European Medical Writers Association

The Write Stuff

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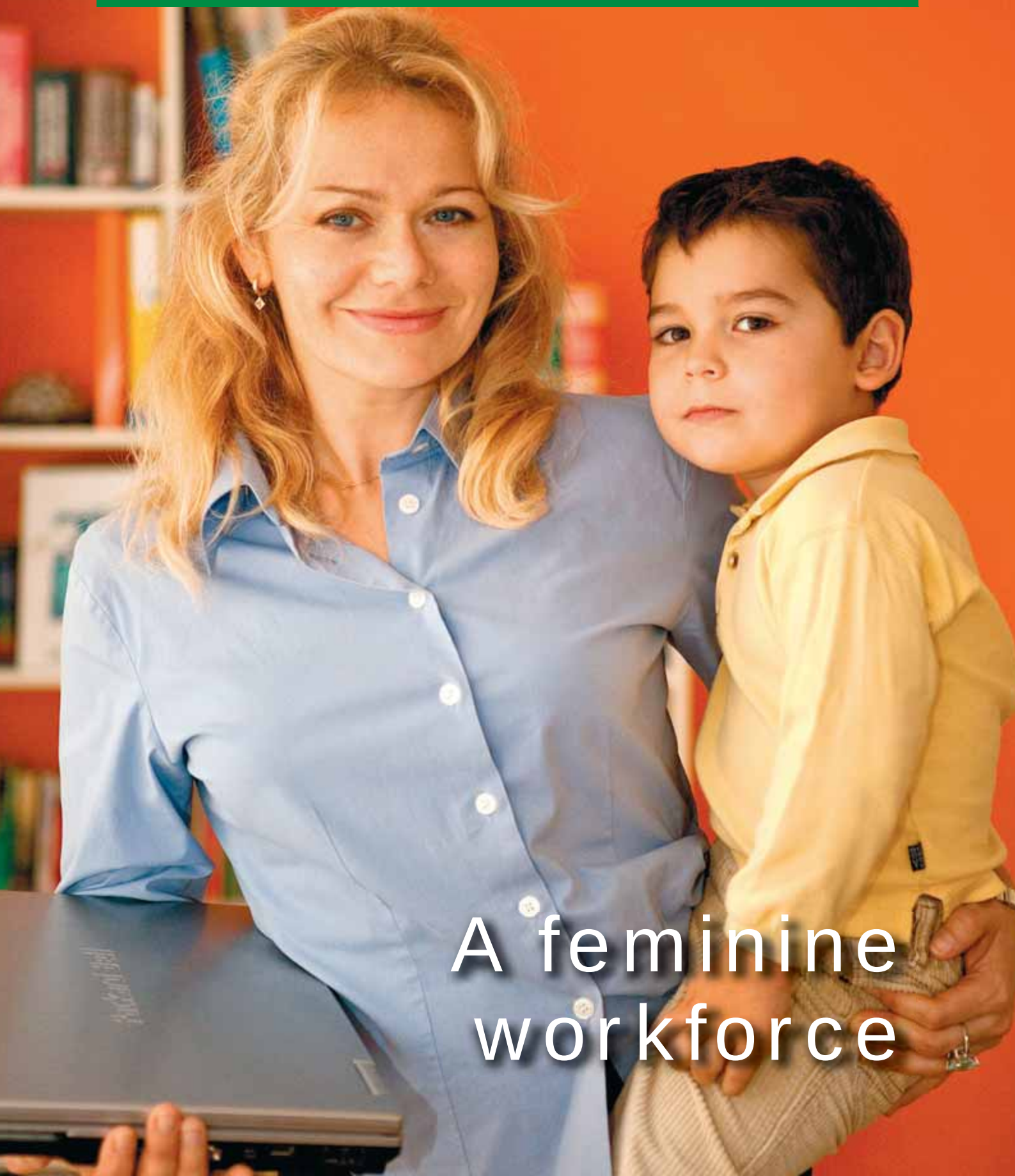

A feminine workforce

Journal insights

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

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

Subscriptions

Subscriptions are included in EMWA membership fees. By writing to emwatws@associationhq.com non-members can subscribe at an annual rate of:

- €35 within Europe
- €50 outside Europe

Instructions for contributors

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

Timelines

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• Half page	**€500**	• Half page	**€100**

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TOC

A feminine workforce

Vol 19, No. 4, 2010

Cover picture
Cover photograph from Nadja Meister (nadja.meister@inode.at)

Regular features

From the Editor's desk

Is medical writing a model for a workforce with feminine values?

by Elise Langdon-Neuner

Why is this issue of *The Write Stuff* devoted to a feminine workforce? One reason is to mark women reaching 50% of the workforce in the US, which was also the reason *The Economist* dedicated its first issue this year to the topic of what happens when over half the workforce are women [1][1]. Another reason for the issue's theme is that most EMWA members are women. Navel-gazing the attraction our profession holds for women and the effect its female-dominated workforce has had on the profession might help us to answer the interesting question posed by *The Economist*.

