

EMWA

European
Medical Writers
Association

The *Write Stuff*

The Journal for European Medical Writers

Vol. 15, No. 4, 2006



‘Schweinerei’

EMWA Executive Committee*President:***Michelle Derbyshire**

MD Writing Services,
Herfststraat 25A,
B2400 Mol, Belgium.
Tel: +32 (0)14 322832, GSM: +32 (0) 486 245908
president@emwa.org

*Vice-President & Programme Manager:***Julia Forjanic Klapproth**

Trilogy Writing & Consulting GmbH
Paul-Ehrlich-Strasse 26
60596 Frankfurt am Main, Germany
Tel.: (+49) 69 255 39511, Fax.: (+49) 69 255 39499
vicepresident@emwa.org

*Immediate Past President:***Adam Jacobs**

Dianthus Medical Ltd
Lombard Business Park
8 Lombard Road
London, SW19 3TZ, UK
Tel: (+44) 20 8543 9229, Fax: (+44) 20 8543 9885
ipp@emwa.org

*Treasurer:***Wendy Kingdom**

1 Red House Road
East Brent, Highbridge
Somerset, TA9 4RX, UK
Tel: (+44) 1278 769 214, Fax: (+44) 1278 769 214
treasurer@emwa.org

*Secretary:***Julia Cooper**

PAREXEL International Ltd.
101-105 Oxford Road
Uxbridge, Middlesex, UB8 1LZ, UK
Tel: (+44) 1895 614 403, Fax: (+44) 1895 614 323
secretary@emwa.org

*Public Relations Officer:***Kari Skinningsrud**

Limwric as
Leiv Eirikssons gate 8
NO-2004 Lillestrøm, Norway
Tel: (+47) 63800448, Mobile: (+47) 41338765
pr@emwa.org

*Website Manager:***Shanida Nataraja**

Discovery London, Pembroke Building
Kensington Village
Avonmore Road
London W14 8DG, UK
Tel.: (+44) 207 173 4121, Fax.: (+44) 207 173 4001
webeditor@emwa.org

*Education Officer:***Virginia Watson**

Cardinal Health
Frankland Road, Blagrove
Swindon, Wiltshire, SN5 8YS, UK
Tel: +44 (0)1793 864108 (direct), Mobile: +44 (0)7976 399156
Fax: +44 (0)1793 613394
education@emwa.org

EMWA Head Office

Industriestrasse 31, CH-6300 Zug, Switzerland
Tel: (+41) 41 720 3306, Fax: (+41) 41 720 3308
info@emwa.org
EMWA website: www.emwa.org

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.

Articles or ideas should be submitted to the Editor-in-Chief (see below) or another member of the Editorial Board.

Subscriptions

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

- €35 within Europe
- €50 outside Europe

Instructions for contributors

- The **Write Stuff** typically publishes articles of 700–2800 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by email as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

Timelines

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

Advertising rates (in euros, €)

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

Behind the press

The Editorial Board	
Journal Editor	Elise Langdon-Neuner Baxter BioScience Wagramer Strasse 17-19 A-1220 Vienna, Austria Tel.: (+43) 1 20100 2067 Fax.: (+43) 1 20100 525 editor@emwa.org
Assistant Editor	Barry Drees
Copy editing	Judi Proctor Chris Priestley Julia Chamova Richard Clark Rosalie Rose Ursula Schoenberg
Columnists	Alistair Reeves Karen Shashok Alison McIntosh Diana Epstein Susanna Dodgson Joeyn Flauaus Dianthus team

Cover picture

Cover photograph from Nadia Meister (nadia.meister@inode.at)

You asked for it... you got it!



EMWA Annual Spring Conference 2007

plus a Focus on Medical Communications Today

The upcoming annual Spring conference is starting to take shape. The always superb selection of workshops from the **Professional Development Programme** will be offering:

- Foundation and advanced training in all aspects of medical writing.
- Workshops covering regulatory topics and fundamental medical writing skills.

In addition, the conference will have a **Medical Communications theme**. There will be plenary sessions, discussion panels and seminars to specifically explore hot topics in the world of communications today:

- Product Branding (with plenary session by Beverley Law from Dew Gibbons, London)
- Medical Journalism and the Press
- Science Communication
- Writing for Patients (with plenary session by Liz Woolf, Head of CancerHelp UK)

So block your calendars now and come to this conference... there will be **something for everybody!**

See you in Vienna 2007!

Julia Forjanic Klapproth
EMWA Vice President





From the editor's desk:

Cheating is a 'Schweinerei'

By Elise Langdon-Neuner

So, why are there lots of pigs on the cover of *TWS*? These cuddly toys introduce a thorny topic: cheating. People who cheat annoy those who don't. In German-speaking countries, those who don't cheat would most probably express their indignation on discovering the deeds of those who do as a 'Schweinerei'¹. The equivalent expression in English would be 'swinery' in its figurative context —long fallen into disuse.

No area of human endeavour is free from cheating, not even where seeking the truth is the maxim as it should be in science and medical writing. But to tackle the problem of cheating it is important to establish whether cheating is an intrinsic human characteristic, impossible to hinder in those prone to cheat, or whether external circumstances drive people to cheat. Opinions differ. Two authors, Vedran Katavic, a research integrity editor at a medical journal in Croatia and Miguel Roig, a cognitive psychologist working in New York, give their opinions in their articles in this issue of *TWS*. Both authors teach university students.

The case of the spotted mice illustrates the difficulty of identifying the reason why a person cheats. In one of the most blatant frauds of recent years Dr William Summerlin touched up skin grafts with a felt-tip pen to simulate dark skin on white mice. Why did he do it and what made him think he could get away with it? Summerlin claimed to have developed a procedure that overcame rejection of a skin graft. This brought hope for an end to the laborious process of transplanting pieces of a patient's own skin, which has to be done over a long period and makes the patient vulnerable to loss of body fluids and to infection. However scientists in other laboratories who attempted to repeat these experiments were unable to confirm the results. Eventually Summerlin was exposed with the help of some of his immediate co-workers. Peter Medawar, who won the Nobel Prize for his work on tissue transplantation, suggests that Summerlin might have been a 'bad apple' [1]. There is an unproven charge that Summerlin cheated in exams during his studies, which if established might support the idea of 'intrinsic proneness' mentioned above. But Medawar also believes it is conceivable that Summerlin could actually have obtained positive results in his earlier experiments if the mice had become muddled up in such a way that donors and recipients were closely related hybrids, which would have allowed successful skin transplantation. Being convinced in his own mind might have caused

Summerlin's resort to deception. This would explain why an intelligent man might have thought he could get away with manipulating his data. He was confident that sooner or later he or workers elsewhere would obtain confirmatory results. Thus he closed the door on the real truth.

Barry Drees describes in his article in this issue of *TWS* how he was pressured by the career structure in science and by work conditions in his laboratory, to risk cheating. He believed that he would be able to make amends later. When things turned out otherwise he was faced with a moral dilemma. The unacceptable circumstances that put him in this position played a role in his decision to switch to a career in medical writing.

Increasingly medical writers are also facing pressure to manipulate data, and to unethically 'cherry-pick' or ghost-write. The difficulties we face as medical writers in 'being honest' are bravely pondered in Ursula Schoenberg's article in this issue. When Marilyn Larkin was pressured to rework two review articles she had written under contract for a medical communications company to position a product more favourably, she asked the company to reduce her fee and rewrite the drafts themselves [2]. Susanna Rees [3] and David Franklin [4] rank among other whistleblowers in our profession.

Is the solution to these pressures for medical writers to take on their employers by whistleblowing? Whistleblowers are

Should medical writers blow the whistle?

exceptional people as I realised when I once had the privilege of hearing Dr Graham Pink speak. Dr Pink exposed the Stockport Health Authority (UK) in an article published in *The Guardian* in

April 1990. He had worked as a charge nurse on a geriatric ward at Stepping Hill Hospital in Stockport. What he reported to the press was the drastic understaffing of the ward at night, which resulted in inadequate care and in distress to patients. He had first written to the chairman of the authority in August 1989. It was not until he had written fruitlessly to local members of Parliament, the Regional Health Authority, the Department of Health in London, the national nurses' professional body, the Secretary of State for Health and finally to the Prime Minister that he ultimately turned to the press. He was dismissed from his job shortly after publication of his article in *The Guardian*. It took until June 1993 before an industrial tribunal ruled that

¹ Schweinerei is pronounced swine-er-i (the 'i' as in 'ice').

he had been unfairly dismissed. In his talk he said that the price of truth is high. He had endured three years of unremitting vilification and persecution at the end of which he had lost his livelihood and a considerable sum of money fighting his case.

Plagiarism is another practice not unknown in medical writing but I would expect professional medical writers to be skilled and knowledgeable enough not to need to fall into this trap. Nevertheless the borderline between copying and paraphrasing is tricky. The article by Christine Parkhurst and Elizabeth Moore in this issue describes how the computer search engine Turnitin can be used to teach students to paraphrase. This article will not only benefit medical writers who teach but is also a useful self-help guide for medical writers themselves.

In the context of plagiarism, the case of Asim Kurjak was presented as a case study by Sir Iain Chalmers in his recent article in the *BMJ* [5]. In Chalmers's paragraph headed 'Naming and shaming' he says that journals and institutions should take plagiarism more seriously, and use systematic reviews for editorial peer review as well as software designed to detect plagiarism. Indeed *The Journal of Cell Biology* already uses software to detect image fraud in manuscripts. Their next plan is to set up a screen of algorithms to find specific types of image manipulations using software developed under a grant from the FBI [6]. More importantly, however, Chalmers advocated that those found guilty of plagiarism should be exposed very publicly.

Would this be the cure for iniquities in medical writing? I agree with Chalmers that in cases of 'bad apples', and where other methods have clearly failed, exposure is called for. But who needs to be named and shamed?

Should it be the companies—and they are in the majority—that employ medical writers but have not even shown willingness by signing ethics guidelines that have been produced by medical writers [7, 8]?

Should it be the journal editors who are failing to ask the right questions and adopt the procedures laid down by the ICMJE guidelines? These guidelines, issued by the International Committee of Medical Journal Editors, state that editors should ask authors to disclose whether they had writing assistance and to identify the entity that paid for this assistance [9]. According to Laragh Gollogly and Hooman Momen from the World Health Organization in Geneva, editors could do more than they are at present and are in a good position to promulgate reasonable standards

Just to demonstrate what wonderful people friends who copyedit your text can be, here is my original text for reference 11 'Medical Reviews Face Criticism Over Lapses by David Armstrong. Wall Street...' And the comment I received 'No. 11 contains what could become a classic howler—congratulations!'

Who needs to be named and shamed?

Call for papers on teaching medical writing

Articles on teaching medical writing are invited for publication in the March issue of *TWS*. The deadline for submission by email to langdoe@baxter.com is **15 January 2007**.

Comma conflict: Call for papers on 'the comma'

TWS is hatching the courageous plan of running the theme 'the comma' in one of the 2007 issues of the journal. A series of articles will make up a treatise on this highly controversial topic. Articles small and great are invited from those who dare. The deadline for submission by email to langdoe@baxter.com is **1 April 2007** (no April fools!).

of practice [10]. Although these authors hardly touch on practices medical writers could be involved in they do state that "incentives for people to cheat are too great to ignore...the rewards for getting away with it, compared to the likelihood of getting caught, make trying a very attractive proposition".

Should it be medical writers who are named and shamed? This seems to be at least the view of David Armstrong at the *Wall Street Journal*. He pointedly pointed the finger at a medical writer who declared that she had given editorial support and that the report was supported by an unrestricted educational grant from her employers. Her crime was to omit to specifically state that this company had also employed and paid her [11]. The article in which Armstrong made his accusation drew on a report in *Science* about a review article in *Neuropsychopharmacology*. The

Whose responsibility is it to tackle medical writing iniquities?

editor-in-chief of that journal, who was also first author of the review article, had failed to inform readers that the authors were paid advisers of the company that manufactured a device reviewed in the article. My reference to this is not, however, to insinuate that medical writers should hide from the limelight behind a banner of victimisation.

In tackling cheating we need to remember that even a barrel of perfectly round and rosy gene manipulated apples might have a bad one hidden in it. Thinking that the blight of cheating can be eliminated is unrealistic and like gene manipulation not necessarily desirable if the price is a policing society. But at least groups can work together to engender a culture in which the practice of putting writers under pressure—or temptation—to cheat their way to success is at least shunned, or even formally proscribed. Only exceptional people can fight alone, which is beyond what should be expected from medical writers. For others annoyed by iniquities there is a need for not only medical writers and their organisations to tackle medical writing iniquities, but also for employers of medical writers and

>>> From the editor's desk:

journals to show willingness, rather than being content for the finger to be pointed at medical writers, who are only at the blunt end of a culture that favours rotten apples.

That is where this editorial would have ended had it not been for EMWA's salary survey. Another German expression equivalent to 'Schweinerei' is "Sauerei". 'Sau' is a female pig. I wondered why a word that expresses disapproval should have a sex at all and decided to avoid it. Ironically the salary survey reveals that in general male medical writers earn more than female medical writers. What is the justification for a woman starting a career in medical writing being paid almost 45% less than a man starting off? It's a Schwinerei.

Elise Langdon-Neuner

Editor-in-chief
langdoe@baxter.com

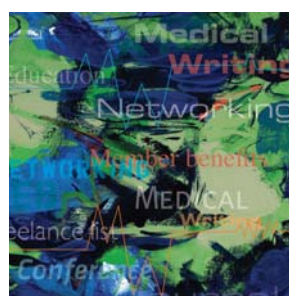
References:

1. Medawar P. The Strange Case of the Spotted Mice. Oxford University Press. 2006
2. Larkin M. Whose article is it anyway? *Lancet* 1999;354:136
3. Rees S. Who actually wrote the research paper? How to find out. <http://bmj.bmjournals.com/cgi/eletters/326/7400/1202>. Accessed 21 November 2006.
4. Lenzer J. Whistleblower charges drug company with deceptive practices. *BMJ* 2003;326:620.
5. Chalmers I. Role of systematic reviews in detecting plagiarism: case of Asim Kurjak. *BMJ* 2006;333:595-6.
6. Kennedy D. Good News—and Bad. *Science* 2006;311:145.
7. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin.* 2003;19(3):149-54.
8. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin.* 2005;21(2):317-21.
9. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. 2006. <http://www.icmje.org/index.html>. Accessed 21 November 2006.
10. Googolly L, Momen H. Ethical dilemmas in science publication: pitfalls and solution for editors. *Rev Saúde Pública* 2006;40(N Esp):24-9.
11. Armstrong D. Medical Reviews Face Criticism Over Lapses. *Wall Street Journal* 19 July 2006 at www.post-gazette.com/pg/06200/706933-114.stm. Accessed 21 November 2006.

What's news at EMWA?**New brochure about EMWA now available**

First I would like to thank members for their response to the questionnaire included in the March 2006 issue of *TWS*. The questionnaire asked members for their comments on the cover of a draft brochure for EMWA. Your comments were a great help to the EC. There was no doubt that our first efforts needed to be scrapped! For interest the results of the questionnaire are set out in the table below.

Summary of the responses received to 7 questions on suggested brochure design				
Question	Agree	Neutral	Disagree	Total
1 The layout is modern and eye catching	16	13	6	35
2 The brochure design is timeless	13	12	10	35
3 The blue goes well with green EMWA logo	22	8	5	35
4 The pill bottles are too 'corporate' for EMWA	17	8	10	35
5 Too fussy design	19	5	11	35
6 Lettering on the front gives headache	21	6	8	35
7 I like the design of the brochure	5	15	15	35



EMWA members will soon receive a copy of the new 8-page EMWA brochure in the post. After much discussion between March and November this year, the EC were unanimously pleased with the final design when it was presented at the EC meeting in Brussels. Attendees at the Brussels conference

also had the opportunity to pick up a copy, and we have been delighted with the positive feedback. I hope you also like the brochure and find it useful to recruit new members.

The brochure was designed by the Norwegian artist and graphic designer, Idun Slevikmoen. If you take a look at her website you will see a picture called "Eksotisk blå" (exotic blue) (http://www.iduns.no/galleri.php?m=3&gk_id=3&show=tumbnails). The brochure uses this painting as a background. Words associated with EMWA and lines like the 'MW' in our logo have been superimposed on this background, with I believe a beautiful and original result. I think we can all be proud when we hand out a brochure of this high quality to potential new members.

Please contact me at pr@ewmwa.org or the EMWA headquarters at info@emwa.org if you have ideas of conferences, meetings or courses where brochures can be handed out—and of course if you would like some more brochures sent to you for distribution.

Kari Skinningsrud

EMWA PR Officer

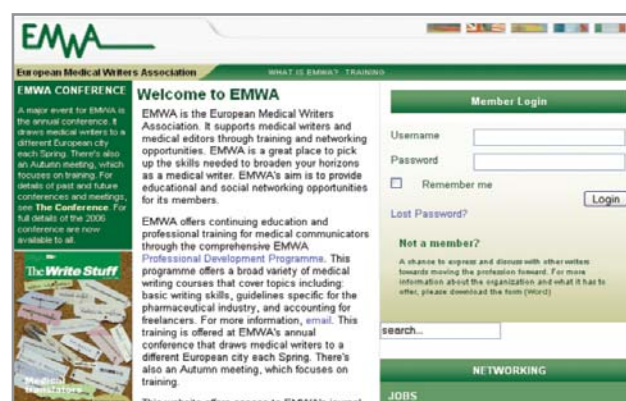
Coming soon: New look and features on the website

EMWA's website (www.emwa.org) has had an 'extreme makeover'. The new site, which will be launched in early 2007, offers expanded functionality and a number of additional features and services.

We are keen to increase the involvement of the EMWA membership in generating content for the website. If you are interested in joining the web team, please contact me at webeditor@emwa.org.

Shanida Nataraja

Website manager



What's news at EMWA?

The EMWA Professional Development Programme (EPDP)**and a call for workshop leaders**

The EMWA Professional Development Committee (EPDC) currently has over 40 workshops available. There are also 15 advanced and foundation workshops under development, some of which we hope will be ready for the Vienna programme. These include¹

- Posters
- Sharpen up your Writing
- The Clinical Study Protocol
- Optimising the Document Review Process
- Patient Narratives for Clinical Study Reports
- Content and Structure and Collocations in Medical Writing and Translation

The short workshop on Kaplan-Meier Analysis, which was given in Lyon, is being expanded to a full workshop to include regression analysis.

Topics of other workshops under development include:

- Remote management
- Medical devices
- The CTD clinical summary
- Pharmacophonetics

The EPDP is a central feature of EMWA and it is important that we offer a wide range of workshops. We would therefore like to expand the range of workshops offered at the annual conferences and November meetings even further, and we are seeking new workshop leaders, particularly for the following areas:

- The Investigational Medicinal Product Dossier (IMPD)
- Biologicals
- Immunology
- The Risk Management Plan
- Marketing
- Topics relevant to Medical Communications

However, all ideas for foundation, advanced and short workshops topics are welcome and we invite your proposals.

If you would like to contribute to EMWA by developing and running a workshop or if there are topics which you would like to see in the programme please get in touch with me at education@emwa.org or contact any member of the EPDC.

Virginia Watson

Education Officer

¹ Please note these are provisional titles only and may change.

