality research is not published in open access journals or that they skimp on the peer review process or that all open access journals charge publication fees.

1 http://www.earlham.edu/~peters/fos/newsletter/04-02-09.htm

From ghostwriters to ghost journals

Testimony given in an action brought by a patient against Merck in Australia revealed that Merck had paid Elsevier to print several issues of a journal which they titled The *Australasian Journal of Bone and Joint Medicine*. The journal, which was apparently produced for advertising purposes, contained articles favourable to Merck products and closely resembled a peer review journal. Its pages contained no indication of its association with Merck (*The Scientist* News Blog at http://www.the-scientist.com/blog/print/55671/).

Following an internal review Elsevier has announced its intention to provide guidelines for its pharmaceutical services divisions when producing reprints, article compilations or custom publications on behalf of pharmaceutical companies.

Conflicts of interests

Conflicts of interest have been in the news over recent months. The nosiest of the news has doubtless been *JAMA*'s run in with Jonathan Leo [1] who wrote a letter to the *BMJ* [2] about an undisclosed financial conflict and omission in a paper published in *JAMA* to state that psychosocial intervention was as effective as taking the drug. The somewhat unfriendly reaction from *JAMA* followed by the edict that those who raise such issues with the journal's editors in future are to keep mum until the journal has completed its own investigations [3] have for some been hard to reconcile with its reputation as a flagship of publication ethics.

Then there was the case that questioned intellectual conflicts of interest. If you make an independent analysis of a drug does this mean that you have an intellectual bias that precludes you from sitting on an advisory panel for the FDA? This was the point raised by Lilly when they telephoned the FDA. Days later Sanjay Kaul was told by the FDA that his invitation to sit on a panel to discuss Lilly's drug prasugrel had been rescinded. Heart*wire* has published a roundup of these cases and asked various opinion leaders for their views [4]. The conclusion that Heart*wire* came to was that although hardworking physicians and researchers are drowning in conflict of interest paperwork the only way forward is ever-more disclosure.

1. For Jonathan Leo's perspective see http://online.wsj.com/public/resources/documents/leo_statement_for_WSJ.htm
2. For the BMJ's perspective see Hopkins Tanne J. *JAMA's* new rule on whistleblowers' silence during investigation creates controversy. 2009;338:790
3. For JAMA's perspective see http://jama.ama.assn.org/misc/jed90012pap_E1_E3.pdf
4. http://www.theheart.org/article/963203.do

A week in the life of ... Linda Liem

by Linda Liem

If I had to describe a typical week in my life as a freelancer a year ago, it would have been much easier than it is now. Last year I really had something like a regular week, so let's start there.

It's one year after I started working as a freelance medical writer and in that time I've built a little business with a healthy load of repeat clients, several new clients that were referred to me and a few leads to new clients. My two daughters, Karina aged 2 and Cinta aged 7, are doing fine in the nursery and at school and the afterschool playgroup, so I can spend about 30–32 hours a week on my freelance activities.

My typical regular week

Monday. Normally, I would start on Monday morning by planning and organizing my week. To stay organised, I have a workbook that I use for my ToDo lists and a stack of storage bins, marked "Action needed", "Pending" and "File" where I keep all my project files. Also, I mark all e-mail messages that need action. Thus, I start my week by going through all these filing systems and checking my planner against all action items. Although this may cost me some time, it does save me the worry of potentially missing anything important and resets my mind in working mode. Since I only have a short afternoon today, I usually use the rest of the day for all those little tasks that I've found during my planning session. This may include acquisition, making follow-up telephone calls or writing e-mails, doing administrative tasks or scanning pharmaceutical newsletters to find interesting news for a pharmaceutical newsletter that I'm editing.

At 2.45 PM, my working day is temporarily suspended and I get my bicycle to pick up Cinta from school, 10 minutes from our house. We go home to sit down a bit, but at 4.20 PM I have to take her to her dancing class. During her class, I cycle like mad to the nursery, approximately 15 minutes away from us, where I pick up Karina. We cycle back, pick up her sister again and can go back home. After the kids have gone to bed, I pick up my work again for an hour of two before finally calling it a day.

Wednesday. Today it's kids time. Only in very urgent emergency situations will I try to find a babysitter and sit down at my desk again. This happens about once every two months, but luckily my parents and mother-in-law are always happy to come over, if they are available. If not, my poor husband has to rearrange his schedule to help me out.

Tuesday, Thursday and Friday. The children go to the nursery and afterschool playgroup on these days, so I have a whole working day waiting for me. Although I prefer to work on one project at a time, I usually have several projects active, since some are being reviewed by the client. Ideally, I can use these days to work according to planning. However, as life is full of surprises, this rarely happens. Sometimes a client is late with comments, but expects me to keep to the deadline. Maybe another client calls with an urgent project that needed to be finished yesterday. I might get a call from the nursery or school that I have to pick up a sick child. In those cases, I pick up my trusty planner again to see if I can shift something or when I can make up for the time lost. This tends to be in the evening after the kids have gone to bed. So, I savour the evenings that I don't have to catch up on anything, pour myself a glass of wine, and try to let my work rest until the next day.