It is possible of course that the reason for more female than male medical writers is simply that women are better at medical writing than men. On page 251 of this issue, Adam Jacobs reports a quantitative analysis of job applications received by his firm which he did to find out if women's prevalence in the profession is because they have more aptitude for medical writing or if women just want to become medical writers. Adam admits that his research did not produce a clear answer, so it might be less tenuous to pursue the avenue that more women than men are attracted to medical writing. But why?

Medical writing is a service profession. The growth of the service sector has been one of the main factors favouring women's entry into the workforce as it has enabled women to compete equally with men on intellectual terms, whereas in the declining heavy labour industries where physical strength was important, they could never have completed equally. Astute intellect and a high level of education are a prerequisite for all the professions, where women seem to be making the greatest inroads. When I started work in 1974 I was a novelty, a women working in a profession. My first job as a solicitor was in Norwich, where I became the second female partner in a firm in the city. By the time I left my London firm in 1986 half of the solicitors we were taking on were women. The novelty was gone and—fortunately—so was the attitude that any women in a high position had slept with the senior partner.

Nowadays almost 60% of university degrees in America and Europe are gained by women. That educated women have the best chances in the workforce is evident from the 80% of women in the US with a college education who work as opposed to the 47% of women at the other end of the spectrum without a high school diploma who work. Currently 51% of professional workers in the US are women.

However, it's a different story in mainstream business. Less than a third of the students taking full-time MBAs in the programmes ranked by *The Economists* between 2002 and 2010 were women. It is not that women are not welcome [2], Professor Valter Lazzari, director of the MBA programme at a school in Milan, was quoted in the article as saying "They [women] are more analytical, reflective, and more cautious. They are less prone to the problem of overconfidence. I am pretty sure if we had more women in charge of banks, the financial crisis would not have happened in the same way."

The main barrier for women studying MBAs is that the programmes require 4 or more years of work experience, which is an obstacle for women planning a family. The cost and taking time out from a job to study are also viewed as risks which women prefer to avoid when the future is uncertain. Most interesting though is that women view the programmes as competitive and geared to Type A personalities. The business schools are beginning to tackle these problems, e.g. by dropping the work experience requirement, and promoting a supportive image to deflect the male-dominated, ruthless one. However, career structure in mainstream business has yet to accommodate women and reap the benefit of their talents. Less than 13% of board members in America are women. Britain's Equality and Human Rights Commission calculate that at the current rate it will take 60 years for women to gain equal representation on the boards of the FTSE 100. A study of female graduates from the University of Chicago's Booth School of Business found that only half of the women who subsequently had children continued to work. Few allowances are made for an interruption in the rollercoaster high level business career path. Something which could help in this direction is the increasing practice of companies giving employees sabbaticals whereby men and women can take breaks in their careers for various reasons: childcare, further education, a vacation or to undertake voluntary work. As *The Economist* points out in this way breaks in a career become less a mark of female exceptionalism.

In the meantime more women enter the professions but many of these women do not have children either, for instance 40% of professional women do in Switzerland do

1 Unless otherwise stated the statistics quoted in this editorial are summarised from this source.

not have children. Among the professions medical writing sticks out as particularly well suited to home-working, flexible hours, job sharing, freelancing and small business setups that accommodate career interruptions for bearing children and provide the flexibility for a woman to care for her children. It would be interesting to know how many female medical writers have children, but I suspect that the proportion is higher than in other professions. On page 286 Raquel Billiones reports her experience of well-educated women who enter medical writing as a way out of their stay-at-home mother and trailing spouse role.

I believe there is another reason for the disproportionate number of female medical writers. As evidenced by Thomas Schindler's analysis of job posting on the EMWA website (page 272), most medical writers have degrees in science. These women most probably started their working life in a laboratory as Margaret Thatcher did, but became disillusioned with their chosen path, at which point they might have chosen to become politicians but medical writing, where a scientific background has clear advantages, seems a more logical choice. Alexandra Jellicoe has a plausible theory for why women are less likely to thrive in the research environment—science is sexist. Read more about this on page 255.