New at head office

EMWA members who attended the conference in Brussels in November had the pleasure of meeting Faeda Abdul. Faeda joined Nancy Barkan at EMWA's head office in Zug in July this year. She has taken over from Judith Westhoff as client manager for

EMWA. Amongst her many responsibilities are dealing with member registrations, payments and renewals. She also works very closely with Nancy organising our conferences. Faeda is always pleased to answer queries and can be contacted by telephone on +41 41 720 3306 or email at f.abdul@agshq.com.

Faeda moved to Switzerland from Zimbabwe in 2002 and has an international heritage fitting to EMWA. One grandparent is from Pakistan, another from Malawi, another from Saudi Arabia, Yemen and another from Britain. Her special interest, apart from EMWA, is working with under privileged/orphan children in Zimbabwe to provide financial assistance for their education and living expenses. She and others will be organising a fund-raising show in February in Zurich. Faeda also has a keen interest in cooking and previously owned a catering company in Zimbabwe.

And Faeda's first impressions of EMWA? "Even though I have recently joined EMWA, the warm personalities and support of the association makes me feel as though I have been affiliated with EMWA for years. My first EMWA conference was a challenging and gratifying learning experience. Meeting the executive committee and the workshop leaders at first made me very nervous but they were all wonderful and encouraging. The delegates were great and it was a pleasure to meet them, certainly the interaction with everyone was the highlight of the conference for me. Looking forward to Vienna! See you there."

**Call for conference mentors**

EMWA would like to introduce a conference mentoring scheme for new members (or first-time conference attendees) at the annual conference in Vienna in 2007 as a way to promote networking between experienced and new members.

To be a conference mentor, all you have to do is

- Let us know you are interested in volunteering!
- Contact your designated mentee once before the conference.
- Attend a "Meet Your Mentor" event at the beginning of the conference.
- Be an informal source of information to your mentee about the annual conferences and EMWA in general.

If you plan to attend the conference in Vienna and would like to volunteer as a conference mentor, we want to hear from you. Contact me at (kelly.goodwin@zlbbehiring.com) to sign up or for more information.

Kelly Goodwin Burri

kelly.goodwin@zlbbehiring.com



Message from the President

by Michelle Derbyshire

I'm going to use this opportunity to brief you, the membership, on some proposals that the Executive Committee (EC) would like to bring to you at the next Annual General Meeting (AGM), which will take place during the spring conference in Vienna from 22-26th May 2007.

It is important for EMWA that the EC is constantly refreshed with 'new blood' and new enthusiasm and ideas from within the membership. We realise it can seem a little daunting for members to jump from knowing nothing about the EC and its functions and responsibilities to suddenly having the responsibility of an executive officer on their shoulders. For this reason the EC have started setting up sub-committees, under the supervision of an EC officer to further develop EMWA and allow more participation from members. These sub-committee members will have the opportunity to attend EC meetings as observers to make the possible transition from sub-committee to EC smoother. Therefore I am soliciting any member to please make themselves known to either myself (president@emwa.org) or another committee member if you would like to take part in a sub-committee and play a more active role within EMWA.

The most important change that will be proposed at the AGM is to the term served by the President and Vice President (VP). Currently the VP becomes the President and then the Immediate Past President. This translates into a 3-year term on the EC. We would like to propose that the role of the Immediate Past President is removed from the EC and that the President and VP each serve a 2-year term, i.e. the person would serve 4 years in total. The reason for this is that the posts take some time to develop and a single year goes very fast. The other proposal related to these posts is that currently the VP arranges the spring conference and the President the autumn meeting. However for the new VP the autumn meeting would be a better 'training run' before the larger spring conference and would therefore allow some 'on-the-job training' before tackling the higher workload of a spring conference. We hope that this will take some of the pressure off of a new VP and make the post more appealing. The President will also oversee a sub-committee of conference 'assistants', from which it is hoped that some of the members of this sub-committee might enjoy the conference organisation tasks so much as to consider becoming future VPs. Another change the EC will ask the membership to approve is the abolition of the University Liaison and Membership Officer positions in order to slim-line the EC.

The Executive Committee invites nominations for 5 positions, to be elected at the AGM in Vienna: VP, secretary, PR officer, treasurer and education officer. The member-

ship will be informed of the timelines for nominating someone for election to these posts by an email to all members. Candidate statements must be submitted to the VP by 7 February 2007. These will be published in the March issue of *TWS*. According to the Swiss constitution, you will also be asked to reaffirm your choice of EC by a vote of confidence for the remaining EC officers to continue for another year in their current positions.

It is more important than ever that you as members voice your opinion and vote on these proposals and for the new EC members at the next AGM. We intend to explain them in more detail in an email to you all before you are asked to cast your vote.

On the very important issue of finances, Wendy Kingdom, our treasurer, reports that EMWA's finances are in a healthy position. Over recent years we have had to build up a substantial reserve as our insurance against a disaster, such as having to cancel a conference at the last minute due to a world crisis. Although this reserve must be maintained, we have also been able to spend some money on the new website, brochures and adding value to our conferences. More information about these developments can be found in 'What's news at EMWA' following this Message and in the announcement of the Vienna Spring Conference on page 112. The results of EMWA's salary survey are also reported in this issue of *TWS*. Kelly Goodwin Burri's new initiative for a conference mentoring scheme to welcome new members is explained in 'What's news' too.

Hope to see you in May in Vienna.

Michelle Derbyshire

*MD Writing Services
Mol, Belgium
michelle.derbyshire@skynet.be*

Happy New Year to all medical writers



This little piggy is to wish all readers a happy and healthy New Year following the Austrian tradition of giving friends a pig token at the stroke of midnight on 31st December.

TWS Editorial Board



The 'cheating'.com academic society: A personal view

By Vedran Katavic

One does not advertise cheating as a model of civil behaviour. Nor does one try to promote it. It has a life of its own. The topic of academic cheating is a topic investigated deeply and thoroughly by a great number of excellent researchers. My experience with cheating relates to both the academic cheating by students and cheating by faculty or scientists in publishing [1]. I am not going to preach or express outrage about the existence of dishonesty and cheating. Nor will I say it is the largest problem academia is facing. I will only try to explore some reasons or reasoning behind cheating. (Un) Luckily, I do not have extensive experience in cheating to be able to tell you about all the ways and the latest technology used for cheating. Most of what I know I got from the Internet [2] or by word of mouth.

Most assume academic cheating is a problem of the classroom but it maybe students' emulation of the society.

Cheating is not new. Nor is it reserved for the classroom or the academia. Even the ancient Greeks had 'problems' with cheating. Some of their athletes, the Olympians, were celebrated as kings and worshipped like gods when they won at the 'Games'. Some of those competing tried to cheat. Once found out, they were either whipped, flogged, banned from the games, or they (and their cities) had to pay fines, in the form of donations for sculptures of Zeus (the 'Zanes'), which were erected at the stadium. How many were beaten and banned from the games I do not know, but quite a few Zanes were unearthed during archaeological excavations in the late 19th century.

Let me fast forward to modern times, and continue by paraphrasing W.C. Fields (a US actor, 1880-1946) [3]: A goal worth achieving is a goal worth cheating for. He aptly put into words what many believe to be true, if not right. So it seems there is nothing new under the sun two and a half millennia later.

What is interesting about cheating are our own attitudes towards it [4, 5]. From my experience, there are two: one can be complacent or one can be outraged by it. One's attitude greatly depends on earlier behaviour and experience. It also depends on the society's norms, especially the 'hidden' agenda. By hidden I mean the things one sees or things that happen without consequences despite existing rules and regulations. This is a great push towards the acceptance of cheating. On the other hand, one's attitude may change against cheating in several typical scenarios:

1) You become a teacher, invest your time in teaching and stimulating the minds of your students, remembering what motivated you to study. The more you invest, the less likely it is you will complacently accept the fact that your students are cheating. The overwhelming feeling of having been cheated remains a painful and lasting memory. As a teacher one thinks back to what you and other students did in the past, thinking how much better off the students would be if they didn't cheat; 2) you become a parent and want to be proud of the accomplishments of your children, and you don't want someone else's cheating to rob your children of their innocence and their future; or 3) you experience an episode of cheating (one's own or by someone close to you) gone sour, in humiliating circumstances and with painful consequences.

Most assume that academic cheating is a problem of the classroom. That it is, but it may also be only a symptom, students' emulation of the society. It may be mirroring a country's perceived overall level of corruption [6]. Academic cheating may be more prevalent in situations of increased peer or societal pressures, where students are expected to do too much in too little time, or the tests have no (perceived) relevance or reward. The students (may)

Cheaters will always be prone to cheat but maybe we can influence their 'window of opportunity'.

cheat, or try to cheat as best as they can, using the oldest and most basic ways of cheating like cheat-sheets or cribs, or even inventing new techniques involving advanced technology. Occasionally one gets to hear in the news that a school has decided to install devices that jam mobile phones or the like. Some of the cheaters invest so much time into creating the elaborate schemes that most would say it may well have been easier to study. Some teachers have recognised the effort and the 'genius' of cheating, and have opened museums with exhibits of creations from 'caught' attempts of cheating [7]. Obviously such schemes show that the problems run deeper and are not isolated incidents.

Let me change track a little and move away from the classroom. Why not change track completely and move away from studying or preparations (any and every which way) for examinations, and go deeper into the mind of cheaters. And when I say cheaters, I do not have a specific stereotype in mind. I do not believe there is a specific 'type'. To delve deeper into the mind of a cheater I will use the com-

>>>

>>> The 'cheating'.com academic society

plete opposite from preparing for an exam, e.g. playing computer games, with the accent on playing. Playing computer games can be fun. One can be competitive and play against one's peers (on-line or at LAN parties) or less competitive and play against the computer. The accomplishments in playing against the computer are less tangible, and have a smaller overall social 'value' or prestige with one's peers. Rather they have a pure psychological effect of reward for the player to have 'accomplished' something by virtue of one's reflexes, wit, logic or any combination thereof. So, where is the 'logic' in cheating in games? I do not know. But the number of web pages offering cheat codes, hints, and walk-throughs for computer games is huge, and the number of people using those codes also. What do the cheaters accomplish? Do they fool themselves into believing they mastered a game, and that they are good at it? Or do they just not care. I would say the latter. I would then transfer and translate that answer to the academic environment. The less the students recognise the importance and the joy of learning, the more likely it is they will not care. They will care about passing exams, moving ahead in their 'studies', but will lack the drive and the pleasure of having those moments of clarity when all knowledge comes into place, like a big jigsaw puzzle. The cheaters rob themselves of the greatest feeling there is. Instead of enjoying the fruit of one's labour, they worry if will they be caught and when, what will happen, how embarrassing that might be, etc. drowning in the sea of not caring. And what do they achieve? They cheat themselves, their colleagues, their teachers, the school, and in the end the whole system—accomplishing nothing. Imagine a world where everybody cheated everybody. How would engineers or doctors be confident they are performing well, if their best is just not good enough?

Some people have made cheating their business. There are many on-line services that cater to specific needs of the student population in need of off-the shelf, or maybe custom-made essays, or even doctoral dissertations—hence the title of this article. (Before deciding on the title, I had to go on-line to check if I were not endorsing some website of the same name—which I did and had to change it). What the legal status of those 'companies' is, I do not know. I do not know if you sign a contract with them giving you exclusive rights to 'original' work, or you yourself run the risk of being cheated in the cheating process by getting just another copy of text used over and over again. For some schools, new websites (a brief list among other plagiarism-related resources can be found at ref. 8) help detect and reduce such flagrant dishonesty. But not all schools can benefit from such on-line detection simply due to the nature of their assignments.

***To prevent cheating
we have to set
achievable goals,
reward success justly
and invest more time
in reinforcing
students' knowledge
and skills.***

Adams and Pimple [9] re-evaluated the intrinsic and extrinsic motivators that drive us to indulge in socially acceptable or unacceptable behaviours. They conclude that the intrinsic factor (propensity) to do misconduct is of lesser importance than the extrinsic factor (opportunity) and that situational prevention is key to reduction of misconduct. Although counterintuitive, this actually does make sense. The cheaters or the ones prone to cheating will always be equally prone to cheat, but maybe we (and their peers) can influence their 'window of opportunity' to cheat. Some say that Honour Codes are a good tool to reduce academic dishonesty. I would say that is true only if, by subscribing to the Honour Code, students and faculty start caring for the bigger picture. Otherwise it is just another piece of paper or another rule to be ignored.

Achieving something through cheating, may be attractive for some. Fortunately, this is not so for all. But the temptations are great. Our students may not necessarily be (mis)fortunate ancient Greek Olympians, trying to cheat their way into glory. In the long run, no one remembers the (small-time) cheaters. They live with their shame as best they can, as well they should. To be able to prevent cheating, we must lead by example.

An unfortunate anagram of teaching is cheating. Hopefully, or rather metaphorically, we can influence one by changing the other. What we might have to do to prevent cheating is change teaching by setting achievable goals, rewarding success justly and according to academic principles, investing more time in reinforcing students' knowledge and skills, constantly re-evaluating our perceptions and effectiveness. It takes getting to know one's students, becoming the students' partners, involving them in the excitement of learning and teaching, rather than being their 'executioners'. We, as teachers have to stop teaching at or against the students, and rather learn and teach together with the students. So, maybe it is time we all changed. In time the pressure of truthful and honest students-peers will make it almost impossible to be a cheater. So the students may grow up to be responsible researchers. The easiest way to do just that is by caring and not by cheating.

Vedran Katavic

Research Integrity Editor, Croatian Medical Journal
University of Zagreb School of Medicine, Croatia
vkatavic@mef.hr

References:

1. Katavic V. Five-Year Report of Croatian Medical Journal's Research Integrity Editor – Policy, Policing, or Policing Policy. *Croatian Medical Journal* 2006;47:220-7.
2. http://teachopolis.org/justice/cheating/cheating_how_to.htm (Accessed October 2006).
3. <http://www.quotationspage.com/quote/961.html> (Accessed October 2006).
4. Hren D, Vujaklija A, Ivanisevic R, et al. Students' moral reasoning, Machiavellianism and socially desirable responding: implications for teaching ethics and research integrity. *Medical Education* 2006;40(3):269-77.
5. Hrabak M, Vujaklija A, Vodopivec I, et al. Academic misconduct among medical students in a post-communist country. *Medical Education* 2004;38(3):276-85.
6. Magnus JR, Polterovich VM, Danilov DL, Savvateev AV. Tolerance to cheating: an analysis across countries. *Journal of Economic Education* 2002;33:125-35.
7. <http://glibandsuperficial.blogspot.com/2005/11/shpargalki.html> (Accessed October 2006).
8. <http://library.uww.edu/guides/plagiarism.htm> (Accessed October 2006).
9. Adams D, Pimple KD. Research misconduct and crime lessons from criminal science on preventing misconduct and promoting integrity. *Accountability in Research* 2005;12(3):225-40.



On the causes of academic dishonesty

By Miguel Roig

In examining the problem of student cheating, Vedran Katavic suggests that we should focus on external, rather than on internal factors. Indeed, many of the explanations given by students who cheat are extrinsic in nature. For example, students often claim that they cheat because they feel pressured to get high grades (or avoid failure) from parents, teachers, etc. They also rationalize their academically dishonest behaviors by explaining that their busy schedule leaves them very little time to study, and that they need to get a high grade in order to qualify for financial aid or to enhance their chances of securing a good job upon graduation. Such emphasis on external factors is also consistent with much of the social psychological literature which has demonstrated that the power of the situation often trumps individual dispositional factors [1]. As a cognitive psychologist, however, I have always found it difficult to accept the dominant role of the situation as the main causal factor of behavior. Instead, another interpretation is that our perceptions and expectancies of situational factors play a crucial role in our behavior, that the two types of variables (situational and individual) interact in unique ways, and that they both must be taken into account in order to have a more complete understanding of the causes of our actions.

If there is one general principle that the social sciences have taught us it is that a full explanation of the causes of most human behavior requires a comprehensive and nuanced analysis of intrinsic and extrinsic factors. Thus, any useful model of behavior must include both types of variables. For example, psychologist Bernard Whitely [2] has proposed a model of student cheating whereby external as well as internal factors exert their effects on students' decision to cheat depending on their strength at a given moment in time. Cheating becomes a function of the relative contribution of certain key variables and their unique interaction. Accordingly, the probability that a student will cheat may be low, if students' academic-moral code is such that they hold strong negative attitudes toward cheating regardless of the benefit-to-risk ratio favoring getting caught. Likewise, students who hold tolerant attitudes

toward cheating will likely cheat, particularly if they feel pressure to get high grades, etc., unless the benefit-to-risk ratio is such that there would be a strong likelihood that they will get caught.

According to Donald McCabe [3], perhaps the leading researcher in the United States in the area of academic dishonesty, an institution's academic integrity climate is an important mediating variable in student cheating. He cites evidence indicating that schools with traditional honor codes report less cheating than those with no honor codes. Another important factor and one that probably covaries with the institutional climate, is students' own tolerant attitudes toward cheating [4, 5]. These and other findings from the burgeoning academic dishonesty literature, together with nearly two decades of college teaching experience, lead me to believe that student cheating is primarily the result of the way in which students view education. Many students these days see a college education mainly as a credentialing process whose primary purpose is not to learn about oneself and the world, but rather to increase the students' chances of getting a better paying job after graduation. If learning were perceived by students as the main purpose of a college education, would it make sense to cheat on examinations? Of course not. Academically dishonest behavior would be truly meaningless in that context and would be analogous to a concerned patient with a known life-threatening condition who deliberately cheats on medical tests in order to avoid getting the true results of his/her condition (Perhaps the medical literature contains pathological cases of patient cheating. If so, I think the reader would

To decrease cheating we must focus on internal factors... to make students recognize the importance of acquiring skills and knowledge.

agree that if they do exist, such cases are likely psychiatric in nature and quite rare). On the other hand, if the mere acquisition of an academic degree is the students' main purpose for attending school, then the entire spectrum of academically dishonest behaviors (e.g., cheating on examinations, plagiarism, using fraudulent excuses to submit late work) become meaningful alternatives. Undoubtedly, such misplaced goals are at least partially responsible for the prevailing attitude amongst college students that cheating 'is just not a big deal'.

>>>

>>> On the causes of academic dishonesty

The high incidence of cheating has led to a flurry of educational interventions within the past few years designed to target this class of misbehavior. Many institutions have now enacted honor codes, implemented software to detect plagiarism, and expanded their academic dishonesty policies. In spite of these and other related changes, the rate of student cheating continues to be high at most institutions. I believe that the main reason for this outcome is that most of these interventions target mainly situational variables. If my analysis above is correct, then to win this war on cheating educators must focus on the more difficult task of changing students' attitudes and perceptions.

To decrease cheating, let alone eliminate it, we must focus on these internal factors. Specifically, we need to find a way to make students recognize the importance of acquiring the skills and knowledge imparted to them in school, for only when they possess the critical reading, writing, and communication skills that are acquired by doing actual college-level work will they be able to carry out the tasks that will earn them a high-paying position and subsequent career advancement. Being able to cheat and to plagiarize successfully throughout their college careers may save them time and effort in completing these assignments, but such an approach will rob them of the opportunity to learn the crucial skills that are so important in the modern workplace.

As educators we have a moral obligation to reduce cheating. Thus, it is important that we attend to all of the factors that are known to mediate academic dishonesty. We should not focus on external factors at the expense of internal ones. To fight the cheating epidemic effectively we must change students' current perceptions of the purpose of getting an education. We need to do a better job of winning students' hearts and minds and convince them of the genuine value of learning. This type of attitude change will not be easy and may require a much broader social effort. Until we come up with a formula to do so, our current efforts at curbing cheating will only have limited success.