Weekend. The weekend is the time to recuperate and spend time with my family. Only in very urgent emergency situations will I try to find a babysitter and sit down at my desk again. For the rest, see Wednesday.

A big change

Seeing my successful transition to a freelance medical writer, my husband was also longing for a change. After many considerations, we decided to move to Norway after he managed to find a new job there. Thus, I notified my clients that I was moving to another country and that I would suspend my writing activities during the summer months, but that I would be available again in September for work—with a view of the fjords. Luckily, I could say goodbye to the Netherlands knowing that I had a few small projects waiting for me in September.

Moving house can be pretty drastic, but moving country is really radical. We had to find our way through an administrative jungle both in the Netherlands and in Norway, find our bearings in a new society, learn a new language and help the children adjust. I had to close my company in the Netherlands and open it again in Norway. There are so many things that need to be done and that we need to find out. Since my husband is working full time, most of this is falling on my shoulders. In addition, I blog about our adventures here to keep family and friends informed, I look after the children and teach Dutch to Cinta (the kids have to be able to communicate with their family, after all). In Norway, foreign children have the right to receive lessons

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>>> A week in the life of … Linda Liem

in their mother tongue as long as they need extra Norwegian lessons. Since we're the only Dutch people in our village, the school agreed to appoint me as her Dutch teacher for 2 hours in the week. To be able to cope with all of this, I drastically reduced my freelance activities to about 10–15 hours a week. Unfortunately, but not unexpectedly, this was not so difficult, because some clients became very quiet for some reason. Luckily, a few clients stayed loyal and kept me going, albeit somewhat erratically. The children have settled in really well and it even seems that I'm picking up my pace again! So, let's see how I'm spending my week now.

My current typical week

Monday and Friday. I wait until Cinta is on the school bus and take Karina to the nursery. When I come home, I make myself a thermos full of tea, grab a mug and head for my desk. I have from 9.00 AM until 2.30 PM before Cinta comes home again. As before, I still start the week by going through my files and checking my planner. If I have a project active, I use my time for that. If not, I do other tasks that are usually not work-related. After Cinta is home, I help her with her homework. When we're finished she can play, while I pick up the other one around 4.00 PM. At 4.30 PM, my husband comes home (a working day in Norway is only 7 hours) and I can prepare dinner. After dinner, I take Cinta to football training and an hour later, I pick her up again. I might work for a few hours after the kids have gone to bed. Wine is more expensive and harder to find here, so I save that for the weekends.

Tuesday. I wait until Cinta is on the school bus and take Karina to the nursery. When I come home, I make myself a thermos full of tea, grab a mug and head for my desk. This is my regular day for my Norwegian language homework and for preparation of the Dutch lessons of this week. However, if I have a writing project, I work on that and postpone the homework to the evening. At 1.25 PM, I go to school and teach Dutch to Cinta. After that, we pick up some groceries and drive home where she can do her homework. Around 4.00 PM, I pick up Karina and prepare dinner. When my husband is home we can eat and after that we have some time together before the kids go to bed. I might work for a few hours after the kids have gone to bed.

Wednesday. Today the kids are free and at home. It's a bit far for my parents or my mother-in-law to come over, so I don't work today. In the summer, we meet with other mothers and their children for a little hike and lunch outdoors. I might work for a few hours after the kids have gone to bed, but then again, I might also go to the ladies gym evening or the local ladies club, which is once a month, where we eat something, talk (well, I mainly listen) and have a nice evening.

Thursday. I wait until Cinta is on the school bus and take Karina to the nursery. Then I drive on to the Norwegian language class that lasts all morning. Occasionally though, I have to skip class because I need the time for a writing project. After that, I pick up some groceries and drive to school for another hour of Dutch teaching. When we're finished, we go home and I help Cinta with her homework. Around 4.00 PM, I pick up Karina and prepare dinner. When my husband is home we can eat and after that we have some time together before the kids go to bed. I might work for a few hours after the kids have gone to bed.

View from our house

Weekend. The weekend is the time to spend with the family. I mainly use the evenings as my backup time to get work done and try to keep the weekend as free as possible, so we can do other things, e.g. go out into countryside, that is all around us (see photo above). When I don't have to catch up on anything, I pour myself a glass of wine and enjoy the weekend.

Next year?