We learn on page 257 in Diarmuid De Faoite's interview of Beate Hanson, a leader in science, that there really is a glass ceiling which she had to overcome to reach her position. Science does seem to be exceptionally sexist but it appears that all the rules in any workplace are still laid down by men. One aspect of this is something Wendy Kingdom tackles in her article on page 252 about how women's career progress might be stymied by the way they use language. Both Alexandra and Wendy discuss in their articles how mainline business career progress is determined by criteria that suit the hierarchical and competitive male psyche rather than the cooperative female way of working. However, a medical writer must be able to operate in an area where female talents are especially in demand—liaising in a cooperative manner with other departments and organisations. Perhaps therefore feminised rules apply in medical writing—more about this later.

Another intriguing and relevant factor is that people in the medical writing profession—mainly women—are happier than the average American. Diana Epstein's survey of 99 participants at the 2003 EMWA Lisbon conference revealed a happiness mean of 5.9% for medical writers, well over the average happiness mean for Americans of 4.8% [3]. Contrast this with the General Social Survey in the US which has followed attitudes in the US since 1972 and 5 surveys in other countries that found women are getting progressively sadder while men become happier [4]. Moreover in contrast to men, the surveys found women become less happy as they get older, which correlates with the main factors driving these statistics: having children makes women less happy and prosperity makes men happier. Marcus Buckingham, a former Gallup researcher, puts women's unhappiness down to the stress of working and running a home [4]. No wonder women become medical writers; where super-human powers are called for, this profession supplies the necessary flexibility for mums to bounce back and forth in their work and family roles.

There is though a fly in the ointment where medical writing is a particularly poor choice for women—pay. Women are generally paid less than men, especially if they have children. In America women without children do earn almost as much as their male peers, but mothers earn less. The Equal Pay Act came into force in the UK in 1970. It was the culmination of strike action taken by women workers at the Ford motor plant in Dagenham, Essex now immortalised in the newly released film 'Made in Dagenham'. The women were not prepared to continue doing the same work as male colleagues for 87% of the pay received by the men. They settled the dispute at 92%. Despite equal pay legislation things have far from improved. A typical full-time female worker in the US and UK only earns about 80% of the salary a typical full-time male worker receives. But even more shattering, a salary survey of EMWA members conducted in 2006 found that the starting salaries of female medical writers were 45% less than the starting salaries of their male medical writer colleagues [6]. What could possibly be the justification for this?

The appeal of medical writing for women is probably a combination of the job's adaptability to a mother's routine and that it enables women to practice science in a co-operative environment in which they thrive. Nevertheless bearing in mind that men are clearly in a minority in the profession, it is curious that many medical writing groups are led by men. More than once I have heard female medical writers say that men are welcome to the 'top jobs'. Could it be that even in this women's profession the rules for getting to the top involve games that women do not want to play? Why have women even in a female-dominated workforce not managed to change the ground rules? And how is it that men earn more than they do for doing the same job? Taking the example of medical writing, the answer to *The Economist*'s question "what happens when over half the workforce are women?" could be "not much"—until women themselves start to do something about it.

Elise Langdon-Neuner
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TWS December 2010: Take a closer look

The theme of this issue of *TWS* is 'The feminine workforce'. The theme and articles relating to it are discussed in 'From the Editor's desk'. I enjoyed putting December's issue together because it covers such a breadth of topics. In line with the female theme, Joselita Salita (page 259) discusses two reports on women's health which were published in 2009, one from the World Health Organization presenting a global picture and the other from the Faculty of Medicine Carl Gustav Carus in Dresden, Germany focussing on the EU member states. Joselita concludes from the reports that more gender-specific research is needed to improve health policies. Women are, however, more health conscious than men, which is why I asked Alice Knight (page 261) to write about ergonomics for medical writers in this issue. We all spend a large portion of our time bent over the computer and in so doing we build up health problems for ourselves in later life. Alice gives practical advice on how to avoid the otherwise inevitable consequences.

Regulatory writers will be interested in the article on newsletters (page 264) by Monica Ardura and Keith Dawes. They see newsletters as an interesting and useful diversion from writing regulatory documents that medical writers can easily slip into. There is also of course Greg Morley's column for regulatory writers, which this month discusses Ernst and Young's report on the effectiveness and efficiency of The European Medicines Agency (EMA).