Miguel Roig

Department of Psychology
St. John's University, New York USA
roigm@stjohns.edu

References:

1. Ross L, Nisbett R. The Person and the Situation: Perspectives of Social Psychology. 1991; New York: McGraw-Hill.
2. Whitely BE Jr. Factors associated with cheating among college students: A review. *Research in Higher Education*, 1998; 39:235-74.
3. McCabe DL, Treviño LK. Honesty and honor codes. *Academe*. 2002; 88:37-41, <http://www.aaup.org/publications/Academe/2002/02JF/02jfmcc.htm>.
4. Roig M, Marks A. Attitudes toward cheating before and after the implementation of a modified honor code: A case study. *Ethics and Behavior*. 006:16;163-71.
5. Roig M. College Students' and Professors' Attitudes Toward Cheating: A 12 year follow-up. Poster paper presented at the 18th Annual Convention of the Association for Psychological Science, New York, May, 2006.

Ig Nobel Prizes in medical writing

The Ig Nobel Prizes are awarded for fun and to raise the general public's awareness of science. The prizes are awarded each year around the same time as the Nobel Prizes and are sponsored by the journal *Annals of Improbable Research*. Scanning the list of past Ig Nobel Prize winners, provided by Wikipedia, shows that medical writing is well represented:

- **1992 Literature:** Yuri Struchkov ([hppt://iucr.org/iucr-top/people/struchko.htm](http://iucr.org/iucr-top/people/struchko.htm)) for the 948 scientific papers he published between 1981 and 1990, averaging more than one every 3.9 days.
- **1993 Literature:** E.Topol, R. Califf, F.Van de Werf, P.W. Armstrong et al ('al' here = 972 coauthors) for a medical research paper which has more than one hundred times as many authors as pages.
- **2000 Computer Science:** Chris Niswander for inventing PawSense (<http://www.bitboost.com/pawsense>) software that detects when a cat is walking across your computer keyboard (useful invention for felineophile medical writers).
- **2004 Economics:** The Vatican for outsourcing prayers to India (comforting because it's not just medical writing).

Others prizes do not seem to have such a direct connection with medical writing...

- **2003 Peace:** Lal Bihari from India for leading an active life even though he had been declared legally dead, waging a posthumous campaign against bureaucratic inertia and greedy relatives, and creating the Association of Dead People. Lal managed to obtain a passport from the Indian government to travel to the US to accept the prize only to discover that the US government do not allow dead people to just walk into the country.

Any nominations for future awards can be posted on the website of *Annals of Improbable Research* at <http://improbable.com>. One nomination for next year is for the Japan Industrial Design Promotion Organization which gives 'G-Mark' stickers for good design. A manufacturer of adult sex aids entered a product, which impressed the judges, but after the initial excitement the judges regretted that they could not consider the product for the award because they had no means of testing its performance or function.



How I almost committed scientific fraud

By Barry Drees

Ever since I was a doctoral student in molecular biology at the University of California, San Francisco, I have been interested in the reporting of scientific fraud and subsequent discussions in the popular press among non-scientists. I remember the spectacular cases of John Darsee and the even more notorious David Baltimore/Imanishi-Kari which carried on for years, cost a Nobel Prize winning biochemist his position as head of Rockefeller University, involved the FBI forensic laboratory, and ended up being dismissed completely [1]. The press clearly loves these stories, partly because they reveal that although scientists insist that they are mere objective investigators of natural phenomenon, underneath they are human beings like everybody else, with similar desires, vanities and temptations. But the part of all of this that always struck me as amazingly ill-informed was the wonderment on the part of scientists and non-scientists alike as to why anyone would do such a thing. I can understand that someone who has never worked under the intense ‘publish-or-perish’ pressures of the modern academic world—made all the more competitive when the commercial world enters the scene as the pharmaceutical industry has recently—might wonder, but have senior scientists really forgotten what it was like to be a struggling young scientist, battling for recognition and funding? Perhaps a book or television series (‘Desperate Postdocs’ or ‘Science and the City’) based on the politics and passions of the modern gene-tech laboratory is needed to inform non-scientists and jog the memories of tenured professors back to reality. With this thought in mind, I offer a short story from my truncated scientific career to illustrate the environment which I believe can easily lead one to scientific fraud.

Many more people study science than can ever hope to find academic jobs. The competition to distinguish oneself to secure one of the few available positions in academia is fierce. Indeed, the hierarchy of a university laboratory seems designed to make this situation even worse. PhD students are in a state resembling slavery. There are no grades or other tangible ways to measure achievement while working towards a PhD. Candidates are utterly dependent on the good graces of their advisors. At the same time, the advisors’ career advancement, their ability to attract funding, and status all depend on the work of laboratory technicians, postdoctoral scholars, and PhD students. The technicians and postdoctoral scholars are protected to some degree: the technicians by labor law as employees of the university, and the postdocs because they have some independence through already having their doc-

toral degrees and frequently their own funding. PhD students, on the other hand, are pretty much helpless in the face of abuse from their advisors. It is hard to escape to someone else as other potential PhD advisors are hesitant to be seen to be poaching students from their colleagues. To progress in a scientific career and secure a good postdoctoral position, students need to not only obtain a PhD, but also to get positive recommendations from their advisor. As advisors’ career advancement is dependent to some degree on the students in their laboratories, the pressure for advisors to drive their students can be intense. What exasperates this is that scientists are mostly chosen for their scientific brilliance and not for their interpersonal skills or management ability.

All this can lead to an almost unbearable pressure to produce results. There is no doubt that science, particularly genetic engineering, is an awful lot of hard work. If you want to succeed, there is no alternative to spending a great deal of time in the laboratory doing very repetitive work, like running gels and sorting cells. PhD advisors can easily think that the true key to success is to work in the laboratory day and night. Thus a macho ethic frequently develops among the people in the laboratory, who compete to spend the most time in the laboratory and 18-hour days, 7-days a week can become the norm. My advisor had the particularly irritating habit of suggesting experiments and wanting to see the results by the next day. This ruined any chance you might have wanted to discover what a real life was like. Standing up for yourself and simply refusing to do it right away seemed far too dangerous, given how dependent you were on impressing the advisor that you had the qualities to be a great scientist. What seemed like just great enthusiasm for science began over time to seem like the pathological behaviour of a micromanaging control freak. I got really fed up with the situation and the spirit of rebellion began to fester. Many times I had to cancel a social activity in order to run another experiment that my advisor had just dreamed up.

Eventually I found myself saying that I would do the experiment and then after he left would just go out anyway. The next day, when he asked what the results were, it was easy to say, “Oh it worked like we thought” and figure that you could run the experiment later in the week. I tried this a few times, but of course, eventually the experiment did not work. Now I had to either admit that I had lied and had not done the experiment when requested or I had to produce results that showed that I had . . . or appeared to have done. Someone doing the research usually knows exactly how the data need to look, which makes the temptation to

>>>

>>> **How I almost committed scientific fraud**

fake it 'just this once' awfully hard to resist. This is especially the case when admitting that you had lied is an excellent way to destroy your chances of a favourable recommendation and thus a good start to an independent research career. Like any kind of dishonesty however, just this once, if successful, quickly becomes a habit and feeds on itself. It can eventually lead to career destroying patterns of scientific fraud. As the title of this article suggests and as you may suspect, I teetered on the brink and peered into the void, but drew back and took my lumps. I admitted that I had lied about doing the experiment. It took me a few more years, but eventually I realized that I just wasn't cut out for a research career and became a medical writer instead.

It is strange to read about the 'scientific pursuit of truth and knowledge' that the press seems to have swallowed whole from scientists, followed by the amazement that scientists could commit fraud. I believe that the single-minded pursuit of research careers, forgetting that we are all human beings with very human failings, is one of the main causes for researchers to take that fateful step to committing fraud.

Barry Drees

*Trilogy Writing & Consulting
Frankfurt am Main, Germany
barry@trilogywritng.com*

Reference

1. Shashok K. In the Bookstores... Pride and Pressure to Publish: The Baltimore Affair. *TWS* 2000; 9 (1): 16-9.

Reflecting on honesty: Honesty is not the best policy

It is the only policy. It is the only way to conduct business in the long-term. Of course, all of us could get away with telling lies in the short term but it is no way to live. Perhaps it is my Calvinist upbringing as a Scot.

When I started out running my own business almost fifteen years ago, I was desperate to win new clients and I tried to tell people what I thought they wanted to hear. However, this was not always terribly successful and I realized it was better to tell people the unvarnished truth then help them deal with it if there was a problem. This was much more successful.

Only now, as I approach the end of my career, do I really know what kind of job suits me best. I started off as a forensic scientist before it became very sexy, then went into drug research, clinical pharmacology and, finally, became a medical writer and translator. As a young man I was interested in both science and languages and reasoned that it would be better to adopt science as a career and pursue languages as a hobby. If I had to do it again, I would abandon science and take up languages full-time. My ideal job would be a sort of "facilitator" at meetings and congresses, going about talking to the French in French, the Germans in German, and also saying a few words to the Russians, Spanish and Poles.

Which brings me on to the challenge of dealing with people from different countries. Here, too, truth is the key. A few years ago I was involved in a major project from a big American company which included presentations in different languages in a number of European countries. The structure of the presentation was fairly complex, to be completely honest it was horrendously complex, and I told the clients so. They did not believe me and told me it had gone very well in Texas a few months before. I gently pointed out to them that Texas was not Frankfurt or Milan but they ignored my advice. So, the complex presentation was made and there were huge problems and a lot of the audience simply walked out before the end because of the difficult concepts involved or, at least, the difficult way

they were presented. To be fair, the clients came up to me and admitted they had been wrong and we then went on to develop a simpler but just as effective presentation.

So, right from the start, it is important to tell clients about differences they may encounter when dealing with people from other cultures. I have always had a good relationship with people from Southern Europe, the Middle East and the Far East because I know quite a lot about their cultures and I respect them. However, one thing I have learned from the Japanese is how to avoid saying "No". This is often seen as crude and impolite. It is much better to say "Yes, but...". You are not lying by saying "Yes", you are simply softening the blow.

I once worked for an Italian company as a medical writer and I enjoyed it very much. My colleagues were very friendly, talented and very hard-working. However, the company sent me on a management course run by a major Italian business school. This was against my wishes because I believe that nature has either made you a good manager or not. Surprisingly, I quite enjoyed the course but found the macho management ethos very amusing and slightly worrying. You know the sort of thing: if you cannot win the way you want then win anyway you can. I simply do not believe that gung-ho tactics work in the 21st century.

So, what advice can I give people out there starting a career? Well, the most important thing is to tell the truth. It may not be easy on occasions but it will be best in the long run. And one other thing. Keep your sense of humour! An honest person with a sense of humour is almost priceless.

David Jack

DrDavidJack2@aol.com

David Jack has a PhD in clinical pharmacology and is a past president of The British Society for the History of Pharmacy. He has worked in the Swiss and Italian pharmaceutical industries and taught at universities in the UK and Iran. Since 1992 he has been a freelance medical writer, editor and translator running his own company, Medical Writing, Editing & Consultancy Ltd. He has published numerous scientific papers and journalistic articles including the Financial Times management report on The Japanese Pharmaceutical Industry and contributions to Pfizer's online newspaper, *The Pipeline* (Sandwich edition) and to the *Lancet's* humorous Jabs & Jibes column.



(Doing) The Right Stuff

by Ursula Schoenberg

Just for the record: The editor sweet talked me into this. Asking someone working in ‘communications’ (a phrase that was coined when ‘public relations’ started getting a bad name) to contribute something on ‘being honest’ is, some might argue, like asking the Pope to write an article on Safer Sex. And I’m still not sure this is a good idea.

There is a certain irony in the timing here, as I am grappling with a dicey professional issue right now. As a public relations consultant working on implementing marketing strategies, heavy duty ethical questions only started to loom since I moved into the pharmaceutical area of communications, and I was pretty naïve in the beginning. Picture a guppy moving into a shark bay. I have by this time advanced to about moray eel status. To elucidate:

I am, by proxy, working for a pharmaceutical company that is launching a new product which it is marketing at a patient population with a bona fide medical problem—and I have not done too badly off of this client in the last months. However, due to the nature of this illness, in the not-too-distant future the company will be able to expand the existing indication into something that can be marketed as a lifestyle drug, with the promise of an even more captivating profit margin. The expression ‘disease mongering’ hovers over step two of the project (I’ve seen the data), and, viewed dispassionately, the work I do right now is paving the way for it.

So if I have an ethical backbone, I would start to prepare my exit strategy. In recent weeks I have been visited with the ghostly voices of grade school teachers saying “Ursula is not working up to her full potential...”, which I interpret as a sign that I should be re-thinking my priorities. Trouble is, I do like the money, i.e. what it can do for me. I have caught myself rationalizing wisps of ethical qualms that might be cropping up later, along the lines of “well, if people are stupid enough to let themselves be talked into using this stuff...”.

A slippery slope, as was brought home to me on a walk with my little daughter last week. We went out to pick some apples that had fallen off some trees in a nearby farmer’s orchard that is publicly accessible, and I blithely announced that we were going to “steal some apples”. Semantically correct, but pedagogically stupid, as I realized that being honest about not being honest was going to get me into hot water. I visualized myself years down the line trying to explain why it is not a good idea to lift the lipstick from the drug store, but it was OK to take those apples back then.

If being honest is, as one of my dictionaries defines, being ‘marked by firm adherence to a code of moral or artistic

values’, I’m not doing too well on the moral front right now. I fare marginally better on the second point. In Dorothy Sayers’ novel ‘Gaudy Night’, when the writer Harriet Vane is asked what she would not lie about in her professional life, she says “...saying that somebody’s beastly book is good when it isn’t”. That’s me, folks. When someone starts to slaughter language, I can be honest to the point of abrasiveness.

So with a little luck my client will get hold of this poignant exploration of my demons and put me out on my ear. Not before complimenting me on my eloquence, of course. And now you know why it can be hard for me to do ‘the right stuff’.

Ursula Schoenberg

Creative Communications Solutions
Frankfurt/M, Germany
u.schoenberg@t-online.de
<http://www.sci-tech-specialist.de>

Worth reading

‘Publishing Clinical Trial Results: The Future Beckons’ by Elizabeth Wager .

(<http://clinicaltrials.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pctr.0010031>)

The author would be interested in any comments which can be posted on

<http://clinicaltrials.plosjournals.org/perlserv/?request=read-response&doi=10.1371/journal.pctr.0010031>

or sent direct to her at liz@sideview.demon.co.uk

PowerPoint plagiarism

A truly diverse website is that of Edward Tufte at www.edwardtufte.com. Reading the site you learn that Edward Tufte writes, designs and publishes books on analytical design. He is Professor Emeritus at Yale University, where he taught courses in statistical evidence, information design, and interface design. The site has a forum entitled ‘Ask E.T.’ Among the subjects covered is a topic that will increasingly be an issue in future: ‘Plagiarism detection in PowerPoint presentations’

www.edwardtufte.com/bboard/q-and-a-fetch-msg?msg_id=0002V4&topic_id=1&topic=

Nipping plagiarism in the bud: Using Turnitin to teach novice science writers how to paraphrase

By Christine Parkhurst and Elizabeth Moore

Introduction

Avoiding plagiarism is a problem for authors trying to publish in the health sciences, especially if they are bilingual students writing in English as an additional language. Learning the skills required to paraphrase and cite correctly should begin early on in the author's education. However, composition courses and writing centers rarely address the needs of novice science writers, and science courses rarely address writing skills such as paraphrasing and citation. Using Turnitin, a computer search engine designed for plagiarism detection (<http://turnitin.com/static/home.html>), can be an effective method to learn and practice paraphrasing skills; this method will be discussed here, and compared with conventional classroom and writing center methods.

We will discuss our experience working with novice science writers whose first or best language is not English, using both conventional teaching methods and Turnitin. This will be based on our respective experience: Christine Parkhurst teaching composition at Massachusetts College of Pharmacy and Health Science (MCPHS,) and Elizabeth Moore as a Writing Center Fellow at Barnard College/Columbia University. First, we will discuss how undergraduate health science and science majors in the U.S. learn to paraphrase and cite through conventional classroom and writing center methods, using both MCPHS's more traditional methods of composition instruction and Barnard College's writing center as examples. Then we will discuss how students at MCPHS learn to avoid plagiarism by doing exercises that use Turnitin. We will also discuss the drawbacks and limitations of using Turnitin for this purpose.

Conventional classroom paraphrasing instruction: MCPHS

In the U.S., most composition classes don't teach novice science writers to write from biomedical journal sources, and most science classes don't attend to students' writing. Science majors often exit their composition course sequences without having practiced writing from biomedical sources. This was originally the case at MCPHS. Now students learn paraphrasing and citation by writing on biomedical topics from journal sources, and by practicing with Turnitin (described below.) However, at MCPHS, our students are all health science majors; the pharmacy program is the largest in the U.S. Over thirty percent of the students are bilingual, although only about four to six percent are

non-U.S. residents with student visas. Students graduate with a professional degree in fields such as Pharmacy, Nursing, and Optometry, or they go on to further study in medical school or other professional schools. Some will publish in their fields, and some publish brief monographs even before they graduate. By the time students enter their final two years of the curriculum, they are expected to be able to write on technical topics in their field. This means that students face problems with genre conventions, and many struggle with paraphrasing.

In my composition classes at MCPHS, originally students learned paraphrasing and citation skills by writing on conventional liberal arts topics. When they wrote research papers from biomedical journal sources in their advanced writing course, many students once again began to copy and paste long chunks of text, and some used sources they didn't attribute accurately, or at all. Now students learn paraphrasing from the start by doing summary or synthesis assignments, and then writing biomedical review articles, all based on medical, pharmacy or nursing journal article sources. (How they practice for this by using Turnitin is discussed below.) If students use sources they don't attribute, by using inaccurate references or no references, professors have to play a cat-and-mouse game to find the source or sources the student has plagiarized. Therefore, students are required to submit copies or links to their sources. If students learn early on that they can't copy language from their source texts, they are more likely to avoid the copy and paste style that leads to unintentional or intentional plagiarism. Most student plagiarism is unintentional, though, and checking the student's too-perfect text against the original text often shows that the student has copied too closely. This can be pointed out by underlining matching text, or discussing the too-close text with students working on early drafts. Students improve by doing multiple revisions that are progressively more correct. This is effective, but time-consuming, so not many assignments can be done in this way.

After students exit the class, consistent source checking usually stops. Clinical professors do not normally have time to check student writing against all its declared and undeclared sources. If a professor recognizes blatant plagiarism, the penalties for academic dishonesty are applied, of course. This requires sufficient familiarity with students' writing styles to spot suspiciously perfect or technical text. Clinical professors may ask students to take papers to the writing center, but these professors usually focus on

Nipping plagiarism in the bud

content rather than attending to student writing per se. Many institutions of higher education in the U.S. now have student- or faculty-staffed writing centers that can provide an additional means of detecting and addressing student plagiarism, as well as serving the more general writing needs of the student population.

Writing Center paraphrasing instruction: Barnard College/ Columbia University

Barnard College of Columbia University seems to be using Turnitin primarily as a tool for guarding against intentional, “malicious” plagiarism, but the problem of unintentional or partial plagiarism—especially in the sciences—remains. Barnard’s emphasis on writing across the curriculum is evidenced by its Writing Fellows (discussed below), who interact with and aid students of every subject. It is Barnard’s strong belief that the ability to write coherently, honestly, and originally is a skill essential to every major, including the sciences.