As a friend told me, it doesn't appear that we have become less busy, but rather that we now spend more time on things we enjoy doing. Working as a freelancer has enabled me to be much more flexible than before, with all its ups and downs. e.g. being able to attend school performances, but also working till deep in the night. Although I'm spending much more time on other things now, I still have a lifeline to my freelance activities, which is something that would have been impossible with a regular job. Right now, I'm trying to figure out what direction I'd like to take, so I really couldn't say what my typical week next year will look like. However, I have learnt to deal with uncertainty and know what I am capable of, so I'm confidently looking forward to whatever the future may bring.

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Ghost Coast ethics

In the United States, institutional review boards (IRBs) can be run as commercial companies paid by pharma companies. One company has recently been temporarily suspended by the Food and Drug Administration (FDA) for approving a 'ghost' clinical trial[1]. The FDA employed undercover investigators to prepare a sham medical study plan which they submitted to three companies. Two refused to approve the plan but the third, Coast, approved the plan. Coast have been required by the FDA to refrain from approving new studies or enrolling patients in their 300 ongoing studies until they produce evidence that they are putting proper operating procedures in place.

[1] http://www.nytimes.com/2009/04/15/business/15device.html

Comment from Adam Jacobs

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The US IRBs are analogous to, but not the same as, European Research Ethics Committees (RECs). As a member of a REC, I sympathise with Coast. It is not the job of a REC to do any kind of audit. Our job is to determine whether the study, as presented to us, is ethical. Of course if we suspected that the trial was made up, we would ask some tough questions and maybe refer the case to an appropriate authority, so if the trial was obviously implausible, I hope we would spot it. But the general principle is that we have to take on trust what the investigators tell us.

List of medical writing articles written by EMWA members in other journals

In the EMWA Members Satisfaction Survey conducted last year a request was made for *TWS* to publish a list of medical writing articles written by EMWA members in other journals. In the last issue of *TWS* members were invited to send citations to articles relevant to medical writing/biomedical publication or on topics of general interest to medical writers which they had published in 2008 and 2009 [*TWS* 18(1)43]. The response to this call was not huge as seen from the following which is a list in alphabetical order of the citations received to date with the names of the EMWA member written in bold. The list has also been published on the EMWA website (www.emwa.org). Members are entreated to send citations to their articles for publication in future issues of *TWS.* These citations will also be added to the list retained on the EMWA website.

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Vital signs

Dear *TWS*

I really enjoyed reading Gabi Berghammer's article on English as the lingua franca of science published in December's issue of *TWS* (17(4): 213-219).

There is something I'd like to say, though. In the section 'Are English-speaking scientists at a competitive advantage?', Gabi refers to NNES (non-native English speaking scientists) and she cites figures from Thomson ISI in relation to the contribution of NNES to 'international' science. Of course, those NNES that do contribute a lot to international science—and are not that disadvantaged in comparison to NES—are those from the developed world, such as Switzerland, Denmark, etc. (see Fig. 2 of that article). Let's not forget that for these scientists the tasks of learning English and writing SOUND scientific papers are much easier—for many reasons—than it is for those that live and work in developing/peripheral countries (the so-called off-networked scientists) for whom learning English is not such an easy matter at all. I would however like to stress, as I express in my paper on scientific multilingualism [1], that I strongly believe, as Gabi argues, that more funds should be allotted to the translation of scientific research papers. For those interested in these issues, I highly recommend Isaac CH Fung's paper [2]. Sedef Uzuner has also written an excellent review on the topic [3]. ■

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Dear *TWS*

I was interested to read Alistair Reeves' short piece on whether to use the plural form for "More than €4 million were invested..." [1]. Although I agree with his use of the plural, Alistair then went on to write 'euros'. The plural 'euros' is used in French and Spanish, but in English the plural is, in fact, 'euro', the same as the Italian, Swedish, Dutch and German plural (in German with a capital 'E', i.e. 'Euro')[2]. ■

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Author's reply

Thanks to Richard Clark for putting me right on the 'correct' plural for euro. An official body may well have decided how we should pluralise euro in 'community legislative acts', but since when has an official body decided on how we speak and write English in other fields? We have said pounds for long enough, so why the difference for the euro? The singular use of the word pound together with a number more than 1 is dialectic in the area I come from (North-East of England: It cost me twelve pound fifty), and we didn't need an administrative body to tell us that twelve pounds fifty is the accepted, non-dialectic use. It will be interesting to see what happens when the UK adopts the euro (if ever, of course)—I suspect that the plural 's' will rapidly establish itself, or maybe the 's' will become the dialectic form. British guests who recently visited us said: "We haven't managed to get any euros yet". The Official Treasury Euro Resource website in the UK [1] uses both plurals ("These case studies show how real firms have benefited from being able to trade in euros."), otherwise elegantly avoiding the plural by using 'the euro'. In a speech in 2001 [2], the Irish Minister of Finance said: "For the … programming periods, we have received some 11 billion Euros in Structural and Cohesion Funds"; and another Irish minister said in a speech in 2009 [3]: "This means that 1 out of every 2 euros of public sector pay is being borrowed". Both latter quotes are from an official government website. It therefore also seems that capitalisation of the euro is not restricted to German.