For those interested in medical journals Neville Goodman (page 269) reports his research on changes in the words most commonly used in article titles. He investigated the use of words such as 'novel', functionality', 'paradigm' and 'represent' and he discusses the implications of their increasing appearance in titles of biomedical articles. Journal watch and the Biomedical shorts column will alert you to the latest articles relevant to medical writing and there's EMWA's press release in response to Fugh-Berman's article on the ghostwriting of publications on page 280.

Globalisation is the topic of EMWA's spring 2011 conference in Berlin. This issue of *TWS* takes up the baton with an article from a medical writer in India about her career in an outsource company. The Translation section tackles the problems of globilisation for scientists whose first language is not English but who need to publish their research in English. Brian Budgell describes the development of a corpus of English biomedical language and an English test for biomedical purposes which is being piloted with student cohorts in Australia, China, Japan and Malaysia.

Alistair Reeves has taken time out from his grammar articles but his fans will be pleased to see that he has contributed to the *Words Grammar & Co* column. Together with Wendy Kingdom he also writes on page 281 about the proposal to create a style guide with a difference, The EMWA Style Guide. Also in this section, Alison McIntosh provides a taster for her upcoming *TWS* issue on careers in medical writing with her discussion on how we might help budding medical writers to gain the experience they need to embark on a career in medical writing. Stephen de Looze adds a report on EMWA's involvement in Europe's first-ever fully-fledged MSc in Medical Writing. Then there's Thomas Schindler's (page 272) analysis of job postings on the EMWA website. His first analysis published in March 2009 (*TWS* 18(2):124-126) covered postings on the site in 2007 and 2008. The update looks at what happened in 2009.

Don't miss the latest contributions to the acknowledgements debate (page 287) putting forward the reasons why freelance medical writers feel they can be jeopardised by their acknowledgement required by biomedical journals in articles they write or help to write. Finally it could happen to any of us, another article not to be missed is an unsettling personal account on page 276 from a medical writer accused of plagiarism and how the medical writer dealt with this serious issue.

The editor

Message from the President

Dear Friends and Colleagues,

by Laurence Auffret

I hope this message finds you well.

"It's 6.15, time to wake up" said Adele in her croaky voice. Adele is a speaking clock, my morning wake-up call when winter darkness hits and I can't wake up with the sun. My mind drifts to the 20 languages and cultures that will make up my day, to the warmth and dedication of colleagues working on challenging documentation projects, and their "yes we can" attitude, all of which carry us further forward and always delight me.

With the delocalisation of clinical trials in recent years, my work environment has greatly changed to serve the needs of the pharmaceutical industry which no longer limit their clinical documentation to English or the major western European languages. Assisting investigators meetings in Eastern Europe and producing clinical trial documents in Chinese are frequently on my schedule. Culturally bound behaviours, the socio-cultural dimension of the concept of pain as well as shifting interpretations of the CONSORT guidelines make me wonder about the wider impact of globalisation on medical writing.

EMWA's Spring conference in Berlin (10th-14th May 2011) will boast an EMWA Professional Development Programme of 64 workshops and master classes. In addition there will be 9 seminars and 6 plenary talks on the theme of GLOBALISATION. Given the interest we have received from members and potential delegates we are expecting this 32nd EMWA conference to be the largest to date.

I am still looking for a survival guide to the challenging economic climate—sharing resources, thinking about others and being creative are the key areas I feel are important that we strengthen. The value of our association shines under a new light: training, interacting with colleagues and reaching out to industry players from around Europe and the World have become invaluable. So with so little time or resources, how do you reap the most benefits from your membership? How do you push the boundaries to maximise your EMWA experience?

Those members who benefit the most year after year are motivated individuals who work on a committee, a board, or volunteer all year round or at events. So gear up and maximise the value of your membership!!

There are many areas in which your expertise and commitment can make a difference to yourself and to EMWA. Whether you are a freelance medical writer or work in a company with an in-house medical writing team, getting involved helps you gain valuable skills and make contact with key industry specialists.

Your input can help showcase your skills, as an individual or as a representative of your company:

- reporting on events you have attended
- assisting with the *TWS* editorial board
- writing news items for the LinkedIn and Facebook sites
- organising the Buddy scheme for the conference
- marketing on a local or European level
- organising local meetings
- delivering workshops

Some volunteers cross over the boundary to take up official posts, and during our Berlin Spring conference, we will also be voting to fill a number of positions in the Executive Committee. Therefore, I would like to receive your nominations for the positions of Vice President, Treasurer, Honorary Secretary, and Public Relations Officer. We can assist you by explaining what responsibilities the positions entail, what kind of networks you will be involved in, how your expertise can help EMWA grow and most of all what industry insights we have gained through serving as board members. To stand for election at our next AGM in Berlin, please send me a short presentation (400 words) by e-mail before 24th January if you want to feature in the next *TWS*, or by 15th April 2011 if you need a bit more time.