The Erica Mann Jong Writing Center is set up as a resource for undergraduate students at Barnard College and for Columbia students enrolled in classes at Barnard College. The Center is staffed by Barnard students, all of whom are paid a small annual stipend, and all of whom have shown strength in both writing and peer-to-peer communication. Before working with their peers in the Center, all Fellows are required to take a one-semester course called The Writer’s Process on the pedagogy of writing and the philosophy behind peer tutoring (though the term “fellowing” is used instead). Writing Fellows are by no means exclusively English majors; in fact, the directors of the writing center make an effort to recruit strong writers from all majors, including the sciences.

Each semester, Fellows split their time between walk-in hours at the writing center and the specific course to which they are assigned. These courses range from first-year English composition courses to advanced Psychology and Environmental Science classes. The latter tend to require the type of technical writing that invites a certain amount of unintentional plagiarism. Fellows are encouraged to look for language that seems implausible or inconsistent with the student’s speaking ability or with her other work. If a Fellow encounters such language, she will often ask the student to see her sources. Kaitlin Kratter is a former Writing Fellow at Barnard who is now a TA for a 1000-person introductory undergraduate astronomy class at the University of Toronto, where she is a graduate student in astrophysics. When confronted with possible plagiarism, Kratter says, “. . . it is often helpful to explain the place for direct quotes, and to ask students to see if they actually understand the words they are using. I have tried to explain that if they do not understand a phrase, . . . they should definitely not include it in their writing.”

In my experience as a Fellow, the students who were most likely to borrow language were also the students who felt

least comfortable with their own writing ability—typically, non-native speakers. To change or paraphrase was, to them, to risk inaccuracy. Though within the Writing Fellows program there exists no protocol for how to deal with science-specific plagiarism, perhaps this fact in itself is evidence of Barnard’s commitment to teaching strong writing across the curriculum. All plagiarism, whether intentional or unintentional, whether related to humanities or to the sciences, is diagnosable using the same techniques.

Both peer-staffed writing centers and Turnitin can be tools for teaching students—in a nonjudgmental way—what constitutes plagiarism. Although Barnard’s students take its honor code seriously, learning to summarize or synthesize articles while using a minimum of borrowed language is an acquired skill.

Using Turnitin to teach paraphrasing at MCPHS

Class assignments which require students to synthesize and paraphrase journal sources raise students’ consciousness about what does and does not constitute plagiarism, and give students practice paraphrasing while writing in genres they will have to master. When MCPHS acquired a Turnitin site license, new assignments made this process more efficient and effective, although not perfect, as will be discussed. Students can do many more assignments, more autonomously; this additional practice helps them master paraphrasing and citation skills.

For each class, I set up a Turnitin class account with a login and password. Students then access the class account and set up their individual accounts. Students write their summary and synthesis assignments using a word processing program such as Microsoft Word. They then access their Turnitin account and enter their assignment in its Inbox. Any number of assignments can be created. There are menu options for each assignment: for example, a due date can be assigned, and papers can’t be submitted after the due date. There is an option to exclude all material in quotation marks from the percent of matching text, which is an improvement over Turnitin’s previous algorithm. I have students simply cut and paste their assignments in, although they can also be downloaded. When students submit a paper, they click on the Submit icon, and Turnitin’s Web crawlers then compare what the student has submitted to every document in its data base.

The result of the comparison is the Originality Report. Turnitin is careful not to label a paper as plagiarized or not. It simply reports any matching text that it found as a percent match. Papers with more than five percent matching text deserve a second look, depending on length. The Originality Report can be viewed by clicking the Report icon. A split screen comes up, with the student’s text on the left and a reference identifying any matching text on the right. The matching text is flagged by being highlighted in color in the student’s text, with a number corresponding to

> > >

>>> **Nipping plagiarism in the bud**

the source reference on the right. If there are three sources of matching text, for example, there are three colors and three references. Clicking on the reference for the match will bring up the original text and its source. These can then be viewed on the split screen.

It's possible to cut and paste suspicious-looking phrases into other search engines such as Google. What makes Turnitin's Web crawlers faster than Google's for this sort of detective work, is that the student enters the entire text and then Turnitin's Web crawlers do all the comparisons for the entire text at once. Entering suspicious phrases in Google may bring up a match, but each phrase must be entered individually. The Originality Report in Turnitin is generated quickly, either instantly for short texts or after a few minutes for longer texts. The professor can ask students to submit their assignments, and the next day view a list of all the students' documents and their Originality Reports. Any that have a percent match higher than a few percent can then be viewed. A more important advantage of using Turnitin's algorithm is that its Web crawlers find matching text even if the entire sentence doesn't match. Normally search engines only see identical text as a match; they agree with students who think that changing a word here and there is enough to make the text different.

I use the option that permits students to see their own Originality Reports. This turns out to be a powerful tool for teaching students how to paraphrase. Because students know that they will have their text checked by Turnitin, they do their best to paraphrase. They then get an Originality Report. If half the text appears in color with matches, it's a shock to the student who thought that changing fifty percent of each sentence was enough. The impartiality of the computer means that the student can't complain or try to argue that some words were changed: it's not identical, and that should be good enough. Even students who were clearly in the habit of getting high grades on what were essentially plagiarized papers learn to rephrase completely by the third or fourth assignment. Students internalize the experience of rewriting and trying to change the text completely enough so that next time it doesn't match. This year, for the first assignment done by 44 students, almost a quarter of the papers had matching text that ranged from 20%-50%. By the third assignment, only three students had matching text over 5%, and the highest percent match was 18%. As the assignments become more difficult, the percent of matching text still stays low.

Because students see which strings are close enough matches to be flagged, we can then have more substantive discussions about the paraphrasing spectrum. On one end are chunks of text that match but should not be paraphrased. Some are easily recognized (ex. "Center for Disease Control and Prevention.") Students try to paraphrase other strings that really shouldn't be paraphrased, but students are not yet familiar enough with the genre to recognize that. For example, "new prescriptions for selec-

tive serotonin reuptake inhibitors," flagged as a match, should not be paraphrased "novel prescriptions for medications that prevent the reuptake of serotonin selectively." Although "new" and "novel" generally mean the same thing, in this context "novel" would amount to a claim that the prescription is "interesting and innovative" as opposed to a "new" rather than a "refill" prescription. Students more familiar with the genre would not attempt to paraphrase SSRI, but would recognize it as a compound noun. Further along the spectrum are chunks consisting of lists of technical terms that are symptoms or side effects, for example; these also can't be paraphrased without distorting meaning ("[This may cause] dizziness, drowsiness, dry mouth, nausea or vomiting.") Still further along are chunks of text that should be paraphrased to the extent possible, but are difficult to paraphrase without distorting meaning (for example, methods sections or data-rich results sections.) When students have used Turnitin enough to paraphrase automatically whatever they can easily paraphrase and should paraphrase, the remaining matching text is the correct starting point for a discussion of how to paraphrase and cite correctly, and how to make sure that the resulting text is still an accurate and genre-appropriate representation of the original meaning. This requires interaction with a human, not a computer.

However, there are caveats. Turnitin adds students' texts to its data base, and this is controversial in terms of intellectual property rights. Since I have students do exercises to practice paraphrasing using Turnitin, this seems less like depriving them of intellectual property, and they benefit directly. Also, most of the medical, pharmacy, and nursing journals students work from are not part of the Turnitin data base. For paraphrasing assignments, I use short excerpts from articles (less than 10%,) one time only, and enter those excerpts myself so that I know they will come up as matches. Turnitin permits use of non-technical sources on biomedical topics as a lead-in to more difficult journal sources. Using another search engine such as eTBlast that is tailored to searching biomedical texts would deal with this issue for more advanced writers. Another problem is that Turnitin is confused by many sentence-level grammar errors. Students' text may not come up as a match when it should, if Turnitin is unable to parse it. Therefore, work with 0% matching text should also be checked to see if sentence-level grammar is the issue. Finally, the content of student paraphrases may no longer be accurate once the language is sufficiently dissimilar. This is, of course, a major problem in science writing, but it can reveal underlying problems with students' reading comprehension which can then be addressed.

Conclusion

Conventional classroom and writing center methods for teaching students to avoid plagiarism can be effective, but are time-consuming. Therefore, students may not get as much practice as they need. Professors' lack of time to do

consistent source-checking, and lack of familiarity with students' actual writing styles, may allow intentional or unintentional plagiarism to slip through unrecognized. This reinforces students' misperception that plagiarism is acceptable, or not likely to be spotted, and they continue to plagiarize difficult text. Using Turnitin for summary and synthesis assignments based on technical sources such as journal articles saves time by doing automatic source-checking for matching text. Because this is much less time-consuming than comparing sources and student text by hand, students can do many more assignments. Turnitin is consistent in flagging matching text. The additional practice helps students learn to paraphrase automatically whatever can be paraphrased easily. More advanced students begin to develop genre awareness and write in a more genre-appropriate style. Discussion of the remaining matching text helps students recognize text that cannot or

should not be paraphrased, understand the issues concerning hard-to-paraphrase text such as symptom lists or methods and results sections, and become conscious of the importance of paraphrasing in a way that doesn't distort meaning.

Christine Parkhurst

Massachusetts College of Pharmacy and Health Sciences, Boston, Massachusetts, USA
Christine.Parkhurst@mcphs.edu

Elizabeth Moore

Morgan Library, New York, New York, USA
lizmoore1234@gmail.com

Christine Parkhurst is an Associate Professor of English and Humanities at Massachusetts College of Pharmacy and Health Sciences, Boston, Massachusetts, where she teaches composition and health communication. Elizabeth Moore was a Writing Fellow at Barnard College, and is currently an Assistant Editor at the Morgan Library, New York, New York, and a free-lance writer.



NAWP CENTENARY ESSAY COMPETITION 2006-2007

A rare opportunity for to put your professional opinions into print

To mark its successful centenary year in 2005, the UK **National Association of Women Pharmacists** is launching a Centenary Essay Competition; open to all pharmacists registered in the UK and Europe. Agreed funding means that only pharmacists can be awarded the financial prizes, **but NAWP also welcomes entries from others individuals with relevant expertise** and they too will have their entries considered for publication and commendation. This will be a once only event, inviting entrants (men and women) to write a literature-based essay of 1200 words on a specified topic. The Pharmaceutical Journal has agreed to consider the prize-winning essays for publication. Winners will be invited to present their work to a NAWP meeting, subject to their willingness and it is planned that all high quality entries will be published by NAWP.

There are two classes of entry: **Academic** and **Professional**.

Entries in the Academic class are to be based primarily on research and review literature published in pharmacy, scientific, medical, nursing and/or behavioural journals.

Entries in the Professional class may draw from these sources if appropriate, but may also draw from professional experience and media sources (magazines, newspapers, TV etc).

Entries are to be submitted by 1st February 2007, in English. The competition will be judged by three judges appointed by, but independent of, NAWP.

The topic of the essay is:

Pharmacy and ageing: Are medicine-taking issues under-recognised in behavioural research?

Background to the topic

The media frequently report study-findings that claim to show that mental function in older people can be influenced by activities such as doing crossword puzzles, taking exercise or socialising. However, pharmacists are well aware that in many countries ageing is associated with increasing use of medication and that this in turn brings benefits and inconveniences. Prevalence of the use of prescribed and non-prescribed medicines, the number of dosage units being taken daily, side effects, and the efficacy of long-term medication are issues that are natural concerns of pharmacists, but awareness of these points comes less naturally to some other disciplines concerned with health and social issues. Authors are therefore asked to question whether behavioural studies investigating mental function in older people adequately recognise the consequences of high levels of medicines usage by those over the age of 60.

For further details and an entry form, contact enquiries@nawp.org.uk or write to Mrs Brenda Ecclestone, Hon Sec. NAWP, Princess Royal Cottage, Butterow West, Rodborough, Stroud, Glos. GL5 3UA



Communication of the benefit risk profile in the Clinical Overview section of an application for marketing approval of a new medicinal product

by Sarah Hemingway

Introduction

Many people involved in the drug development process will contribute to interpretation of the clinical data and evaluation of benefit risk, and the role of the Communicator is to work with this team to organise the different elements of benefit risk evaluation and document a clear, balanced view of the clinical value of the product. According to Regulatory guidance (ICH M4E [1]), the Clinical Overview is the document within a pharmaceutical registration dossier in which the applicant should present the overall analysis of the benefits and risks of the product in its intended use. The purpose of this article is to help Communicators understand elements of the benefit risk evaluation, and propose questions and points that should be addressed during the processes of critically evaluating a new product and preparing a Clinical Overview.

An ineffective drug is obviously of no value, and no drug is completely safe—hence the decision to market a new medicine is based on an evaluation of the benefit risk balance. The question that must be addressed is: *“Do the benefits outweigh the risks in relation to the intended clinical use?”*

Thus the Clinical Overview must critically assess the value of a new product in the indication for which it might be marketed, based on clinical trial data presented and summarised in the application. Furthermore, the Clinical Overview explains and justifies the content of the proposed prescribing information for the product. Labelling text follows a prescribed format, designed to include the basic information on the product needed by a prescriber to reach a benefit risk decision in relation to the potential treatment of an individual patient. Labelling is then translated into patient information, which influences patient perception of benefit risk of a prescribed medication.

Analysis of benefit risk is a complex process; quantitative techniques have been proposed [2-5], but the issues vary between products and the evaluation may rely on clinical judgement alone. The case for approval of a product is made in the following 5 stages:

- Clarify the unmet medical need that is addressed by the new medicine
- Confirm that the clinical database is adequate to characterise the benefits and risks
- Present the analysis of clinical benefit
- Present the analysis of clinical risk
- Address the key question: ‘Do the benefits outweigh the risks?’

Unmet medical need

A new medication is introduced to address an unmet medical need, represented either by patients who receive no treatment (who experience discomfort and disruption of daily activities, with consequent social impact, and in whom there may be a risk of the condition deteriorating), or those in whom there are drawbacks associated with the existing treatment (e.g. limited efficacy, adverse drug reactions (ADR) or over-complex dosing regimens). The acceptability of the balance between benefit and risk for a new therapy may depend upon the severity of the condition to be treated: for potentially life-threatening illness, a higher level of risk may be more acceptable than in less serious conditions. Where treatment already exists, benefit risk will need to be compared with current therapy, and it may be appropriate to refer to published clinical guidelines, in which the benefit risk profiles of existing therapies are evaluated and treatment algorithms proposed.

The ‘Product Development Rationale’ section of the Clinical Overview must address the question: “What is the unmet medical need for this product?” Having identified the unmet need, the applicant should then set out the criteria that a drug must meet (or surpass) in order to be judged to have met the unmet need with an acceptable balance of benefit and risk.

Adequacy of the clinical data to support evaluation of benefit risk

Before attempting to show how the benefits of a new medicine outweigh the risks, consideration should be given to the question of whether the clinical database is adequate to characterise the benefits and risks: if either the benefits or the risks are not well enough understood, the application may be judged to be premature. Furthermore, the impact of any major issues of data quality on the conclusions must be addressed. The Clinical Overview should include a statement, with justification, that the information on a new medicine is adequate to support a conclusion on the benefit risk.

Communicating clinical benefit

Efficacy

Efficacy is (clearly) the most important determinant of benefit: the drug must be shown to be efficacious in the patient population in which it is to be indicated. Points to be discussed when presenting conclusions on clinical efficacy are noted in Box 1.

Communication of the benefit risk profile...

Box 1: Critical evaluation of clinical efficacy

- Are the trial methodology and endpoints used for efficacy evaluation valid and relevant to the intended use?
- Is the population studied representative of the population indicated in the prescribing information?
- Are the methods of statistical analysis robust and appropriate?
- Is the size of the effect on efficacy variables shown to be clinically relevant?
- Is the medication effective in important patient subgroups? (e.g. young/elderly, males/females, normal/impaired renal function, normal/impaired hepatic function, disease variants, e.g. degrees of severity or commonly used co-medication)
- How does the choice of control groups (placebo and/or active) support the assessment of clinical benefit? (Comparison with an active control may help assess the overall clinical utility of a new product)
- Are the design of the clinical programme and analysis of the data in accordance with regulatory guidance (both published guidelines and any specific agency advice received during development of the product)?

If the clinical trial population was too broad and not homogeneous, i.e. there is clear evidence that there were groups of responders and non-responders, it might be possible to characterise the responder group, based on a measurable biological characteristic; a confirmatory clinical study in the identified subgroup could well be necessary. Alternatively, the prescribing information may need to recommend use of a trial with the drug, with discontinuation in case of poor response. (If the eligible population is defined too narrowly, e.g. in terms of a specific biomarker, patients who could benefit from treatment might be excluded unnecessarily.)

Patient Reported Outcomes

'Quality of life' assessment and other Patient Reported Outcomes (PRO) may contribute important evidence of benefit, provided that the instruments used are fully validated and appropriately applied [6,7].

Patient acceptability

Patient acceptability may provide a component of clinical benefit. For example, it may be possible to demonstrate that the new therapy contributes to a better clinical outcome by offering a more acceptable formulation or frequency of administration, resulting in improved patient compliance with medication compared with the existing standard treatment. Other patient benefits of a new product over existing treatment could include reductions in laboratory testing, dietary restriction or concomitant medication. For a new drug, such characteristics are unlikely to provide a sufficiently compelling benefit in the absence of an efficacy or safety advantage. However, there may be benefits of replacing an old formulation with an improved one.

Communicating clinical risk

At the time of submitting a marketing application for a new medicine, the extent of patient exposure is too limited to adequately characterise a low frequency ADR; hence the novelty of the compound itself constitutes a risk. The risk of a rare ADR can only be assessed with extended exposure in the post-marketing context, but other risks can be described on the basis of clinical trial safety data. For a new indication or formulation of an established product the risk may be more easily characterised using existing post-marketing data. Useful questions for the evaluation of risk are noted in Box 2 (for a detailed consideration of risk evaluation refer to the FDA Reviewer Guidance on Conducting a Clinical Safety Review [8]).

Box 2: Possible sources of clinical risk

- *What are the ADR observed in the clinical trial population?*
The evaluation includes analysis of adverse events (AE) in the entire patient population, in the population with the labelled indication, and in the subgroups that may have differing susceptibility to ADR, usually young/elderly, males/females, normal/impaired renal function, normal/impaired hepatic function, disease variants, e.g. degrees of severity, good/poor prognosis, and presence of commonly used comedications
- *Are there adverse effects that might be expected, based on the pharmacological activity of the product or class effects associated with related products?*
- *Are there unconfirmed safety 'signals' based on low-frequency AE observed in clinical trials?*
Such signals may not be fully characterised at the time of an application if they represent rare ADRs
- *Are there fatal AE or other serious or significant AE that warrant particular attention?*
AE that lead to discontinuation of treatment or require specific intervention, marked laboratory abnormalities, or potentially important abnormalities (e.g. a single seizure or syncopal episode) should always be fully discussed
- *Do variable bioavailability, drug interactions or other pharmacokinetic characteristics result in unpredictable exposure to the drug or an active metabolite?*
In assessing such risks, the focus should be on changes in exposure that are large enough to be clinically relevant
- *Do unwanted pharmacological effects occur at therapeutic doses?*
Unwanted effects may be either an exaggeration of the desired effect, or other effects, e.g. QT prolongation, sedation
- *Are there risks shown in toxicology studies in animals, but for which there may be no clinical evidence, e.g. carcinogenicity, or teratogenicity?*
The existence of biological data indicating that such a finding is species-specific is helpful in assessing the extent of the risk it represents, but a potential risk remains until there has been extensive exposure in patients, without ill-effect

>>>

>>> Communication of the benefit risk profile...