But at least none used the plural 'euroes'! ■

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Dear *TWS*

I enjoyed reading the article by Alison McIntosh on the 'broad-spectrum medical writer' in the March issue of *TWS*, probably because it reflects the situation I find myself in as a self-employed medical writer and translator. I also found the response by Mary Jane Lunsford remarkable, suggesting that medical writers strictly confining themselves to regulatory writing are *more* than medical writers–they are 'experts'.

Many freelancers started out their careers as medical writers in a regulatory environment, writing submission documents, clinical study reports, protocols, and the like. They did not mysteriously appear on the medical writing scene out of the blue. However, leaving behind "line managers who determine whether you can write certain types of documents", as Alison aptly describes the process of becoming a self-employed writer, the work of freelancers is likely to become more multi-faceted as clients ask them to take on a wider diversity of projects.

Many of us have long-standing relationships with our clients and know their core business and requirements. It's just that the spectrum of texts we get to work on is wider. Why would the broad-spectrum medical writer not be able to write top-quality regulatory documents for one client and linguistically more challenging promotional material for another? Broadening one's areas of activity and linguistic competences is not only a continuous challenge, it also provides exciting insight into new aspects along a product's life cycle–and it is great fun.

I do not think it serves the image of our profession as medical writers to try to drive a wedge between 'medical writers' and 'experts'. Yet, this is what happens when speaking of "freelancers who can contribute […] as an expert, not just as a medical writer." What is the profile, I wonder, of someone who is 'just a medical writer'? ■

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Linguistics corner

In the 1980s the first issue of a linguistic journal entirely devoted to the teaching of medical English and to publishing the results of research conducted on medical discourse was published at the University of Kuwait. It was called *The EMP* (English for Medical Purposes) *Newsletter,* and was edited by a very enthusiastic British linguist, Nigel Bruce, who was then teaching EMP at Kuwait University. Needless to say, the newsletter was very warmly and positively received by all the applied linguists and English language practitioners who, one way or another, were involved in EMP.

Very sadly, though, Operation Desert Storm wiped out Nigel's EMP work in the Arab world, and the *EMP Newsletter* ceased being published. As a consequence, those interested in and conducting research on medical discourse had to look for new outlets for their publications. They thus started sending their papers for publication to applied linguistics journals, such as *English for Specific Purposes, the Journal of English for Academic Purposes, LSP and Professional Communication, IBÉRICA* (the official journal of the European Association of Languages for Specific Purposes), *Communication and Medicine, The ESPecialist, Hermés, Asp* (Anglais de Spécialité), *Text, Discourse Studies, Interface*, etc.

With the very timely birth of the special section on translation in *TWS*, I thought that a 'special corner' could be dedicated as well to summarizing the results of applied linguistics research that deal with medical discourse. I submitted that idea of a 'Linguistic Corner' to the editor, who wholeheartedly embraced the idea under one condition, though: that I be the section editor!! More work… but I accepted!

The aim of the 'Linguistic Corner' will be to publish the abstracts of papers related to oral or written medical discourse that I believe could be of interest to *TWS* readership. Being a fervent proponent of scientific multilingualism, my intention is to mention papers written not only in English, but also in other languages (e.g., Spanish, French, German). In the case of abstracts published in a language other than English, I'll contact the authors and ask them to provide an English-language abstract of their work.

I hope you will all enjoy the new Section as much as I do the translation section. ■

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Abstract 1

Charpy J-P Milieux professionnels et FASP médicale: de l'autre côté du miroir, ASp (Anglais de Spécialité), la revue du GERAS n°45-46, 2004, pp. 61-79.

GERAS: Groupe de recherche et d'etudes en Anglais de Spécialité ASp est la revue de ce Groupe et est publié par l'Université de Bordeaux (France)

In his paper, Jean Pierre Charby highlights and analyses the relationship between the medical profession and "medically-based fiction". Medical thrillers belong to the genre described by M. Petit in 1999 as "professionally-based fiction" (PBF)-namely, works of popular fiction resting on the experience of professionals. They are reputed to be a pretty accurate reflection of the world of medicine. The diachronic study of medical thrillers is a recent field of research within the genre of PFB, and it is generally agreed that the novels of a small group of American writers (R. Cook, M. Palmer, T. Gerritsen) form the core of medically-based fiction.

This specialised genre related to PFB is characterised by specific features, both external (in the paratext, i. e. on the fringes of the text) and internal (within the text), which are clearly identifiable in the paratextual, textual, narrative and linguistic fabric of medical novels of suspense. The author proposes to show that, beneath the surface and beyond the conventional clichés of the editorial paratext, medical thrillers integrate the specific nature of the discourse and practices of the medical community, and reflect the sociocultural preoccupations and the ethical standards of the medical profession.