Our sponsors' investments also provide us with the resources to host our conferences, maintain the website, fund *TWS*, etc... The list is long and wide-ranging. I am grateful for your commitment; we could not achieve much without your support.

On these early morning thoughts, I start my day with the strong sense of belonging to a great team of friends and colleagues. Just one little thing would help though, I wish Adele could make coffee.

I wish you all a relaxing time during the Christmas break.

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When a woman behaves like a man, why doesn't she behave like a nice man?

Edith Evans

What's news at EMWA

How can we help potential medical writers gain medical writing experience?

by Alison McIntosh

For the first time brief oral presentations on different aspects of medical writing were presented by EMWA members at a half-day session during the 30th EMWA Conference which took place 11-15th May 2010 in Lisbon. A call for abstracts on topics that might 'encourage lively debate' had been sent out by the EC a few months earlier and submitted abstracts were reviewed. Following acceptance the authors had to prepare a 10-minute power point presentation.

When the call for abstracts came into my inbox I had just taken the third or fourth call from a person asking if I knew whether volunteering to work for a company for no salary would provide them with the type of work experience that would help them find a medical writing job. Clearly, I do not know the answer to this type of question, but I decided to submit an abstract that might help define what kind of experience employers are willing to accept.

I hoped to kick-start some discussions that people might find useful and following my presentation I was asked to submit an article to *The Write Stuff* (*TWS*) based on the presentation in Lisbon. I should emphasise that the content of my talk was my own viewpoint and does not represent an EMWA viewpoint. Hopefully, this article will continue the discussion and stimulate interest with the EMWA membership. A short summary has already been reported in *TWS* [2010; 19(2):90-91].

People hoping to start out in medical writing find themselves in a 'Catch 22' situation because more and more advertised positions are asking for candidates with medical writing and/or pharmaceutical industry experience. The age-old conundrum is how to deal with this prerequisite when you cannot access a relevant job.

A quick review of the adverts placed on the EMWA website is a prime example with candidates requiring "*...at least 2 years' experience within a medical communications agency or the pharmaceutical industry*" or "*...pharmacovigilance experience or other relevant experience*" or "*...proven track record of medical writing and editing*" or "*...prior medical writing experience within healthcare industry.*"

Alison McIntosh will be taking the points she raised in the presentation in Lisbon further with the March 2011 issue of *TWS* which she is guest editing and which will have the theme 'Medical Writing Careers'.

Gaining suitable experience

To my mind there are three main routes to gaining suitable medical writing experience (detailed in Table 1): working in a relevant position for either a nominal amount or no money, enrol on a training course or receive on-the-job training.

Table 1. How to gain suitable experience

Work Experience	• Organised internships with companies • Volunteer to work for no pay • Shadowing
Enrol on EMWA PDP and complete workshops	• Are credits gained within the EPDP recognised by employers and rewarded? • Is the EPDP recognised as a way of gaining relevant experience whilst trying to obtain a medical writing position?
On-the-job training	• Employers accept people without experience and train them accordingly • Part time study

Many questions arise from the use of internships to gain experience. How long would a person need to have worked for the experience to be worthwhile? Does the person get paid? Importantly, could companies willing to accept applications in this manner be identified and perhaps advertise them on the EMWA website?

Another route might be the use of bursaries. Could a limited number of bursaries be made available through EMWA to gain experience? Are there companies who would support such an initiative and can they be identified and listed on EMWA website? A bursary could take the form of monetary remunerations to potential writers attending EMWA workshops at a conference. This could be an EMWA initiative or EMWA partnering companies willing to support this type of initiative.

For those lucky enough to find a job, experience is often gained via on-the-job training through in house training courses and/or mentoring by more senior writers. This may be well organised or occur by ad hoc training. One very large question is whether enough employers accept people without experience and train them accordingly?

Is there a need for an EMWA/University validated professional qualification?

The unique structure of the EMWA conferences has major strengths in that:

It offers **practical** and **relevant** training for medical writers employed in the pharmaceutical industry

Participants learn from experienced writers in a practical and not a theoretical manner

The unique strengths of the EMWA programme should not be lost and are essential to separate any potential joint EMWA-University venture from other courses already on offer to budding medical writers (Table 2). It is essential that if training is offered/endorsed by EMWA it is recognised by employers as adding value.