Risk Management

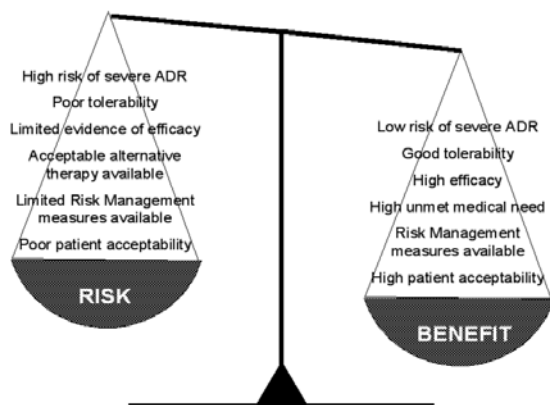
The team should address the question: “What measures are needed to minimise the risk of treatment?”

Availability of measures to mitigate known or potential adverse effects are relevant to the overall assessment of risk; e.g. a risk associated with variable plasma exposure to the drug might be overcome by dose adjustment, based on the results of monitoring drug effect or plasma concentrations, either at the onset of treatment or regularly throughout the time a patient receives the medication. Alternatively, it may be possible to identify a patient characteristic or a biomarker that helps to select at-risk patients so that they can be excluded from treatment. More usually, measures such as product labelling, prescriber and patient education, enhanced monitoring, or restricted prescribing are adopted to minimise risk (refer to the guidance on documentation of risk management measures [9-11]).

The key question: ‘Do the benefits outweigh the risks?’

Ideally, a new product should provide a high level of benefit with low risk. However, if the unmet medical need is high, a product with limited (but demonstrable) efficacy or a recognised risk may still be a useful medicine and receive marketing approval; major factors influencing the benefit risk analysis are shown in Figure 1.

Figure 1: Factors influencing the benefit risk analysis



In presenting the benefit risk conclusion, it may be helpful to consider the following points:

- How to compare benefits and risks? Some efficacy measures are less clinically significant and some risks are more acceptable than others – is there a single variable that can be applied that combines both benefit and risk, or is it possible to objectively apply ‘weighting’ in assessing benefits in relation to risks [2-5]?
- Is the benefit risk appropriate to the intended use?
 - If the unmet need is high (a serious or life-threatening medical condition, for which there is no effective therapy, or an existing therapy with poor safety), a greater level of risk, or greater variability in efficacy may be acceptable. If the unmet need is low

(a non-serious medical condition, or availability of an existing effective and well tolerated therapy), the efficacy must be higher and more reproducible, and risk must be lower.

- The evaluation should take account of whether the product is a preventive medicine or intended for treatment of an existing condition: for a preventive medicine it is important to weigh the risk of no, or inadequate, prophylaxis against the benefit risk of the medication, whereas for a treatment the question is how tolerable is the condition (or how beneficial and safe is existing therapy) compared with benefits and risks of the new product. Benefit may need to be greater and risk lower for a preventive medicine that may be used long-term by relatively healthy people.
- Has the correct dose been selected to optimise the benefit risk? The dose should be high enough for predictable efficacy, but with good tolerability and minimum risk of ADRs. Is dose adjustment needed to optimise benefit risk for some patient subgroups (e.g. those with intrinsic or extrinsic factors affecting drug exposure)? Would dose titration enhance benefit or reduce risk?
- Is benefit risk the same across the indicated patient population – are risks or benefits more evident in some subgroups? If the overall benefit risk balance in the clinical trial population is less favourable in relation to unmet need, is there a patient subgroup in whom the benefit risk may be more favourable, either because of a better response to the new treatment or because these patients are less well managed on existing treatment? In such a case, the indication might be adapted to maximise the benefit risk ratio.
- Do PRO and patient acceptability contribute to benefit, particularly for a medication intended for long-term administration?
- How might the product fit into current treatment guidelines—should it be adopted as first-line or second-line treatment?
- Do the measures needed to mitigate a possible risk require a high degree of physician education and patient understanding and compliance? A key question in evaluating risk management measures is “How effectively can risk management be applied?” Is the benefit risk acceptable in patients who may, for any reason, not comply with labelled precautions, or escape the risk management measures altogether?
- If the application is for a new indication or new formulation of an approved drug, does the new information alter the benefit risk profile?

At present, the benefits and risks of a new medicine are judged on the basis of analysis of clinical study data in the indicated population. For the future, the possibilities of individualised medicine—the ability to select patients who will benefit or exclude those who are at risk of a serious ADR – may result in a very different approach to analysis of benefit risk.

Conclusion

The Clinical Overview section of a Common Technical Document application for marketing authorisation represents an important opportunity for the applicant to present the benefit risk profile of a new medicine, in the context of current therapy for the indication and the unmet medical need for a new treatment. The approach to evaluating and documenting benefit risk, and providing a realistic appraisal of the place of the new agent in treatment protocols, will vary according to the type of medication and its intended use, and can be complex. However, using questions such as those described in this article, a Communicator working with the team responsible for authoring the Clinical Overview can make a significant contribution by facilitating the processes of critically evaluating a new product and describing its benefit risk profile.

Sarah Hemingway

Principal Medical Communications Scientist
AstraZeneca, UK.
sarah.hemingway@astrazeneca.com

Acknowledgements

I gratefully acknowledge the comments made by Dr Paul Gisby and Dr Peter Held during the preparation of this article.

References

1. International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH). The Common Technical Document for the registration of pharmaceuticals for human use. Efficacy M4E. Clinical Overview and Clinical Summary of Module 2. Module 5: Clinical Study Reports. (2000).
2. Holden WL. Benefit-Risk Analysis. A brief review and proposed quantitative approaches. *Drug Safety* 2003;26:853-62.
3. Beckmann J. Basic aspects of risk-benefit analysis. *Seminars in Thrombosis & Hemostasis* 1999;25:89-96.

A journal rejected your Nobel Prize paper?

Jan Miguel Campanario is looking for a journal to publish his research. His paper¹ has been rejected by 6 journals to date although it was mentioned in an editorial in *Nature*². His research was by questionnaire to winners of Nobel prizes. He found that 36 Nobel laureates had initially received rejections from scientific journals of their manuscripts relating to research for which they had subsequently received a Nobel Prize. In most instances he concluded the rejection had been because of resistance to scientific discovery. The reasons he put forward for this were:

- new theories or discoveries often clashed with the orthodox views held by referees
- referees did not appreciate the potential or interest of new discoveries because, e.g. they were not derived from accepted knowledge or did not relate to the current body of knowledge.

1 <http://www2.uah.es/jmc/nobel.html>

2 Coping with peer rejection *Nature* 2003;425(6959):645

Communication of the benefit risk profile...

4. Chuang-Stein C. A new proposal for benefit-less-risk analysis in clinical trials. *Controlled Clinical Trials* 1994;15:30-43.
5. Edwards R, Wilholm BE, Martinez C. Concepts in risk benefit assessment. A simple merit analysis of a medicine? *Drug Safety* 1996;15:1-7.
6. US Food & Drug Administration. Guidance for industry. Patient reported outcome measures: use in medical product development to support labelling claims (Draft, February 2006).
7. Committee for Medicinal Products for Human Use (CHMP). Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) in the evaluation of medicinal products (EMA/CHMP/EWP/139391/2004, July 2005).
8. FDA Reviewer Guidance: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review. February 2005. (<http://www.fda.gov/cder/guidance/3580fnl.pdf>)
9. International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH). Pharmacovigilance Planning (E2E) (November 2004).
10. Committee For Medicinal Products For Human Use (CHMP) Guideline on risk management systems for medicinal products for human use (EMA/CHMP/96268/2005, November 2005)
11. US Food & Drug Administration. Guidance for industry. Development and use of Risk Minimization Action Plans (RiskMAPs) (March 2005).

Ig Nobel weapons for author's editors

Medical literature is entrenched by an unnecessarily complex writing style, the aim of which is more to impress readers with the author's intellectual prowess than to enlighten them. The Ig Nobel Prize for literature this year should have important consequences for medical literature. The award was made to Daniel Oppenheimer, who is a professor of psychology at Princeton University in the USA, for his research report "Consequences of erudite vernacular utilization irrespective of necessity: problems with using long words needlessly" (*Applied Cognitive Psychology* 2006;20(2):139-156). Oppenheimer's findings show that readers believe authors who use simple, clear language to be generally cleverer than those who use unnecessarily long words and complicated language.

Oppenheimer presented students with samples of graduate school applications, sociology dissertation abstracts and translations of works by Descartes. He adjusted the text and font style to produce samples of the same text that were easy to read and samples that were difficult to read. Students rated the intelligence of the authors of the simple text as higher than that of those who had written the text that was difficult to read.

Sadly these findings are unlikely to deter authors from writing text that is difficult to understand, but they have potential in the armoury of an author's editor confronted with an author who insists that simple language is unscientific. And another piece of armoury, if anyone can find it, would be data that show papers with simpler wording have higher citation rates. Professor Oppenheimer told me that several people had mentioned such data to him but he has never seen an original paper reporting these results.

Elise Langdon-Neuner

langdoe@baxter.com

Results of the 2006 EMWA Salary Survey

by Kelly Goodwin Burri

The first ever EMWA salary survey was announced at the annual conference in Lyon this past spring. The purpose of the survey was to obtain data regarding the salaries of biomedical communicators for EMWA members. In addition to salary information, we also collected data on other factors that typically influence income levels, such as education, work experience, and type of employer. For the purpose of the survey, we defined a salaried employee as anyone employed by a company, institution, or individual and paid a salary or hourly wage. To open the survey, an email announcement was sent to all EMWA members after the Lyon conference providing information about the survey and a link to the online survey site. EMWA members meeting the definition of a salaried employee could participate in the survey between 6 June and 4 July 2006.

We had 230 respondents take part in the salary survey. Although not all respondents provided answers to all the survey questions, 208 provided usable data regarding their annual income and 180 included the country in which they primarily worked. Most respondents were located in the United Kingdom (75 responses), followed by Germany (46), and France (15). Responses were not limited to those working in Europe—medical writers in Japan, Singapore, South Africa and the USA also took time out to complete the survey. All salaries reported in non-Euro currencies were converted to Euros using the exchange rate from the day the survey closed (4 July 2006) as listed on the website www.oanda.com. This was necessary for about half of the respondents (primarily for those in the UK and working outside of Europe).

The majority of respondents were women (69.9%), had earned advanced degrees (61.2%) in the life sciences (71.4%), and had 2 to 5 years of relevant work experience (40.4%). Most worked for companies with more than 500 employees (66.8%), and the most common types of employers were pharmaceutical or biotech companies (52.9%) and contract research organizations (30.7%). More than 90% of respondents were employed full-time and the majority described their job title as medical writer (85.9%). Accordingly, most respondents spent the majority (one-half to three-quarters) of their time writing (42%); additional activities were fairly evenly distributed among the tasks editing, proof-reading, quality control, electronic publishing, supervision or administration, and training.

The average annual income of all respondents was €54,924 (median €50,000). However, there were relatively large variations in income depending on the respondent's amount of relevant work experience, type of employer, level of responsibility, and country or region of primary employment. Overall, men tended to earn more than women; the average annual income of the 58 male respondents was €65,625 (median €59,359), while the 145 female respondents reported an average income of €51,064 (median €48,000). This held true at all employment levels, with the largest difference between men and women evident with starting salaries. Entry level salaries averaged €51,986 for men and €35,915 for women, a difference of almost 45%.

The amount of work experience seemed to influence income levels more than the highest educational degree earned (Table 1). Exceptions to this were with entry level salaries (< 2 years' experience) and those with more than 15 years of work experience. Respondents with advanced degrees reported regular increases in salary with increasing work experience. The results were not so straightforward for respondents whose highest earned degree was a Bachelors or Masters degree; those with more than 15 years' experience were earning less than their colleagues in the 11-15 years' experience category. Medical writers just starting out (most respondents reported working in the field for 5 years or less) can expect to see increasing salaries as they build up more work experience.

Table 1: Income based on education and years of experience

Years' Experience	Bachelors or Masters Degree		Advanced Degree	
	Number of Responses	Mean Income (€)	Number of Responses	Mean Income (€)
< 2	18	38,142	25	46,195
2-5	30	49,448	54	50,483
6-10	14	54,985	28	59,390
11-15	7	82,038	13	74,634
> 15	8	60,366	10	86,986

Pharmaceutical or biotech companies employed the highest number of respondents in this survey and were also paying the highest salaries (Table 2). Communications and advertising agencies provided the second highest average compensation.

Table 2: Income by type of employer

Type of Employer	Number of Responses	Annual Income (€)		
		Mean	S.D.	Median
Pharmaceutical or biotech company	106	63,645	25,093	57,719
Communications or advertising agency	17	55,544	22,784	48,000
Contract research organization	67	43,235	14,797	41,414
Company offering medical writing services	6	42,211	8,468	41,125
Other*	12	48,631	16,438	44,423
All	208	54,924	23,143	50,000

*Category "Other" includes results with less than 5 responses: Academic, Charity, Consultancy, Government body, Hospital, Medical device company, Medical education company, Medical journal.

Increasing job responsibilities also clearly translated to higher salaries (Table 3). Respondents in senior level positions with management responsibilities reported earning more than double that of entry level medical writers. It is also interesting to note that men in the most senior level positions are earning approximately 30% more than their female counterparts (€100,500 versus €80,194).

Table 3: Income by employment level and supervisory or management role

Employment Level	Number of Responses	Annual Income (€)		
		Mean	S.D.	Median
Entry level	27	40,082	11,409	36,796
Middle				
No supervisory responsibilities	77	47,526	12,572	46,514
Supervisory responsibilities	29	52,406	16,687	50,000
Senior				
No management responsibilities	47	57,240	16,446	55,300
With management responsibilities	28	88,303	35,193	85,156

The highest average salaries were reported by respondents working in Switzerland, Scandinavia (results from Denmark, Finland and Sweden were pooled), and Germany (Table 4). No attempt was made to adjust the reported incomes with respect to the cost of living in the given country or region. Anyone now ready to move to Switzerland to work, be warned—it's not a cheap place to live!

Table 4: Income by country or geographic region

Country or Geographic Region	Number of Responses	Annual Income (€)		
		Mean	S.D.	Median
Switzerland	8	81,295	41,884	68,446
Denmark, Finland, & Sweden	13	61,336	14,306	60,327
Germany	46	60,486	20,440	56,450
France	15	55,477	33,151	47,000
Belgium	7	49,863	10,941	49,000
UK & Ireland	77	49,070	17,055	43,289
The Netherlands	5	43,931	14,610	39,295
All*	180	54,371	22,616	50,000

*Less than 5 responses each received from Japan, Singapore, Spain, South Africa, and USA; these data were only included in the overall tabulation.

Overall, job satisfaction was high among the survey participants. More than three-quarters of respondents were satis-

Results of the 2006 EMWA Salary Survey

fied with their current work (78.9%). Fewer were satisfied with their salary (57.7%), but that is still more than half of all respondents that were not complaining. Here's hoping that the rest who are not satisfied with their current salary will be able to use the survey results to make a case for a well-deserved rise!

Kelly Goodwin Burri

ZLB Behring AG
Berne, Switzerland
kelly.goodwin@zlbbehrling.com

The human side of editing a journal

Over the years that I worked as a managing editor I collected the 'human' phrases that popped up in exchanges with authors. Here is a small selection.

Editorial office question: "Please confirm that Prof X has consented to the quote of the personal communication".
Author answer: "I am certain that he will agree to my published attribution. He has such an ego, he will be flattered".

Fortunately there are some authors who accept suggested corrections.

Editorial office: "The adverb 'likely' should not stand alone. Either it should be qualified or another word substituted".
Author answer: "I think we can substitute 'likely' with 'possible'. Do not exitate to re-contact me if there will be any other problems".

Editorial office: "This is an unhappy sentence. Could you please rephrase..."

Author answer: "I like the concept of an unhappy sentence. It suggests possibilities of a semi-colon-leading to intestinal misery or of a hypoglycaemic comma or perhaps a terminal full stop as a result of syntactical suicide".

One of the hardest tasks is to solicit reviewers. A rare reply from a Greek reviewer to a request to review a manuscript: "I would like to thank you for the honor to be selected as a reviewer of your prestigious journal."

Another reply to a request to review: "I cannot review this paper which is totally out of my field of expertise. I do not even know what an 'otoacoustic emission' is.

A non-native English reviewer's comment to a non-native author: "The authors have to check spelling and grammer at many places. Titer is always spelt wrongly as titter throughout the manuscript".

There are even authors who appreciate your hard work: "I wish to thank you for your great task to edit our paper" (Japan).

And short and sweet: "You are an absolute angel!!!"

If anyone has any examples of similar exchanges with authors I would be delighted to hear from you.

Elise Langdon-Neuner

langdoe@baxter.com



Medical Writing Forum at the VII Meeting of Pharmaceutical Medicine (AMIFE) in Spain

by *Vicente Alfaro*

A forum on 'Medical Writing in Spain' was held on 16 November 2006 in Madrid during the VII Meeting of the Spanish Association of Pharmaceutical Medicine (AMIFE). This forum formed part of a more global discussion on 'Outsourcing in the Spanish Pharmaceutical Industry', which was moderated by José Javier García, president of the Spanish Association of Contract Research Organizations (AECIC). During his initial speech, José Javier García explained why it was time to discuss medical writing at a meeting of relevance in Spain such as AMIFE. Medical writing is today the third top niche clinical research organization (CRO) service (requested by 41% of the respondents in a CenterWatch survey) [1]. In fact, the greatest increase in CRO fees (more than 16%) was invested in the preparation of manuscripts for peer-reviewed journals. Data on benchmarking for CROs in Spain [2] have shown that the services of medical writing most offered in 2006 have been protocol writing (89%), final study reports (75%), manuscripts for peer-review journals (75%), and posters for scientific meetings (69%). These data agree with previous findings by EMWA freelance and small business surveys and with American Medical Writers Association (AMWA) surveys, and suggest that documentation related to clinical testing/further drug approval and peer-reviewed manuscripts constitute the most valuable services of medical writing worldwide.

The scheme for the forum was first, a presentation by a person from a pharmaceutical company (myself, Head of Medical Writing at PharmaMar); second, a presentation by a person from a CRO (Roser de Castellar, Medical Director at Trial Form Support Spain), and third, an open discussion. Before starting the presentations, three questions were asked to the audience to promote discussion. The first question was: do you prefer a medical writer (i.e. physician) or a writer of medical texts (including other academic background)? The most common response was that people prefer expert professionals, regardless of their background. Medical writing was defined as the activity of writing scientific documentation by someone who is a specialized writer (the medical writer) and who generally is not one of the investigators involved in the research. Thus, the medical writer is anyone engaged in communication in the medical or allied professions and sciences. The purpose of medical writing is to have a writing specialist working together with the people who produce the scientific data to create documents that effectively and clearly express the messages the data have to tell. The medical writer also

serves to make sure that the documents comply with regulatory, journal or other guidelines in terms of content, format and structure. Therefore, the medical writer was defined not only as a writer but also as an advisor in scientific communication.