In order to better understand the links between professional background and fiction, the author presents the answers to a questionnaire submitted to four doctors-turned-novelists (R. Cook, M. Palmer, L. Ruth Robinson, T. Gerritsen). The responses indicate that medical thrillers are both

convincing and entertaining, which underlines the pedagogical interest of medically based fiction for the teaching of English for specific purposes. ■

Gained in translation

Communication at the multilingual crossroads

Sometimes, translation takes place not between different languages but between varieties of one and the same language. Thus, a patient calling up her doctor to find out about the results of her autopsy is most likely wanting to know about her biopsy results. Or a patient planning a trip to Africa may ask to be vaccinated for fear of being stung by a mephistopheles when what he actually means is anopheles. For translators, interpreters, and healthcare professionals working in settings involving Spanish as one of their working languages, help has arrived. Fernando Navarro, physician and medical translator from Salamanca, Spain, has compiled an amazing collection of medical malapropisms–terms occasionally misspoken by patients–and has translated them into proper medical terms.

At other times, translation does not take place at all–a potential cause of serious harm, as the series of case reports on both missing translations and mistranslations shows. In human communication, fortunately, there's more hits than misses. But it's the misses that remind us that communication is never fail-safe.

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Patientspeak: A Spanish-English glossary of lay medical malapropisms–Part 1

by Fernando A. Navarro

Medical language is so extraordinarily complex that not even physicians always use it properly. It's not unusual, for instance, for specialists with many years of experience to misspell certain technical terms (e.g., *hydroxycobalamin* instead of *hydroxocobalamin*, *Proprionibacterium* instead of *Propionibacterium*, *antibrachium* instead of *antebrachium*, *cachectic* instead of *cachectic*, *hypercapnea* instead of *hypercapnia*, *turalemia* instead of *tularemia*) or to confound similar words or notions (e.g., *keratocyte* and *keratinocyte*, *molality* and *molarity*, *creatinine* and *creatine*, *thyroxine* and *tyrosine*, *cystine* and *cysteine*).

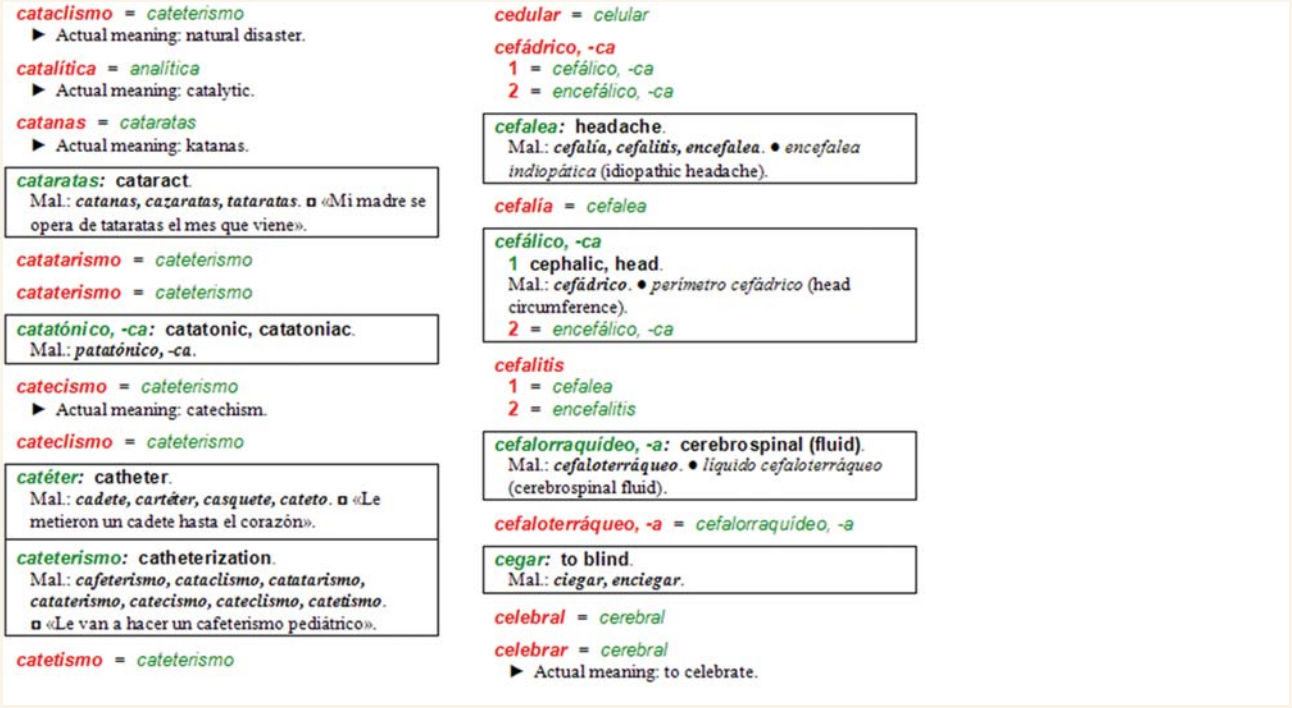
With even doctors often misusing their own specialized language, it is hardly surprising that malapropisms should be common among patients with scant formal education when attempting to pronounce technical terms they have never seen in writing and only heard a time or two from their GP. Such malapropisms do not, however, normally pose any particular difficulty in conversations between native speakers of the same language. For an experienced English-speaking physician, expressions such as *very coarse veins*, *ox vomit*, *electric lights*, *brown kitties*, *blood vile*, *Queen Ann* or *curly B lines*, for instance, can be readily identified with what the patient actually intended to say, i.e., *varicose veins*, *nux vomica*, *electrolytes*, *bronchitis*, *blood vial*, *quinine* o *Kerley B lines*, respectively.