Table 2. EMWA university validated professional qualification?

What form would it take?	• Validated by a university • Full time qualification? • Part time while working? • Endorsed by EMWA or administered by EMWA?
Requirements?	• Needs to be relevant to whole of Europe not just one country • Recognised by employers and students as adding value • Practical and relevant • Value for money?

Other organisations like the Institute of Clinical Research **(**ICR), The Organisation of Professionals in Regulatory Affairs (TOPRA) and The Pharmaceutical Information & Pharmacovigilance Association (PIPA) offer/endorse MSc degrees from UK Universities as part-time courses. These courses are designed for professionals already working in the area and who attend study days. They are a series of modules taken over a maximum number of years. Importantly they are supported by employers and recognised as worthy continued professional development.

Only by ensuring **practical** and **relevant** training for medical writers will EMWA be recognised as offering worthy continued professional development, as well as receiving support for such training from employers. Maintaining these unique strengths will ensure that an EMWA-endorsed certificate becomes a gold standard for training medical writers, not only when they are at the start of their career, but also for those of us who need to continue to learn.

Since presenting this talk in Lisbon, ongoing discussions have resulted in EMWA supporting an MSc programme which will be launched by the Medical University of Innsbruck this autumn (see Box).

If you would like to respond to any of the points in the article perhaps you could start a discussion on the EMWA linkedin group.

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See you in Berlin?

EMWA conference announcement on the back cover

Call for nominations for upcoming Executive Committee positions

EMWA is an organisation run for its members and by its members, and we actively encourage and seek out participation from all our members.

With the May 2011 elections fast approaching we are now looking for members to run for election in the following Executive Committee positions:

- Treasurer
- Honorary Secretary
- Public Relations Officer
- Vice-President

Have you ever thought about getting involved in EMWA 'behind the scenes'? Would you like to help manage our rapidly-growing association and be involved in deciding how we move forward in the next two years and beyond? If so, here's your chance!

As an Executive Committee member you would know everything that's happening at EMWA, make many new contacts in the medical writing field, learn useful management skills, receive free registration, travel expenses and 2 nights accommodation at EMWAs biannual conferences during your term of office, receive great exposure for your company or freelance activity, and significantly improve your CV!

If you're interested and would like to know more about these upcoming Executive Committee positions, please contact: Head office (info@emwa.org) or any of the present EC members directly: Gillian Pritchard (g.pritchard@sylexis.co.uk), Laura Hollyhead (Laura.Hollyhead@ppdi.com), Andrea Palluch (apalluch@inpharmedia.co.uk), or Rita Wellens (rita.wellens@telenet.be).

Call for applications for position of Editor-in-Chief of *TWS*

I have resigned my editorship of *TWS* as of the March issue 2011, by which time I will have been Editor-in-Chief of the journal for 7 years—long enough for any journal to put up with one Editor-in-Chief. The position carries responsibility and work but has many rewards.

Applications are requested for the voluntary position of Editor-in-Chief of *TWS*. Ideally the applicant should have been involved with the journal in some way as a guest or column editor, member of the editorial board or have been the author of an article(s) for the journal. To learn more about what is involved please contact me at editor@emwa.org. Applications should be sent either to me or to the President, Laurence Auffret, at president@emwa.org.

What's news at EMWA

Master of Science in Medical Writing at the Medical University of Innsbruck

This autumn sees the launch of Europe's first-ever fully-fledged MSc in Medical Writing (http://www.i-med.ac.at/ulg/docs/Folder_neu_v5_definitv_Print.pdf). The two-year course is the brainchild of Professor Michael Nogler (Department of Experimental Orthopaedics and Vice Chairman at the Department of Orthopaedic Surgery) supported by Sonja Weber at the Faculty Office of the University.

In order to optimise a critical intake of students at launch, the content has been initially geared to meet the needs of those in academia whose foremost concerns are in the areas of publication and grant writing. However, the course includes within it a comprehensive introduction to basic medicine taught by members of the medical faculty, and the organisers are well aware of the greater scope of medical writing outside the university setting which will lead to further development of the course content once the programme has become established.

Inspired by the wide range of topics presented in EMWA's conference brochures, Michael contacted me in May and invited me to Innsbruck to discuss with him and Sonja how the University and EMWA may each benefit by joining forces both for the roll-out and for the future development of the MSc.