The second question focused on authorship in scientific articles: ghostwriter or star writer? In other words, is the medical writer a person contracted to format results, without any further implications? Or perhaps the medical writer is an expert who fosters the spreading of results and, therefore, should sign as an author? The most frequent response was that medical writing tasks in peer-reviewed manuscripts should be openly acknowledged in a way agreed between the medical writer and the contractor. Apart from signing as an author in the byline, other possibilities discussed were an acknowledgment placed at the end of the article in a particular section, or in a footnote in the first page of the article. At this point, the EMWA guidelines and statements on the role of medical writers in developing peer-reviewed publications [3] were presented, and it was suggested that medical writers should be listed as authors only if they fulfill the criteria of the target journal [usually according to International Committee of medical Journal Editors (ICMJE) criteria] but bearing in mind that, as an author, the medical writer takes on public responsibility for the research.

The third and last question was: quality control or disaster prevention? In other words, does the medical writer, as an expert professional, assure the quality of the communication of results, or perhaps the function of the medical writer is to improve the presentation of results to make them understandable and communicable? In this third question, and contrary to what happened with the two previous questions, the audience showed a divided response, with almost equal percentages. This revealed a perception of the medical writer as an expert who improves the quality of texts, figures and tables, but also as a key professional who increases the success rate in document revision and approval. The difference between poor-quality and high-quality medical writing may mean the difference between a speedy and a delayed submission and approval of a regulatory dossier or of a manuscript in a peer-reviewed journal.

In the past, medical writing has been an underappreciated field by the Spanish pharmaceutical industry, but more recently it has gained attention as an important task in drug development by sponsor companies looking for faster, more efficient ways to bring new drugs to the market.

Medical Writing Forum

Moreover, since 2004 the current national legislation in Spain states that the sponsor is obliged to publish the results from clinical trials, both positive and negative, in scientific journals [4]. This new legislation will surely result in an increase in the publication rate and, therefore, in an increasing demand for medical writers helping in manuscript writing and/or editing.

Contrary to the information reflected in the EMWA [5] and AMWA salary surveys [6], most medical writers working in Spain are freelance or are based in CROs rather than in pharmaceutical companies. The reason for this is that medical writing departments are usually located in the headquarters of pharmaceutical companies and, therefore, they are in countries other than Spain, such as the United Kingdom, Switzerland, or the U.S.A. Most medical writers in Spain are not physicians, and scant information on medical writing is available at a national level. During the forum, the role of associations such as EMWA or the recently created Spanish Medical Writer Association (AERTeM, www.redactoresmedicos.com) in the training of medical writers was emphasised.

The overall opinion at the end of the forum was that medical writing is gaining a position in the Spanish pharmaceutical industry, although training programmes for new professionals (in English, such as the EMWA Professional Development Programme, but also in Spanish) are required.

Vicente Alfaro

Clinical R&D, PharmaMar, S.A., Barcelona, Spain.
valfaro@pharmamar.com

References:

1. Korieth K and Zisson S. JAMA Editorial Policy Questioned. *The CenterWatch Monthly* 2006; 13 (13):1 and 6-10.
2. www.pmfarma.com.
3. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the roles of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21:317-22.
4. Royal Decree 223/2004 regulating clinical trials with drugs. Article no.38. BOE no. 33, 7 February [RCL 2004, 325].
5. Goodwin Burri K. Results of the 2006 EMWA Salary Survey. *The Write Stuff* 2006;15(4): 133-4.
6. Gray, T., and Hamilton, C.W. Findings from the 2004 AMWA salary survey. *AMWA Journal* 2004;19(4):145-51.

Our client is the Swiss-based International Headquarters of one of the world's most prominent **biotechnology** companies, with the corporate mission to be the world leader in discovering, developing and delivering important and highly innovative human therapeutics. On behalf of our client, we are seeking the

International Headquarters Senior Publications Manager


In this high impact position you play a pivotal role in the publication of the company's key clinical and scientific data for the nephrology marketed and pipeline products. You are responsible for managing the execution of English-language medical/ scientific publications, including abstracts, posters, and oral presentations presented at congresses, as well as manuscripts and review articles. You will work closely with a cross-functional team as well as with external authors and investigators. You will also hire and supervise external vendors and contractors to assist you in the preparation of these materials, in addition to doing some writing yourself. To meet the requirements of this

Global Leader

company, you will have a degree in life sciences (PhD or MSc) and several years experience in medical writing or in medical communications within the pharmaceutical industry or in a medical communications agency. You demonstrate superb medical writing in English, excellent communication and managerial competence, combined with outstanding project management capabilities. In addition to this, you are proficient at multitasking, capable of coordinating and leading complex writing projects simultaneously, and able to successfully work in an international matrix environment. You like travelling.

Interested candidates are invited to submit their CV, letters of reference and writing samples.

Your application will be treated with strict confidentiality.

PP PHARMA  **PLANING**
B e r g a u e r + P a r t n e r A G
I n t e r n a t i o n a l H e a l t h C a r e R e c r u i t m e n t

Ms Regina Sager-Desserich
MA Law
direct dial: +41-61-261 94 17
Gerbergässlein 41
CH-4051 Basel
r.sager@pp-pharma-plan.com
www.pp-pharma-plan.com

ARCS Australia endorses ethical practices for medical writers¹

In Australia, members of the Medical Writing Educational Sub-Committee (MW ESC) of the Association of Regulatory and Clinical Scientists (ARCS) have issued a statement endorsing national and international guidelines on appropriate disclosure of medical writing assistance in biomedical publications (see box on page 138). In the medical writing arena, ghostwriting or ghost authorship is the act of preparing an almost final draft of an article before an author is identified—the author's name is simply used as a marketing tool. The implication is that the named author cannot take responsibility for the article because he or she had little or no input into its ideas. The result is headlines like *'Drug companies pay ghost—writers to write favorable reports about their drug.'* This type of ghostwriting or ghost authorship is seriously frowned upon by medical journal editors, medical professionals, the general public and, more importantly, professional and ethical medical writers. In short, it gives medical writing a bad reputation.

The distinction between professional medical writing and the unprofessional act of ghostwriting is becoming increasingly recognised. Medical writers can be legitimate contributors to articles as long as their roles and affiliations are appropriately described and acknowledged. This increases transparency, accountability and trust.

Medical journal editors are very much in support of professional medical writing. Associate Professor Karen Woolley, the president of ARCS and champion of professional medical writing in Australia, has published two articles on this topic in prestigious international journals [1,2]. In Karen's words, "this highlights that medical journal editors have recognised the legitimate role that medical writers have in working with authors to prepare articles for publication,

and identifies the relevant aspects of academic and industry guidelines for authors who work with medical writers".

Unlike other disciplines, medical writers do not have well-established codes to cover their professional interest area (e.g. ICH-GCP covers scientific and ethical standards for clinical researchers). However, there is no excuse for unethical medical writing as there are a number of international guidelines and recommendations for ethical writers to follow. The ARCS MW ESC is taking a stand and endorsing these guidelines. In doing so, we are sending a strong signal that we do not condone unethical medical writing practices. We hope that this statement will create awareness, promote best practice, as well as educate members on the various guidelines and expected practices that exist. Furthermore, we hope that it will incite ARCS members to spread the good word to other professional medical writers, thus leading the way for our profession in Australasia.

Acknowledgement: Special thanks to my fellow MW ESC colleagues who are passionate advocates of ethical and professional medical writing, and have been instrumental in getting this initiative underway.

Ruth O'Halloran

Ruth.O'Halloran@Pfizer.com

References:

1. Woolley KL. Goodbye ghostwriters!: How to work ethically and efficiently with professional medical writers. *Chest* 2006;130:921-3.
2. Woolley KL, Ely JA, Woolley MJ, Findlay L, Lynch FA, Choi Y, McDonald JM. Declaration of medical writing assistance in international peer-reviewed publications. *JAMA*. 2006;296(8):932-4. [These research findings were also presented in an oral plenary at the 5th International Congress on Peer Review and Biomedical Publication. The abstract is available at: <http://www.ama-assn.org/public/peer/prc2005prog.pdf> (pg 9; Day 1 of the Congress)].

¹ This excerpt is based on an article first reported in the Newsletter published by the Association of Regulatory and Clinical Scientists in Australia (O'Halloran R. Newsflash – A First for ARCS! ARCS Newsletter. 2006; 114:28-29).

You can get more than you bargain with jargon

I was reminded recently of a survey of a thousand office workers in Britain conducted in the year 2000. The survey found that two-thirds of office staff used unnecessary jargon terms. The reasons for using the terms were wanting to confuse opponents and seem superior. But attempts to seem superior can backfire. A colleague asked me what 'push back' meant. The only meaning I knew was 'the act of forcing the enemy to withdraw'. My colleague's boss had brought back the term from a recent meeting in the USA. Wanting to show how au fait he was with his American colleagues' jargon, in his next email he asked his correspondent for his 'push back' instead of using the common term 'feedback'. Barry Drees used 'push back' in a panel session at EMWA's recent meeting in Brussels, so I asked him what it meant. I learned that it is not something one asks for but is criticism of your proposal or whatever that you would prefer not to receive, i.e. that hits you back and might force you to withdraw.

Jargon mainly comes from business jargon used in

America. It might be interesting to do a survey to find why Americans are so fond of jargon, but that is another topic. The survey of British office workers found that 40% of them found jargon irritating and distracting, and 10% thought those who used jargon were pretentious and untrustworthy. Among the common phrases that were least understood were win-win situation, holistic approach, think outside the box, gap analysis, rain check, big picture, touch base, strategic fit and benchmark.

Michael Quinion, who reported on the survey in his Worldwidewords website¹, commented that the meaning of phrases like gap analysis for assessing untapped opportunities might not immediately be apparent, but benchmark has been in use in British English for many years and strategic fit is not so hard to figure out. Nevertheless they caused confusion. He recommends sticking to plain English, which could save embarrassment too.

Elise Langdon-Neuner

langdoe@baxter.com

¹ www.worldwidewords.org/articles/jargon.htm

Endorsement Statement

The members of the Medical Writing Educational Subcommittee of the Association of Regulatory and Clinical Scientists (ARCS) to the Australian Pharmaceutical Industry Limited have issued the following statement regarding appropriate disclosure of medical writing assistance in biomedical publications.

The need for appropriate disclosure of medical writing assistance and associated funding sources in biomedical publications has been highlighted in medical writing guidelines for the pharmaceutical industry (1) and in statements from medical journal editors (2-6) and medical writing associations (7,8). The principle of transparency, which these statements and guidelines reinforce, may help to distinguish legitimate, professional medical writing assistance from the unethical practice of ghost writing (4, 9-12).

As professional medical writers in Australia and New Zealand, we endorse the principles described in the:

- Good Publication Practice Guidelines for Pharmaceutical Companies (1).
- Position Statement on the Contributions of Medical Writers to Scientific Publications from the American Medical Writers Association (7).
- Guidelines on the Role of Medical Writers in Developing Peer-Reviewed Publications from the European Medical Writers Association (8).
- Uniform Requirements for Manuscripts submitted to Biomedical Journals: Writing and Editing for Biomedical Publication; Ethical Considerations in the Conduct and Reporting of Research from the International Committee of Medical Journal Editors (3).
- Medicines Australia Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results (13).

References:

- Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin.* 2003;19:149-154.
- Fontanarosa PB, Flanagan A, DeAngelis CD. Reporting conflicts of interest, financial aspects of research, and role of sponsors in funded studies. *JAMA.* 2005;294:110-111.
- International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication; ethical considerations in the conduct and reporting of research. Available at: <http://www.icmje.org/index.html#ethic>. Accessed November 1, 2005.
- World Association of Medical Editors. Policy statement – ghost writing initiated by commercial companies. Available at: <http://www.wame.org/wamestmt.htm#ghost>. Accessed November 1, 2005.
- Laine C, Mulrow CD. Exorcising ghosts and unwelcome guests. *Ann Intern Med.* 2005;143:611-612.
- Tierney WM, Gerrity MS. Scientific discourse, corporate ghostwriting, journal policy, and public trust. *J Gen Intern Med.* 2005;20:550-551.
- Hamilton CW, Royer MG; for the AMWA 2002 Task Force on the Contributions of Medical Writers to Scientific Publications. AMWA position statement on the contributions of medical writers to scientific publications. *AMWA Journal.* 2003;18:13-16.
- Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin.* 2005;21:317-322.
- Daskalopoulou SS, Mikhailidis DP. The involvement of professional medical writers in medical publications. *Curr Med Res Opin.* 2005;21:307-310.
- Jacobs A. Time for the ghosts to take on physical form. *Lancet.* 2004;364:487-488.
- Eaton L. Medical editors issue guidance on ghost writing. *BMJ.* 2005;330:988.
- Wager E. A concern that drug companies cannot ignore. *J R Soc Med.* 2005;98:448-450.
- Medicines Australia Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results. Available at: <http://www.medicinesaustralia.com.au/pages/images/Clinical%20Trials%20Principles.pdf>. Accessed June 9, 2006.

In and out subjects

Dear TWS

I was a bit surprised at Alistair Reeves changing inpatients and outpatients to insubjects and outsubjects [1]. Was he being slightly facetious?!

Richard Clark

Rac.clark@ntlworld.com

Reference

- Reeves A, A subject requiring great patience. *TWS* 2006;15(3):102-4.

Author's reply

'In(-)subject' and 'out(-)subject' do not, of course, exist. The intention was only to caution against using 'Replace all' in Word. I have seen some rather unfortunate results of using 'Replace all' without planning the 'replace strategy', including the first time I did this with 'subjects' and 'patients'. In a text with 'outpatients' and 'inpatients' (hyphenated or not, by the way—it's up to the author), I did a quick 'Replace all' with 'subjects' for 'patients' under the conditions described in the article, and then sent the protocol off for review, only to receive the comment: 'Do "outsubjects" and "insubjects" really exist? Is this something new in English?' Of course, I had forgotten that the terms 'inpatient(s)' and 'outpatient(s)' were mentioned in the protocol, and this had been changed to 'insubjects' and 'outsubjects', because Word just replaces the string of letters, regardless of the character(s) on either side (maybe there are some advanced features here I am not aware of). And I learnt by this mistake: before using 'Replace all', you have to think carefully about it—and it can become quite adventurous. The replacement procedure has to be done in several steps, and sometimes you also have to think of the logical order. In this case: (i) 'Replace all' with a space before lower-case 'patient' or 'subject', which catches all singular and plural mentions not at the beginning of a sentence or bullet point (these are not caught if you like to use hyphens, then you have to put a hyphen before each term—another reason not to use hyphens!); (ii) the same step with upper-case 'patient' or 'subject', because you may have used either word in the singular or plural at the beginning of a sentence or a bullet point; (iii) if you are going from 'patient' to 'subject', just to be sure, search 'in(-)subject' and 'out(-)subject' without specifying the case and correct manually. I'm sure our readers can think out any further steps for themselves. You obviously have to look carefully again when reading through—but I bet that 'Search and replace' in Word is more reliable than your eyes at the end of a long day. As boring as it may be, I usually don't do this with 'Replace all' anymore, but just with 'Replace', and check every single mention. Anything you don't notice should be picked up by your eagle-eyed QCers. All part of the daily perils of the medical writer.

Alistair Reeves

a.reeves@ascribe.de



More myths about English (3)

by Alistair Reeves

I promised you more myths about English [1, 2] after my first 10 (if you would like to know why I wrote a digit here and not 'ten', see 'Myth 1' [1]). Here are a further 5. More will follow. The list is not short!

Myth 11: 'e.g.' and 'i.e.' must be followed by a comma

Eagle-eyed readers of my previous two 'myths' articles will have noticed that I do not put a comma after 'i.e.' or 'e.g.'. If anyone can give me a good reason why they **must** be followed by a comma, other than a questionable convention, I am prepared to revise my opinion that the use of the comma after both is a complete waste of time. This may be because I still prefer to use both with full stops. 'E.g.' means 'for example' ('exempli gratia' in Latin) and 'i.e.' means 'in other words' ('id est' in Latin) or similar. When I write 'for example'—and on the extremely rare occasions when I use 'in other words'—they may well be followed by a comma, but this not reason enough to follow 'e.g.' or 'i.e.' with a comma: full stops at the end of both obviate the need for a comma as far as I am concerned. There is also my usual good reason for not using a superfluous punctuation mark here: if you don't do it, you don't have to check you have done it every time! But if your boss wants it, put it!

By the way: I think it is still preferable to use two full stops or periods with 'e.g.' and 'i.e.'. Some writers and journals are proponents of 'eg' or 'eg.' and 'ie' or 'ie.'. I don't like either of these aberrations, but say: 'Live and let live'—just be sure you are consistent.

Also, every time you use 'e.g.' or 'i.e.' check carefully that it is correct. I often see them confused, and have to check myself that I have not mistakenly used 'i.e.' when I actually wanted to say 'e.g.'.

Myth 12: 'Utilise', 'make use of' and 'employ' should be preferred to 'use' in certain contexts

My advice: **always use 'use'!**

The reader will understand exactly the same if you give preference to 'use' in almost all situations. Consider the following:

- We decided to **use/utilise/make use of/employ** her extensive experience with manic-depressive patients when formulating our new guidelines.
- How did you **use/utilise/make use of/employ** your results?
- We **used/utilised/made use of/employed** straight-sided titanium crucibles.

The very fact that 'use' has only one syllable is enough to put many writers off. It sounds just too plain and simple. But why use a polysyllabic word or phrase when a monosyllabic word does **exactly the same job**? Our business should be simplicity. This is rather like saying 'to initialise a study' when you just mean to 'start' it.

Dictionaries tell you that utilise means 'to turn to use' (whatever that means), 'to make practical use of' (that's a little better), or 'to use effectively' (at least this means something, but if you 'use' something, don't you expect it to have an effect?). There are those who claim that 'utilise' is therefore sometimes better than 'use' and that the subtle difference is **vital** to the reader. This is one subtle difference I don't seem to be able to appreciate. Don't ever write 'make use of' in our context. Reserve 'employ' for when you pay a person to do something. And it should not be necessary to worry whether 'use' might be misunderstood to mean 'take advantage of' or 'exploit' (an argument often used against 'use' by 'utilisers'), because if this what you want to express, in our context at least, you should be using 'take advantage of' or 'exploit'. And remember: 'exploit' is not always negative!

Myth 13: It is better to write 'First', 'Second', 'Third'... rather than 'Firstly', 'Secondly', 'Thirdly'... when enumerating points

It is not better. Some say avoid this altogether, but sometimes it is quite important to enumerate in this way. The reader understands exactly the same thing, whether you use the adjective (functioning here as an adverb) or adverb (-ly). It is pompous to insist that the adjective is linguistically better (it **is** shorter though, and I'm always in favour of that, as you know by now). Remain consistent. Don't go beyond 'thirdly' ('fourthly' and above start to sound progressively ridiculous). Be sure that you are actually enumerating one point, then another, and then another (if you write 'Second(ly), ...', make sure you have a 'First(ly)', otherwise you put the reader in the annoying situation of having to backtrack to count). This is rather like making the reader hunt around for the 'one hand' when you use 'on the other hand' without making sure that you have mentioned the first hand beforehand. Or the reverse! Watch out for this one too. If I have my choice, I don't use 'on the one hand' and 'on the other hand' when writing.¹

¹ Note for German speakers: do not use 'on the other hand' for 'dagegen' unless you have said 'on the one hand' before this. Best is to avoid any mention of hands at all.