The situation is much more complex, however, when two languages are involved, such as in interpretation services in hospitals, emergency wards, healthcare facilities and surgeries. English-speaking physicians or interpreters may find it tremendously difficult to understand what Spanish-speaking patients mean by phrases such as *espina del rosal*, *dolor asiático*, *glóbulos vaginales*, *pólipo frenético* or *tiritas radiactivas.* The traditional absence of such malapropisms in dictionaries, lexicons or other typical reference materials, precisely because they are regarded to be incorrect, compounds that difficulty.

Such, at least, has been the situation to date. Now, however, *TWS* readers can draw from the extensive Spanish-English glossary, the first part covering the letters A–C has now been made available on the EMWA website at www.emwa.org/Journal-public.html. The entire glossary, which will gradually be completed in upcoming issues of *TWS*, will list nearly four thousand medical malapropisms frequently used by Spanish-speaking patients. Very simply structured, the glossary contains two types of terms, lemmata or headwords. A glimpse of the glossary is provided in Figure 1.

The **green headwords** or standard entries, set in boxes, that form the backbone of the glossary are correct terms or technical words often mispronounced by patients. Each headword in Spanish is followed by the usual English equivalent and, on a separate line preceded by the abbreviation *Mal.*, a list of the most common mispronunciations of the term in Spanish. Certain selected headword entries also contain the symbol ◘, followed by a Spanish phrase illus-

Patientspeak: A Spanish-English glossary of lay medical malapropisms



cataclismo = *cateterismo*
► Actual meaning: natural disaster.

catalítica = *analítica*
► Actual meaning: catalytic.

catanas = *cataratas*
► Actual meaning: katanas.

cataratas: cataract.
Mal.: *catanas, cazaratas, tataratas.* ◘ «Mi madre se opera de tataratas el mes que viene».

catatarismo = *cateterismo*

cateterismo = *cateterismo*

catatónico, -ca: catatonic, catatoniac.
Mal.: *patatónico, -ca.*

catecismo = *cateterismo*
► Actual meaning: catechism.

cateclismo = *cateterismo*

catéter: catheter.
Mal.: *cadete, cartéter, casquete, cateto.* ◘ «Le metieron un cadete hasta el corazón».

cateterismo: catheterization.
Mal.: *cafeterismo, cataclismo, catatarismo, cateterismo, catecismo, cateclismo, catetismo.*
◘ «Le van a hacer un cafeterismo pediátrico».

catetismo = *cateterismo*

cedular = *celular*

cefádrico, -ca
1 = *cefálico, -ca*
2 = *encefálico, -ca*

cefalea: headache.
Mal.: *cefalía, cefalitis, encefalea.* ● *encefalea indiopática* (idiopathic headache).

cefalía = *cefalea*

cefálico, -ca
1 cephalic, head.
Mal.: *cefádrico.* ● *perímetro cefádrico* (head circumference).
2 = *encefálico, -ca*

cefalitis
1 = *cefalea*
2 = *encefalitis*

cefalorraquídeo, -a: cerebrospinal (fluid).
Mal.: *cefaloterráqueo.* ● *líquido cefaloterráqueo* (cerebrospinal fluid).

cefaloterráqueo, -a = *cefalorraquídeo, -a*

cegar: to blind.
Mal.: *ciegar, enciegar.*

celebral = *cerebral*

celebrar = *cerebral*
► Actual meaning: to celebrate.

Figure 1 Excerpt from the Spanish-English glossary of lay medical malapropisms
For a complete list, please go to www.emwa.org/Journal-public.html.

trating the use and meaning of the word in a broader context, along with one or several expressions, preceded by a ●, with examples of the malapropisms listed in the entry.

If a green headword is itself sometimes misused in medical contexts, the correct definition is followed by the term or terms for which it is mistaken, duly numbered with red numerals. Such is the case, for instance, of the word *laxante*, which patients may use properly to mean *laxative*, or as a malapropism for *lactante* (infant).