Michael had certainly done his homework and had studied EMWA's strategic plan on our website (http://www.emwa.org/PresidentMessage.pdf) where he noted that *"our Education Officer and his committee are currently investigating the possibility of developing a partnership with a university or other academic institution."* For my part, I was inspired by the enthusiasm, insight and energy that Michael and Sonja had put into drafting the programme, not to mention the resources—from classrooms to e-learning facilities to faculty lecturers—that they had already lined up. It was also obvious that they had done a lot of work 'behind the scenes' to convince the powers-that-be in university administration that this course would attract sufficient students to be a financially viable venture.

I was of course delighted that EMWA had been approached in this way. Following up EMWA's strategic plan, I had in fact taken the initiative over the past year or so to contact various academic institutions where some sort of collaboration seemed worth exploring. None of these leads came to anything, and now here was a major European university reaching out to EMWA for help and support.

Michael was very keen to welcome EMWA workshop leaders as temporary university lecturers, and my next move was to canvass our workshop leaders to see who might be interested in making a contribution. I assembled a dossier in July, which included those workshop leaders who had expressed interest and the topics they currently present at EMWA. Much is still to be decided for the second year.

The MSc course will be structured according to the European credit transfer and accumulation system (ECTS) and will weigh in with 94 ECTS points. The University will credit ECTS points towards the MSc to EMWA members who enrol in the course and are holders of EPDP certificates, though the details must still be worked out.

At the time of writing this item, a month before the Nice conference, I am preparing for discussions with the EMWA Professional Development Committee (EPDC), which will meet in Nice, on establishing a permanent subcommittee to provide a bridge between the University and EMWA that will provide the continuity needed to maintain this collaboration as the MSc develops, and as EMWA members enrol in the course as students or support it as lecturers.

It certainly looks as though our strategic goal of a partnership with an academic institution that will bring real benefits to EMWA members—indeed to the medical writing profession in general—is finally within our reach.

Stephen de Looze,
Education Officer
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Introducing a new member of the *TWS* team

Anders Holmqvist (adobild@yahoo.se) is joining our *TWS* team and will be contributing graphic elements to illustrate and brighten up our pages (his illustrations can be seen on pages 244, 260 and 268). Anders is a graphical designer, illustrator and photographer based in Lund, Sweden. For the last 17 years he has been working with professional medical writers to provide a wealth of material for the pharmaceutical industry.

One example of how he works with medical writers is to produce brochures covering congresses or symposia. Ander's task in the process is to take photographs of the slide shows, lecturers, various posters etc, while the medical writer records the sessions using audiotape, takes notes and makes interviews. Back home in their respective offices (which may be in different countries), they collate everything into a brochure customised to the client's requirements. The medical writer writes the articles (with the help of audio recordings and photographed slides), while Anders does the layout, graphs and any other illustrations and photos. In this way the client has the advantage of getting the whole package in one hit: text, photos, accurate graphs and references in an appropriate and attractive graphical design, without the additional hassle of commissioning and managing a full agency. More details of the way in which Anders can work with medical writers can be found in the article 'Expanding your market by involving graphic design' published in this year's June issue of *TWS* (vol 19(2):115-116).

Searching *TWS* on line: Have you tried?

If you have not tried to search *TWS* online you are missing out on one of EMWA's best resources. To search you should go to http://thewritestuff.emwa.org/. This brings up the search page where you can enter the words you want to search in a box at the top right-hand side of the page. Once the results of your search have come up you need to log in as an EMWA member to gain free access to the article using the tab at the top right-hand corner of the page.

Themes of upcoming issues of *TWS*

Medical writing careers: Alison McIntosh is guest editing the March 2011 issue. A broad range of career topics will be covered including getting started, different medical career paths, and the future challenges for medical writing. Please contact Alison with your suggestions and contributions for this issue at aagmedicalwriting@btinternet.com.

Medical devices: Claudia Frumento will be guest editing the June 2011 issue which will focus on regulatory and communications issues relating to medical devices. Please contact Claudia with your suggestions and contributions for this issue at claudia.frumento@t-online.de.

As always articles or short reports on subjects of interest to medical writers which are outside the themes are also very welcome. Please send articles, letters to the editor and suggestions for individual articles or future issue themes to me, Elise, at editor@emwa.org.

Post your comment on any article in this issue of *TWS* online

Do you have an opinion or comment on any of the articles in this issue of *TWS*? Every article has a facility for comments in the online version of the issue. Place your comment by going to http://thewritestuff.emwa.org/article/1/44/categories/#

Nobody objects to a woman being a good writer or sculptor or geneticist if at the same time she manages to be a good wife, a good mother, good-looking, good-tempered, well-dressed, well-groomed, and unaggressive.