More myths about English

Myth 14: Generic names of pharmaceutical products are written with lower case letters

This is dead simple. US English uses upper case for generic names (e.g. Ramipril) and British English uses lower case (e.g. spironolactone). But maybe it's not so simple: I have no idea what writers in other English-speaking areas do, such as the Irish, Australians, Canadians, and South Africans (I suspect usage is inconsistent everywhere). Please let us know!

Myth 15: British English is better than American English

The only answer to this is a resounding NO IT IS NOT! I include this myth because I was recently confronted again by the naïve opinion that we British have a monopoly on good English. This once got me into a very embarrassing situation. A German-speaking colleague asked my Irish room neighbour at work how to say something in English, and got a perfectly good answer. Then, with the Irish colleague in tow, went to an American colleague in our building and asked the same question. The American colleague also gave a perfectly good—but different—answer. Then the German colleague came to me, with both in tow, having said (the Irish colleague told me afterwards): 'Jetzt gehen wir zu Herrn Reeves—er ist ein richtiger Engländer' (*Now we'll go and ask Mr Reeves—he's a real Englishman*). If ever the diplomacy required of a medical writer was 'heavily challenged', this was one of those situations. I deliberately opted for a different solution so as not to pique either the Irish or American colleague, but left the final decision to our German colleague, reminding him that all three solutions were just as good as each other.

Just whose language is English these days? OK—so the spelling in US and British English differs (I would switch to American spelling tomorrow. When I say this, some of my British colleagues throw up their hands in horror. But we are only talking about black marks on paper to convey a message, or nowadays a computer screen). The fact is: whoever writes English, if they write well, it is good. And if it is written well, you will hardly notice a difference, whether it is written by a person who grew up in Britain, the USA, Canada, South Africa, New Zealand, those from Mumbai who first learn English, or by someone in Singapore, Malaysia or Hong Kong who had all their schooling in English, but may have spoken Mandarin or something else at home. The accent is on **'if it is written well'**. And those who grow up in Britain also have to **learn hard and long** how to write well. English in our context is also no longer the preserve of 'native English speakers'. I am sure there are more medical writers in Europe whose native language is not English who manage to do a perfectly good job, and there are people who can write very well, but not speak so well. Speaking is a very different matter!

Alistair Reeves

Ascribe Medical Writing and Translation, Wiesbaden, Germany
a.reeves@ascribe.de
<http://www.ascribe.de>

References:

1. Reeves A. Myths about English. *TWS* 2006;15(1):22-4.
2. Reeves A. More Myths about English. *TWS* 2006;15(2):58-60.

Free dictionaries of medical and difficult words

The Farflex free medical dictionary uses Houghton Mifflin's *The American Heritage Stedman's Medical Dictionary*, Second Edition as its main source. It describes this dictionary as staying clear of jargon, and thus offering fast and concise information, whether the user is searching for a description of an over-the-counter or prescription medication, a medical abbreviation, a test procedure, a medical research topic, a noted medical personalities or an illness. Over 45,000 entries from all areas of medicine and healthcare are included.

<http://medical-dictionary.thefreedictionary.com/>

The dictionary of difficult words website introduces itself with the following:

"Do you aim to become a member of the literati, or do you wish to be a savant? Do you want to avoid being verbigerative and be succinct instead? Search the Hutchinson Dictionary of Difficult Words' A-Z index of over 13,900 difficult words to increase your vocabulary or just find out what those words really mean!"

<http://www.tiscali.co.uk/reference/dictionaries/difficultwords/>

**Committee on Publication Ethics (COPE) – Seminar 2007**

9.30am–4.30pm Friday 16 March 2007, BMA House, London, UK

The theme of this year's seminar is "How can editors and publishers encourage ethical behaviour and transparency?", with the emphasis very much on prevention. Invited speakers will discuss authorship problems, plagiarism and image manipulation. The new features of the COPE website will be demonstrated with interactive workshops on common ethical and editorial dilemmas.

Editors, authors and all those interested in improving the standard of publication ethics are welcome.

The seminar will include:

- A publisher's perspective from Chris Graf of Blackwell Publishing Ltd
- Ana Marusic (Croatian Medical Journal) will discuss how form design affects authorship declarations
- What's in a picture? The temptation of image manipulation
- Recent developments in plagiarism detection software
- COPE's new website features – including COPE's new flow charts
- Interactive workshops on duplicate publication, authorship disputes, fabrication of data, plagiarism and unethical research.
- Opportunities to network with other editors and share your experiences and challenges

The seminar is free for COPE members and £30.00 for non-members. Numbers are limited and early booking is advisable. For registration or more information please contact the COPE Secretary at cope@bmjgroup.com or call 020 7383 6602.

For more information on COPE see www.publicationethics.org.uk

Time and time again

by Alistair Reeves

Just like the date [1], such an apparently simple matter as the time still causes much consternation amongst writers. Time is not a simple matter, especially in laboratory, pre-clinical, and phase I studies, and can wreak havoc if not properly expressed in other documents, such as conference programmes. Here my answers to some very FAQs subsumed under: ‘How do I express the time correctly?’

Should I write am and pm, a.m. and p.m., A.M. and P.M., or AM and PM? Let me be quite honest: why does the concept of antemeridiem (am) and postmeridiem (pm) still exist? The prime reason is that, like degrees Fahrenheit and gallons amongst others, ‘am’ and ‘pm’ are still in standard use in the USA, and, whilst the British seem to have switched to degrees Celsius and the metric system in general (except for units of length and the indestructible ‘pint’), ‘am’ and ‘pm’ are still in use in the UK. They are also still used in a few other countries, notably Mexico—to my surprise, on a recent visit (I’m not sure about Canada). It is not because this is a practical way of expressing time in our context. I would do away with it tomorrow.

Why bother with digits **and** letters for time when four digits—with a bit of punctuation, if you want—do it all, especially when writing?

With or without full stops or periods, whether capitalised or not—all versions of ‘am’ and ‘pm’ given in the heading of this section are correct; you just have to be consistent within one text. My advice, however, is: never use ‘am’ and ‘pm’ in medical and scientific writing. If I have to use them, I prefer ‘am’ and ‘pm’. You may see the abbreviations ‘am.’ and ‘pm.’, but these are not acceptable; they are aberrations, like ‘eg.’ and ‘ie.’

Is there a space after the last digit of the time and the abbreviation ‘am’ or ‘pm’? 2.43 pm or 2.43pm? It doesn’t matter. Be consistent. I prefer a space (remember to use a non-breaking space: usually << control + shift + spacebar>> in Word), but note that many other writers seem to dispense with the space.

Do I need a leading zero? Not with ‘am’ and ‘pm’. Leading zeros are necessary only with the 24-hour clock (see ‘**How do I write the 24-hour clock**’ below) and look very strange with times using ‘am’ or ‘pm’.

Do I separate the digits used for the time with a full stop or a colon? It doesn’t matter, whether you are using ‘am’ and ‘pm’ or the 24-hour clock. Be consistent. But when using ‘am’ and ‘pm’, a full stop is more common. Never use a semi-colon or a hyphen.

Do I write 2.(:)00 pm or just 2 pm? It doesn’t matter: you either need the punctuation plus two zeros or nothing. Be consistent. Being consistent, however, means that if you have times other than whole ‘clock hours’ in your text (e.g. 2.30 pm), you should also write 2.00 pm. Whatever—when speaking, you just say: ‘two-pee-em’ or ‘two thirty pee-em’.

Is there a difference between the way I express the time when speaking and writing? Yes, there is a big difference. The way this is expressed is influenced by what you are doing, the time of day you are speaking, your language group, and by timetables. **See also the ‘Warning’ below.** When speaking, we usually use times in the context of a conversation, whether for business or pleasure. If you are speaking to a colleague about a meeting, you don’t usually say: ‘I’ll see you at sixteen hundred hours tomorrow’, because, when you say what is more usual: ‘I’ll see you at 4 (o’clock) tomorrow’, a business meeting is not normally expected to be at ‘four in the morning’. You might follow up your conversation with an Email and write: ‘I’ll meet you as agreed at 16(:)00 tomorrow’. You may, of course, be meeting a colleague at 04:00. If so, you would probably qualify the time with ‘in the morning’, and might prefer not to follow this up with an Email.

Times that might be confused (usually early morning or early evening), are generally qualified by saying ‘in the morning’ or ‘in the afternoon’ or ‘in the evening’ or sometimes by adding ‘ay-em’ or ‘pee-em’ when speaking. However, if you ask your colleague when her train is leaving for Milan, she may well say: ‘It leaves at sixteen forty-three’ and not at ‘four forty-three’ or ‘seventeen minutes to five’, although all are just as good as each other. These days in English, at least in Europe, people often speak of travel times using the 24-hour clock, especially if they are not round numbers. If you have flown in North America, you may have noticed it says ‘9.43A’ or ‘9.43P’ on your

1 Note the first ‘e’ (not an ‘i’) in ‘antemeridiem’, and both end in ‘-iem’ and not ‘-ian’. Depending on the dictionary you consult, both terms can also be written with a space after ‘ante’ and ‘post’.

Time and time again

ticket. The 'A' and 'P' are the arbitrary abbreviations used by North American airlines (not only USA) for 'am' and 'pm' (wouldn't 09:43 and 21:43 be so much easier?), and resulted in my having to explain to a colleague here that they are not appropriate for our context 'just because the North Americans do it this way'.

What does 'o'clock mean', and is there a space after the apostrophe? This is the abbreviation for 'of the clock', and there is no space after the apostrophe. It should never be used in scientific or medical writing unless you are quoting verbatim, e.g.: 'I first noticed the rash at 10 o'clock in the evening'. 'o'clock' is used when speaking, using reported speech, or in literature.

How do I write the 24-hour clock? When I was a child travelling on the Continent in the 50s and 60s, this was 'one of the BIG differences' from Britain that added to the excitement—the 24-hour clock! But what a practical institution it is (and the British seem to have grasped this now): always four digits (you always need leading zeros) with a separator of your choice after the first two digits (or no separator if you prefer)—and you have it! No messy 'am' and 'pm'.

Incorrect	Correct
14:25 h, 14.25 h, 14:25 pm, 14:25 o'clock, 2 o'clock pm, 2 pm o'clock, 02.25 pm	14:25, 14.25 or 1425

Look at any train, air or other timetable and you will see that punctuation after the first two digits has largely been dropped (I suspect to save space and ink, but also because it is completely obvious that 'clock time' is the issue). It works, and everybody understands it. I haven't yet managed to jettison the colon in my writing. But what you **never** use when **writing** the 24-hour 'clock time' in English is any abbreviation or complete word for 'hours' afterwards, because this is incorrect. You may add 'hours' when speaking: 'fourteen hundred (hours)' for 14:00 or 'oh-two hundred (hours)' for 02:00 are perfectly acceptable, but sound rather military, or like 'Mission Impossible'.

So what does 14:25 h mean? It means a period lasting fourteen hours and twenty-five minutes, and not twenty-five minutes past two in the afternoon. The 'h' is the SI unit for hour, so by adding the 'h' you are actually expressing the **duration** of a period and not a 'clock time'. There is no need to write 14 h 25 min (not incorrect), but it is best to use the colon here to avoid confusion with the decimal point: is 14.25 h fourteen hours and fifteen minutes or fourteen hours and twenty-five minutes?

I digress: 'h' is the SI unit for time and **not** 'hr' (often still used by writers of US English). 'hr' should therefore never be used in scientific texts. Since SI units are never used in the plural, this also applies to 'hrs'. And while we are on this subject: 's' is the SI abbreviation for seconds, and not 'sec'. And—French speakers take note: 'min' is the SI abbreviation for minute and not 'mn'.

What do 12:00 am and 12:00 pm mean? A prime example of a question that is a total waste of time in our context. Nobody will ever agree on this one—an utter lost cause. Use midday (or noon) and midnight when speaking, and you never have any problems.

If you have a list of sampling times in a study protocol, it will be clear from the context, e.g.: 'Blood samples will be taken at 8.00 am, 8.30 am, 9.00 am, 10.00 am, 11.00 am, 12.00 am, 1.00 pm, 5.00 pm, 9.00 pm, 12.00 pm, and 8.00 am'.

Anyone who says that they understand this to mean that there is a gap of 13 hours between 11.00 am and 12.00 am is being deliberately awkward (and we unfortunately all know someone who is so conspicuously awkward, who will probably also say that there is a gap of 15 hours between 9.00 pm and 12.00 pm!). In this case you may choose to acquiesce and write '12 midday' and '12 midnight'.

Which is correct: 00:00 or 24:00? Also a pointless question in our context. Don't even start to discuss it. It will be obvious from the context.

The list of times for the above example using the 24-hour clock would read: 08:00, 08:30, 09:00, 10:00, 11:00, 12:00, 13:00, 17:00, 21:00, 00:00 or 24:00, and 08:00.

Nothing for your conspicuously awkward colleague to seize upon here—except for the possible discussion of whether it should be 00:00 or 24:00. As I say—don't go there: just agree and be consistent.

What is 12 o'clock? Should never be used when writing in our context, except for verbatim quotes. Spoken, it means midday/noon or midnight and, when speaking, it should be clear from the context. If not, then say 'midday/noon' or 'midnight', 'twelve o'clock at night' or 'twelve o'clock in the morning'.

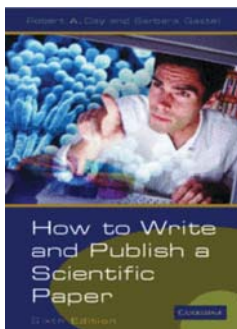
Warning: If a British person says to you 'I'll see you at half-seven', this means that they intend to meet you at 07:30 or 19:30 and **not** at 06:30 or 18:30. This is the colloquial way of saying 'at half-past seven'. It will usually be qualified by 'in the morning' or 'in the evening' if it is not clear. If an American says to you 'I'll see you at a quarter of ten', this means they intend to meet you at 09:45 or 21:45. This is not colloquial, and does not exist in British English. Also, the Americans will also often say 'a quarter after ten'. This is, of course, understood by British English speakers, but they say 'past' and not 'after'.

Alistair Reeves

Ascribe Medical Writing and Translation
a.reeves@ascribe.de
<http://www.ascribe.de>

Reference

1. Reeves A. Dating made easy....TWS 2006;15(1):25–6.



In the Bookstores and on the Net...

A classic expanded and updated

by Karen Shashok

Robert A. Day and Barbara Gastel. *How to write and publish a scientific paper*, 6th edition. Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore, São Paulo: Cambridge University Press, 2006. ISBN 10 0-521-67167-1 (Paperback). GBP 17.99, EU approx. 25.00, US\$ 27.99. 303 pages.

Barbara Gastel, professor of sciences and editor of *Science Editor* (published by the Council of Science Editors), has used her experience training researchers in the USA and abroad to write effectively, along with her knowledge of twenty-first-century media, to expand and update the classic *How to write and publish a scientific paper* originally authored by Robert Day, a professor of English who has served as Director of ISI Press and managing editor of *Journal of Bacteriology* (published by the American Society for Microbiology). The sixth edition of this classic consists of a preface and two brief preliminary sections, 41 concise chapters grouped into eight parts, and three appendices followed by a glossary, list of references, index, and biographical notes about the authors.

As in previous editions, the chapters are short and focussed. The desirable features of each type of written communication are identified and discussed briefly. All elements of manuscripts for journal publication are covered, from title page to figures and tables. Also included in this edition are chapters on other writing-based 'services' scientists contribute to their community, such as peer reviewer's reports and letters of recommendation. In response to recent changes in publication processes and media, advice has also been added on new modes of communication such as e-mail and the Internet. For example, in Chapter 33, 'Writing clearly across cultures and media', the section 'Writing for online reading' (p. 214) provides sensible, easy-to-apply advice that will make the reader's job easier. Blog and listserve postings are not mentioned though, probably because they are not yet widely considered avenues for career-enhancing publication (although there are signs that professional 'discrimination' against electronic media may be disappearing, at least in some disciplines).

This edition also offers help for writers whose first language is not English. Awareness that colleagues from a non-anglophone background may use this book is a welcome feature that acknowledges the increasing participation of these researchers in the creation and dissemination of new knowledge.

Specifically, Chapter 34 ('How to write science in English as a foreign language') is aimed at readers and writers who use English as their second language. To readers of *TWS*,

the authors may sound overly optimistic about journals' willingness to copy edit texts in which the English requires more than a light edit. Perhaps editors' reluctance is more obvious in health science publications, where warnings that authors ensure the material has been edited by a native English speaker before it is submitted have become frequent lately. Fortunately, the optimism is tempered in the section 'More strategies for English-language writing', where the authors advise writers to seek help from a competent editor before submitting their paper:

"Indeed, if a paper seems to contain good science but is written in poor English, a journal may return the manuscript and suggest that it be edited by someone expert in English and then resubmitted. If possible, the person providing feedback on your writing should be familiar with your field of science. Otherwise, although the person may correct grammar problems and other mechanical errors, he or she might not detect errors in scientific expression—and might inadvertently introduce errors (such as when one editor repeatedly changed the technical term 'contracture' to 'contraction')" (p. 219).

The section headed 'Cultural differences to consider' (pp. 217-8) is helpful and should be read by journal peer reviewers, editors, and copy editors. It is reviewers and editors, not authors, who need to increase their awareness of some of the cultural differences in how science is thought about and written, and who need to ask themselves how flexible they could be (as long as the scientific content is easily understandable) in allowing some departure from expectations shaped by their own cultural background and scientific or editorial training (or lack thereof).

Relevant to the issue of differing expectations for how writing should 'sound' is Day and Gastel's word of caution to native users of English not to overestimate their writing skills: "If your native language is English, you still may have a problem because the native language of many of your readers is not English" (p. 185). This is a wise reminder that in science, simple, direct language is the most effective way to communicate, because no researchers (regardless of their first language) have time to spare to struggle with unclear texts. Day and Gastel use many examples to show how easily meaning can become muddled when the use of English becomes careless—as it often does in the hands of native speakers, and as it can if the quality of translation is inadequate. Appendix 2, 'Words and expressions to avoid' (pp. 265-272), should become a standard tool for all scientific-technical-medical copy editors,

and is well worth consulting by researchers and others who wish to communicate successfully in 'good scientific English'.

The authors are careful to point out potential pitfalls connected with many of the different communication challenges, and urge readers to act conscientiously. Ethical issues come up throughout the book, and are handled clearly and sensibly.

The 'Glossary of technical terms' would have benefited from a more thorough update. For example, 'Dual publication' is defined misleadingly (p. 276) as 'Publication of the same data two (or more) times in primary journals. A clear violation of scientific ethics'. Publication of the same data under certain circumstances (e.g. in English and in the authors' first language when this is not English) is in fact considered justifiable and ethical by the International Committee of Medical Journal Editors (www.icmje.org) and other authorities. Terms referring to new media and technologies (Listserve, PDF, PowerPoint, Online submital, and Weblog, for example) are missing, whereas 'Camera-ready copy' is one of the entries that might be ready for retirement.

The humour scattered throughout the book may not be appreciated by readers whose first language is not English. Inability to apprehend the humour may be a disincentive to authors with a different first language who hope the book will train them in the skills needed to compete for the attention of their international peers.