The **red headwords**, which account for the better part of the glossary, are medical malapropisms whose entries refer the reader directly to the correct Spanish term (where the English translation can be found): e.g., *oxinófilo* = *eosinófilo*. Many of these malapropisms are the result of widespread distortions, mispronunciations or mistaken association with technical or general terms with a similar spelling, phonetics or meaning, resulting in words either non-existent or nonsensical in Spanish. Others, by contrast, concur with words that do exist in the language with a meaning of their own; in such cases, the definition is not numbered, but given in a separate note preceded by a ►. This same symbol is used to flag notes on usage or other relevant remarks. Examples would be the word *escarnio*, which actually means 'derision' or 'ridicule', but is a common medical malapropism for *escáner* (CT scan); *soltera* (single woman), in turn, may be heard as a malapropism for *solitaria* (pork tapeworm).

In addition to the above symbols, the glossary includes a few abbreviations for parts of speech or similar (*adj.*, adjective; *m.*, masculine noun; *f.*, feminine noun; *sgl.*, singular; *pl.*, plural) which are used when a distinction must be drawn between different meanings of the same word, e.g.: when used as an adjective, *profiláctico* means 'prophylactic' or 'preventive', while as a noun the same word means 'condom'. A few other abbreviations whose meaning is more obvious may also be found in certain entries: *abbr.*, abbreviation; *coll.*, colloquial term; *US*, lexical or spelling variation used in America.

Inasmuch as patients' use of medical jargon is primarily oral, this glossary will prove to be of particular assistance (I hope) for healthcare interpreters. But it may also be helpful for translators confronted with handwritten notes or patient diaries composed by people with no medical training, and perhaps more generally, for anyone drawn to the study of medical language and its usage.

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Acknowledgement of translators

Translators are rarely mentioned in the acknowledgements sections of biomedical articles. An exception is the English edition of *Deutsches Arzteblatt International*, the Journal of the German Medical Association, which always names translators. For examples see http://www.aerzteblatt.de/int/article.asp?src=heft&id=60459 and http://www.aerzteblatt.de/int/article.asp?src=heft&id=60390.

Hits and misses: Translating in a world of error

By Gabi Berghammer

Many critics, no defenders,
translators have but two regrets:
when we hit, no one remembers,
when we miss, no one forgets.
Anonymous

Whether pharmaceutical drug, medical device, or software application–translation of the documentation shipping with a product is often seen as merely yet another duty to be fulfilled before a product can be introduced to a particular market. For the clinician, patient, or software user at the far end of the manufacturing chain, a native-language document may be the only door providing access to the features of a drug or product. European lawmakers have taken account of this by stipulating that products manufactured in the EU have by law to be supplied with instructions translated into the respective markets' official languages. On the international or diplomatic stage, failure to show foreign-language linguistic sensitivity can cause anything from political distress–to a smile. Here's a couple of misses that have hit the press.

When babel meets medicine

Cemented or uncemented: mistranslation or missing translation?

The importance of translated product labelling is highlighted by a much publicised case from Berlin, where 47 patients having undergone knee replacement in 2006 and 2007 had to undergo re-operation because physicians had implanted the knee prostheses without applying the necessary bone cement [1].

The manufacturer had shipped the device without German instructions for use. As a result, prostheses designed to be implanted using bone cement were mistaken for prostheses not requiring cementing. Because the English phrase 'non-modular cemented' on the package had been taken to mean 'not requiring cementing', hospital staff had sorted the cemented prostheses into the shelf for cement-free prostheses.

The error was not noticed until the US manufacturer started shipping the product with red and blue German-language stickers on the outer carton. The problem with improperly implanted prostheses is that they fail to attach firmly, causing them to loosen and lead to discomfort or pain.

Missing translation leading to deaths due to x-ray overdose

A similar incident is reported from France, where an error in translating English instructions for the use of software is thought to have led to the death of 3 patients following an overdose of x-ray radiation at a hospital in Lorraine [2].

The errors occurred in the treatment of 23 men suffering from prostate cancer. The deaths of three of the four patients who passed away were linked to the error. According to the government report, the other 19 patients suffered complications of varying degrees as a result of the overdose.

It looks as if there was no French version of an English manual for an x-ray machine available, and the staff made an error by misusing the software–presumably the software that controlled the dosage. As a result, 23 patients received too much radiation, and three died. Exactly where the translation error took place is not clear.

Correct product labelling–as important a safety issue as sterilization

Correct and readily understandable instructions for drugs or medical devices may be as crucial a safety issue as sterilization. For products marketed world-wide, this places enormous demands on translation providers, often having to deliver translations into up to 22 or more different languages.

Yet, translation may itself be a source of error or confusion. Crimson Life Sciences recently presented the results of a 2-year audit survey carried out to measure the risk associated with the translation of product labels in the medical and in vitro diagnostic device industries [3]. Their analysis, covering 21 languages, dozens of audits, and more than a million translated words, found that the rate of serious translation errors–errors that may result in patient harm–was 400% higher than the serious-error rate associated with the current industry best practice.

Best practice in this survey was defined by Crimson's translation risk management process. It is based on the only standard so far available that deals with translation quality (i.e., the SAE J2450 originating in the automotive industry) and a proprietary QA methodology, purportedly reducing the risk of serious translation errors by over 60% versus standard processes.

Postponing marketing approval for poorly translated SPCs

Concerns regarding translation quality have also been voiced by the Danish Medicines Agency (DKMA), saying it had become so tired of poor translations of medicines instructions that it was threatening to postpone marketing approval for drugs. A 2007 statement by the DKMA said that the Agency had informed industry that they were not at all satisfied with the quality of the translations presented to them and that they would prepare to publish examples of bad translations on their web site [4]. This was indeed done, without, however, disclosing the companies or drugs in question.

"In some cases", the Agency said, "it is just a matter of poor language and awkward phrasing." In others, however, the translators completely changed the meaning of the text, something DKMA feared may affect patient safety.

To combat the problem, DKMA has told companies to use a "person qualified in Danish medical terminology". The medicines regulator also said that "From now on we intend to return proposed SPC translations to the applicant in case the quality is deemed substandard, i.e., if too many errors and mistranslations are found. Further processing to prepare for granting the marketing authorisation will be put on hold until an acceptable translation has been received."

Sport unites the world–if it weren't for those linguistic nuances...

While translation error in medicine can have grave consequences on patient health or delay marketing authorizations, it can cause serious disharmony in the international arena.

Translation error cost Cuba the use of their top pitchers

A translation error of the World Baseball Classic's rules cost the Cuban team the use of two of its top pitchers [5]. The Cuban team had received an English-Spanish courtesy translation of the tournament's rules. According to the translation, no reliever could pitch the day after throwing "mas que trienta"–more than 30–pitches. What the translation should have said is "treinta o mas"–30 or more. Pitch limits are designed primarily to protect valuable players under contract to major league teams.

Acting on these words, Cuba's manager withdrew two of his top pitchers from the game against Japan after throwing exactly 30 pitches, clearly because he wanted to have them available for next day's game against Mexico. It was only 3 hours before the game against Mexico that he found out that his stars were ineligible to pitch–even though he had been given incorrect information.

The removal of these two top relievers after exactly 30 pitches was immediately surprising, but tournament officials did not learn that Cuba had been misinformed until shortly before the Mexico match. An official pointed out that a note in the Spanish translation warned that this was not the official rules and that teams are supposed to refer to the official, English-language, rules when making a decision.

With the World Baseball Classic's whole purpose being to bring together teams speaking different languages, this incident may not exactly be poised to improving understanding between peoples and cultures.

Thank God the cold war's over...

photo: Sabine Gebele, taken at the Africa festival in Würzburg, Germany [6].

Hillary Clinton pushes the wrong button

It was supposed to be a cheerful reference to US Vice President Joe Biden's recent remark that the new US administration wanted to 'reset' ties with Russia after years of tension [7].

However, efforts to close the rift got off to an unfavourable start as US Secretary of State Hillary Clinton and Foreign Minister Sergei Lavrov met in Geneva earlier this year. Mrs Clinton presented to her Russian counterpart a mock 'reset' button as a gift, symbolising US hopes for better US-Russian relations.

Hillary Clinton assured Sergei Lavrov that her staff had "worked hard" to ensure the Russian translation on the reset button was accurate. According to a smiling Mr Lavrov, however, the word on the button, 'peregruzka', meant 'overloaded' or 'overcharged', rather than 'reset'.

Polish for policemen

Ireland's most careless driver of Polish descent

Finally, there are those cross-cultural gaffes which, luckily, don't do any harm–but are good for a chuckle.

Police in the Irish Republic finally managed to catch the country's most careless driver. He had been wanted from Cork to Cavan after amassing countless speeding tickets and parking fines [8]. However, every time the serial offender–a man of Polish descent and, thus, member of Ireland's second largest immigrant population–was stopped, he managed to evade justice by giving a different address.

Until, one day, his cover was blown. It was discovered that the man the entire Irish police corps had been looking for–a Mr Prawo Jazdy–wasn't exactly the sort of criminal they had suspected him to be. Prawo Jazdy was not the first and last name on the driving licence–Prawo Jazdy is Polish for 'driving licence'.

Finally noticing the error, police checked to see how many times officers had made this mistake. They found that the system had created Prawo Jazdy as a person with over 50 identities. The mistake was corrected immediately by circulating a memo throughout the Irish police force–who are now cognizant of a least two words of Polish.

The long and short of it

Don't save money on translations.

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‘Scientific’ writing

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