The book is an excellent self-help reference for researchers who write, and could be used as a course book or as a supplementary text for doctoral programmes that aim to train researchers in basic publication skills. It is also worth consulting by scientific-technical-medical translators and editors-in-training, because it provides an efficient, solid introduction to science 'genres', and contains useful guidance on scientific writing and style in Part VII.

Experienced authors' editors, translators, and medical writers may find that coverage of some topics is too general to be useful. (For example, regulatory documents and reports of clinical trials are not covered specifically, and the index contains no entry for 'clinical trial'.) Seasoned medical writers are likely to find they need more specific sources such as Instructions to Authors, a discipline-specific style manual, regulatory authority guidelines, etc., for advice on the preparation of the documents they work on. However, *How to write and publish a scientific paper* is targeted not to medical writers, but to scientists and students in all areas, and thus aims to offer basic principles that can be used in all disciplines of science. For these users it can be highly recommended as a complete guide to the types of writing they will be expected to become competent in if they wish to become fluent in good scientific English.

Karen Shashok

Translator—Editorial consultant
Granada, Spain
kshashok@auna.com

You can decrease a patient's temperature

Dear TWS,

I agree with Elise Langdon-Neuner and David Loshak that 'prospective trial' is indeed a pleonasm (trying to correct this, however, is a 'lost cause'), but I am afraid I have to disagree with Elise who concurred in the last issue of TWS [1] in saying that 'decrease is an intransitive verb', and does not allow the possibility that it be used transitively. Not only according to me, but the Oxford English Reference Dictionary [2] and the Shorter Oxford English Dictionary [3], 'to decrease' is both transitive and intransitive, and was first documented with transitive use by the latter in 1470 (I appreciate that this could have changed since 1470, but I have been using it transitively for years, as have many others).

Elise says you can say 'to cause something to decrease'—and this is the definition for transitive use given in the Shorter Oxford English Dictionary [3]. If you are defining something in a dictionary, that sort of description is acceptable, but for me (thanks to Guy Whitehead of AMWA), this is a classic example of the active linking 'voice', which means combining a 'neutral' verb indicating activity (in this case 'cause') with a noun ending in '-tion' or '-ment' (or other endings) or an infinitive (in this case 'to decrease') which actually indicates the action that you wish to convey—and can always be expressed more concisely. So I have no problem with: 'We gave paracetamol and decreased the (patient's) temperature from 39.5°C to 38.0°C.'

Elise also says: 'Decrease suggests a progressive decline', specifically in relation to temperature, so suggesting—because the body temperature does not usually decrease very quickly (i.e. within minutes)—that the use of 'decrease' indicates that this was not rapid. But isn't any directional change 'progressive', however fast or slow it is? And shouldn't you add an adverb if you wish to indicate a degree of speed, unless the verb used really does include an idea of rapidity? You might think the word 'drop' means quickly. But consider the following: 'His temperature dropped from 40.1°C at 20:15 on 2 January 2005 to 38.5°C on 08:15 on 3 January 2005'. A decrease of 1.6°C over 12 hours: not exactly rapid, but adequately expressed.

Elise points out that 'fall' is intransitive. This is definitely the case: you cannot 'fall' a patient's temperature', but their temperature can 'fall'.

Alistair Reeves

a.reeves@ascribe.de

References:

1. Langdon-Neuner E. You can reduce but not decrease a patient's temperature. *TWS* 2005;15(2):61
2. Oxford English Reference Dictionary. OUP 1996
3. Shorter Oxford English Dictionary. Clarendon Press, Oxford, 1996

**Webscout:**

Viennese spring

By Elise Langdon-Neuner

Joeyn Flauaus, our Webscout columnist, has taken a rest for this issue of *The Write Stuff*. As I am a native of Vienna I have compiled a list of websites to help you plan ahead for the EMWA 2007 Spring conference (22-26 May). Combining the conference with a long weekend in Vienna would make a super spring break. There's so much to see and it's difficult to know where to start!

General information

www.vienna.info

The official site of the Vienna tourist board

www.wien.gv.at

The official site of the city of Vienna

www.wienerlinien.at

The official site of Vienna's (excellent) public transport system

www.timeout.com/travel/vienna

TimeOut is a frank guide to what a place is really like and avoids 'touristy gloss speak'. The chapter on literary Vienna should be of interest to medical writers.

www.virtualvienna.net

Although this site is for the expatriate community in Vienna it has some useful information. In particular there are some interesting articles in the writer section. I can recommend the articles on legends and oddities by Bill Ann Lopez, especially 'The puzzle on Vienna's Baeckerstrasse'. If you go (less than a 10-minute walk from the Marriott) to see the fresco she describes be sure to call in at No 7. Vienna has many delightful Baroque and Biedermeier (17th-19th centuries) courtyards but the one at No. 7 Bäckerstrasse dates from 1587 and is a rare example of Renaissance in Vienna. Signs of the original stables are also recognisable. If you have already visited Vienna and think you have seen all the sights, the book 'Only in Vienna', which is described under Duncan Smith, the author's name, in the website's writer section, will make you think again.

Ticket sites

www.wien-ticket.at www.viennaclassic.com

www.oeticket.com

Marriott Hotel

www.viennamarriott.com

Vienna is a compact city with most of the sights concentrated in the 1st district, its centre. The Marriott hotel, which is the venue for the spring conference, is located on the Ringstrasse delineating this district. It is within easy walking distance of the shopping centre as well as almost all of the sights. Schönbrunn palace is outside the centre but can be reached directly by underground from the station in the Stadtpark (good for runners) opposite the hotel. The Ringstrasse takes in many of Vienna's famous buildings: Parliament, Burgtheater, Votivkirche, University, Rathaus (town hall), and Kunsthistorisches and Naturhistorisches museums. In typical Viennese 'gemütlich' (comfortable/cosy) fashion all you have to do to see these sights in one fell swoop is sit on a tram which will take you full circle around the Ringstrasse: No. 1 tram in the clockwise direction and No 2 tram in the anticlockwise direction.

Three star hotels

The following three star hotels are within walking distance of the Marriott Hotel.

Hotel Austria: www.hotelaustria-wien.at

Hotel Kärntnerhof: www.karntnerhof.com

Hotel Post: www.hotel-post-wien.at

Hotel Wandl: www.hotel-wandl.com

Kunsthistorisches (art history) Museum

www.khm.at

The conference gala dinner will be held at the Kunsthistorisches Museum. The museum houses what is considered to be the world's fourth finest art collection. The highlights are its 15th-18th century Old Masters including Titian, Bruegel and Velásquezhis. The Egyptian collection is also remarkable. By the beginning of January the homepage should list the special exhibitions for May 2007.

Walking tours

www.wienguide.at

A walking tour on a topic relevant to medical writers will be offered as part of the social programme of the conference but if you are interested in joining other tours this is the site to find them.

Webscout:**Staatsoper (State Opera)**www.wiener-staatsoper.at

The original opera was built in 1869. The critic it received drove one of the architects to suicide. Bombing in World War II almost completely flattened the opera but it has now been reconstructed in the original style. Even if you don't get to a performance it is worth having a guided tour (times listed on website) and to pop into the Sacher Hotel opposite for a cake afterwards.

Spanish Riding Schoolwww.spanische-reitschule.com

The Spanish Riding School and its Lipizzaner horses are world famous. But tickets are very expensive and you need to book early. The days of the performances are given on this site. A cheaper alternative is to go to the morning exercises and horses' workout. Again you need to check the site for the days when these take place. There is also a Lipizzaner Museum nearby which gives the breed's history and displays riding artefacts.

Vienna Boys' Choirwww.wsk.at

The Vienna Boys' Choir is one of the world's oldest boys' choirs. Maximilian I founded its forerunner in 1498. The boys sing in their blue and white sailor suits at the Burghkapelle every Sunday and in May also at the Konzerthaus on Friday afternoons.

Stephansdom (steffl)www.stephansdom.at (in German only)

St Stephan's cathedral has dominated the centre of Vienna since the 13th century. Its Romanesque origins are still recognisable but the overall impression is Gothic. The asymmetric twin towers result from a difference of opinion between the Habsburgs and the city fathers. The Habsburgs wanted to add a second tower to impress the Pope in their quest for Vienna to be made a bishopric. The city fathers insisted that funds be used on strengthening the city's fortifications against the Turks. The net result was an incomplete second tower topped off with an incongruous Renaissance cupola.

Hofburg and Schönbrunn (winter and summer palaces)www.hofburg-wien.at and www.schoenbrunn.at

The Habsburg's winter palace is a vast rambling complex

of assorted buildings taking up one corner of the 1st district. It is the most visited tourist attraction in Vienna followed by Schönbrunn, the Habsburg's summer place. The Kaisergruft (Imperial Burial Vault) (www.kaisergruft.at in German only) in Tegetthoffstrasse is a fascinating place. All the important Habsburgs are buried here, some with excessively ornate tombs and others plain and simple.

Belvederewww.belvedere.at

The Upper Belvedere and Austrian Gallery (Oberes Belvedere and österreichisches Galerie) holds nineteenth and early twentieth century paintings and not exclusively from Austria. This is the place for Klimt, Schiele and Kokoschka. The lower Belvedere is the place to find Medieval and Baroque art.

Albertinawww.albertina.at

The Albertina palace has recently been renovated and has a magnificent interior. This is another venue for excellent temporary art exhibitions.

Secessionwww.secession.at

The Secession, or golden cabbage (one look at it and you know why), houses Klimt's controversial Beethoven Frieze. This includes female figures representing sickness, madness, death, voluptuousness, debauchery and wantonness. The secession also has temporary exhibitions.

Nationalbibliothek (National Library)www.onb.ac.at

I discovered the National Library after I had lived in Vienna for some time. This would be my 'geheim' (secret) tip. The library is in a Baroque building with an enormous frescoed dome. Over 200,000 books are stacked on its gilded wood-panelled bookcases. You can also visit the Museum of Globes here.

I have not forgotten the cakes and coffee houses. They have been saved for the March 2007 issue of TWS.

Elise Langdon-Neuner

Baxter BioScience,
Vienna, Austria
langdoe@baxter.com

Some useful expressions for the EMWA Vienna spring conference

German	English translation	English
Ich versteh nur Bahnhof	I understand only railroad station	I don't understand a word
Es ist mir wurscht	It's sausage to me	I don't care
Du gehst mir auf den Wecker/Zeiger/ Keks	You are going on my alarm clock/ hand (clock)/biscuit	You're getting on my nerves
Wie du mir so ich dir	As you me so I you	An eye for an eye and a tooth for a tooth
Gib nicht so an	Give not so on	Don't boast so much
Es haut mich aus den Socken	It knocks me out the socks	You could have knocked me down with a feather
Du bist ein Glückspilz	You're a lucky mushroom	You lucky thing!

**Journal watch:**

Product recommendations and writing assistance in medical journals

by Nancy Milligan

Methodological quality and product bias in meta-analyses

We start this issue of journal watch with an interesting article comparing Cochrane reviews with other paper-based meta-analyses for methodological quality and product recommendations bias. We all know that bias in drug trials is common and that reporting of studies with pharmaceutical industry support often favours the sponsor's product. It is exactly for this reason that unbiased reviews are so important in order to report all of the existing information in a neutral manner. Anders Jørgensen and colleagues completed a systematic review comparing pairs of meta-analyses made up of a Cochrane review (which are designed to minimise bias and conflicts of interest) and a similar paper-based review for the same drug for the same disease [1]. The paper-based meta-analyses were separated into those that had pharmaceutical industry support (grants, authorship, or other major assistance), those with undeclared support, and those that had support from not-for-profit organisations or no support. The methodological quality of each pair was assessed with a validated scale to give an overall assessment of quality (scale of 0–7) and product bias. 24 matched reviews were included in the analysis. The total median quality score for the Cochrane reviews was 7 compared with 3 for the other reviews ($p < 0.001$). Of the paper-based reviews, 8 were industry supported, 9 had undeclared support, and 7 had non-profit or no support. The Cochrane reviews were of higher quality than the industry supported reviews ($p < 0.01$) and more often addressed the potential for bias during the selection and assessment of studies. 7 of the 8 industry supported reviews presented conclusions, and all of these 7 included positive recommendations for the sponsor's product compared with none of the Cochrane reviews ($p < 0.01$). This occurred even though the estimated treatment effects of the drugs in both review types were comparable. Papers with undisclosed support, non-profit support, or no support were not significantly different to Cochrane reviews in their degree of product bias. The message for medical writers here is to remember when writing review papers and indeed any research paper, that you have an ethical obligation to develop unbiased conclusions based on the actual results of the study or studies involved. However, it should be pointed out that the conclusions of this study are themselves showing an anti-industry bias, as the study only compared industry supported reviews with Cochrane reviews, but failed to compare like with like (i.e. industry supported versus non-industry supported non-Cochrane reviews).

Declaration of writing assistance in peer-reviewed journals

Numerous guidelines, including those from EMWA [2], have been developed to encourage authors to recognize the contributions of medical writers to published medical research, but still writing assistance appears to be under-reported by authors [3]. Recently, in a letter to the *Journal of the American Medical Association (JAMA)*, Karen Woolley et al. reported the results of a study investigating the extent of the declaration of medical writing assistance in 1000 original research articles from 10 international, high-ranking, and peer-reviewed journals that published acknowledgements [4]. Confirmed use of medical writers was low, reported in only 60 (6%) out of the 1000 articles. 102 articles were supported by a pharmaceutical company; of these, 10 (9.8%) articles reported using medical writers. Even though this study did not examine the extent of undeclared writing assistance, experience suggests that many papers are published without the due recognition of a medical writer. According to the authors of the study, the problem appears to lie in 3 main areas; that authors may be unaware of the need to declare writing assistance (only 2 of the 10 journals in this study specifically requested this in their instructions to authors), that authors are unwilling to declare assistance owing to negative attitudes towards the medical writing industry, and that medical writers often fail to encourage authors to acknowledge their contribution. So it seems that journals have a responsibility to promote the declaration of writing assistance, authors have a responsibility to actually declare the help they have received, and writers themselves also have a responsibility to insist that their contribution be acknowledged.

Advice to authors on the ethical use of medical writers

Finally, in another recent article, Karen Woolley aims to educate authors about the ethical use of medical writers in manuscript preparation and attempts to persuade authors to say goodbye to ghostwriting (undisclosed use of a professional medical writer) [5]. Woolley starts by explaining the difference between professional medical writing and ghostwriting and explains a little about what exactly professional medical writers do and why authors use them, before going on to advise authors on how to work appropriately with medical writers. Woolley suggests that the processes for the ethical preparation of manuscripts is the same as for the efficient preparation of manuscripts, which involves following industry-produced guidelines (such as EMWA's) and ensuring two major things: acknowledgement of the

Journal watch:

medical writer and disclosure of their funding source. The article also explains how professional medical writers should usually follow a standard operating procedure for manuscript preparation which should lay out the responsibilities of both the writer and the author to ensure they work collaboratively throughout the whole process. The most important message to get across to readers of peer-reviewed journals (and certain members of the media who slight the profession) is that even with the assistance of a medical writer, the manuscript's authors retain control over and are ultimately responsible for the data presented and the key messages and conclusions put forward.

Nancy Milligan

Dianthus Medical Limited
nmilligan@dianthus.co.uk

References:

1. Jørgensen AW, Hilden J, Gøtzsche PC. Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review. *BMJ* 2006;doi:10.1136/bmj.38973.444699.OB.
2. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the roles of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21:317–22.
3. Jacobs A. Ghostwriting: survey results (Ghostwriting discussion forum). Presented at the 15th annual conference of the European Medical Writers Association; 2006 May 2–6; Lyon, France.
4. Woolley KL, Ely JA, Woolley MJ, Choi Y, McDonald JM. Declaration of medical writing assistance in international peer-reviewed publications [letter]. *JAMA* 2006;296(8):932–4.
5. Woolley KL. Goodbye ghostwriters!: How to work ethically and efficiently with professional medical writers. *Chest* 2006;130:921–3.

Getting it right: The challenges of medical reporting

What are the issues and responsibilities in reporting risk?

How do you report complex medical topics clearly and accurately?

Who makes a reliable medical source?

The Australasian Medical Writers Association and Australian Science Communicators joined together at the Redback Hotel in Melbourne to host a panel discussion exploring these and other issues in medical reporting. Panel members included Nicola Smith (medical researcher), Carol Nader (*The Age* Health Reporter), Gabriella Rissotto (Channel 9 TV medical reporter-Melbourne) Sarah Meachem (researcher and media consultant) and Sally Coburn (physician and radio science communicator).

The session attracted journalists, scientists, public relations officers, and students in science and journalism. The variety of expertise on the panel and audience diversity made for an engaging and informative discussion.

Among the topics discussed was reporting a balanced story. Traditionally balance is achieved by exploring all sides of the issue, giving them equal weighting. While this is usually considered good journalism, it may not represent the community view. Abortion was the example put forward by panellist Dr Sally Cockburn. She maintains the majority of the community favours pro-abortion laws and that giving equal time to the anti-abortion lobby distorts the community view. Defining and achieving true balance was acknowledged as a difficult, but important issue.

Equally interesting was the question of finding reliable sources. With the increasing involvement of scientists and physicians in biotechnology and pharmaceutical companies, it is becoming more and more difficult to find sources without conflicts of interest. The journalists also raised the perennial issue of separating real news from PR

spin, and the level of research that must go into each story before it is reported.

When reporting a story it is important that the journalist get it right in making the news interesting and accessible to the public while maintaining enough scientific rigor to satisfy the source. All the panel members agreed that sensationalising a finding can be a risk, and the word 'break-through' was used far too often. It may unfairly raise patient hopes and tends to make researchers reluctant to speak to the media. The researchers present noted that they often balance their fear that a story will be reported inaccurately or sensationalised with their desire to get the word out.

Fortunately, researcher and physician fear of the media is being addressed by media training. Courses and workshops are increasingly available for young scientists and doctors to teach them about the media and how to speak with journalists. The trend shows promise in that more and more researchers understand and are comfortable speaking with the media.

The last question of the evening was from a scientist who said that to him the word story implied a beginning, middle and end, wondering why journalists rarely follow up on stories of advances in medical research. This question stimulated discussion of what defines news versus the responsibility journalists have to the public.

None of the issues raised during the evening were resolved, but the session was an opportunity for journalists, scientists and public relations practitioners to meet and consider the challenges of medical reporting from several viewpoints.

L.E. Ohman

Integrative Neuroscience Facility
Howard Florey Institute
Melbourne, Australia
leohman1@bigpond.net.au

Schweinerei

Vol. 15, No. 4, 2006

Vedran Katavic

The 'cheating'.com academic society 118

Miguel Roig

On the causes of academic dishonesty 120

Barry Drees

How I almost committed scientific fraud 122

Ursula Schoenberg

(Doing) The Right Stuff 124

Christine Parkhurst and Elizabeth Moore

Nipping plagiarism in the bud: Using Turnitin to teach novice science writers how to paraphrase 125

Sarah Hemingway

Communication of the benefit risk profile in the Clinical Overview section of an application for marketing approval of a new medicinal product 129

Kelly Goodwin Burri

Results of the 2006 EMWA Salary Survey 133

Vicente Alfaro

Medical Writing Forum at the VII Meeting of Pharmaceutical Medicine (AMIFE) in Spain 135

Alistair Reeves

More myths about English (2) 139

Alistair Reeves

Time and time again 141

Regular features

From the Editor's desk 113

What's news at EMWA 115

Message from the President 117

In the bookstores... 143

Webscout 145

Journal watch 147