Marya Mannes

TWS and its editorial board wish you a merry Christmas and a happy New Year


1818 ... if you please, no reference to examples in books. Men have had every advantage of us in telling their own story... the pen has been in their hands. I will not allow books to prove any thing.
Jane Austen
1907 Old-fashioned ways which no longer apply to changed conditions are a snare in which the feet of women have always become readily entangled.
Jane Addams
1998 We got equal pay once, and then we got it again, and then we got it again, and now we still don't have it.
Justice Mary Gaudron
2004 Women do not change institutions simply by assimilating into them. We need a feminism that teaches women to say no ... when necessary, to the military or corporate hierarchy within which she finds herself.
Barbara Ehrenreich
© Renée Albe

Women in medical writing: A (sadly inadequate) quantitative analysis

by Adam Jacobs

At my company, Dianthus Medical, I employ 5 medical writers, all of whom are women. That doesn't seem to be particularly exceptional in the world of medical writing. Go to any EMWA conference, and the excess of female delegates over male ones is striking. Medical writing seems to be a profession inhabited by many more women than men.

Why might this be? Is it that more women than men want to be medical writers, or is it that women are simply better at medical writing than men, so are more likely to be successful in finding medical writing jobs? Or maybe both?

It occurred to me that I might be able to go some way towards answering this question by looking at the applications I've had for medical writing vacancies at my company. It turns out that I don't really have enough data to draw any very good conclusions, but I'd like to share my feeble attempts with you nonetheless. Perhaps they will encourage someone with a larger dataset to have a go at answering the questions that I have largely failed to answer.

Dianthus is a small company with a low staff turnover, so we don't advertise vacancies very often. We have done so 3 times since 2005 (for various reasons of comparability of data that I won't bore you with, I didn't want to go back in time any further than that), and received a total of 133 applications: 54 in 2005, 13 in 2006, and 66 in 2007. Needless to say, the much lower number in 2006 is because that vacancy wasn't advertised in the EMWA website, whereas the other 2 were.

Our application process has been the same on all 3 occasions: we screen all applications, ask the good ones to complete a writing test, and then invite those who send good writing tests to interview. After that, we offer one or more jobs.

The statistics for all those years combined are as follows:

	Men	Women	Total	% women (95% CI)
Total applications	48	85	133	64% (55–72%)
Sent writing test	13	24	37	65% (47–80%)
Invited for interview	5	13	18	72% (47–90%)
Offered job	0	5	5	100% (48%–100%)

I calculated odds ratios for getting to the next step in the process. These odds ratios are for men versus women, so an odds ratio less than 1 means that men are less likely to be successful at each step. The odds ratios look like this:

	Odds ratio	95% CI
Application to writing test	0.94	0.43–2.07
Writing test to interview	0.53	0.14–2.03
Interview to job offer	0	0–1.56

As you can see, all the confidence intervals are quite wide, so we are very limited in what we can conclude. However, one conclusion that does seem to be supported by my data is that more women than men want to be medical writers (at least at my company: a further limitation of these data, apart from the small sample size, is that I have no idea whether they are generalisable to those who apply for medical writing jobs elsewhere), as the proportion of applicants who were female was significantly greater than 50% ($P = 0.002$, if you want to get technical about it).

We might draw an extremely tentative conclusion that the quality of applications from men and women were similar, as the odds ratio of being sent a writing test was close to 1. However, the confidence interval round that is quite wide, and compatible with important differences in either direction in the quality of applications between men and women. We might draw a further extremely tentative conclusion that women submitted better writing tests than men, as the odds ratio for being invited to an interview after submitting the writing test was substantially less than 1, but again, the confidence interval is wide, so we really can't be sure. The numbers of interviewees offered a job was so small and the confidence intervals for that stage so ludicrously wide that I don't even want to offer an extremely tentative conclusion.

So, the data give reasonable support for the idea that more women than men want to be medical writers. The data are also consistent with the idea that women are better at medical writing than men (or at least can do a better writing test), and even give a very gentle hint in that direction. However, they stop far short of giving anything that could reasonably be described as support for that hypothesis.

At the risk of ending this article with a tired old cliché, more research is needed.

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Alice through the glass ceiling: How women's use of language might be a disadvantage in the workplace

by Wendy Kingdom

A survey published by the Equal Opportunities Commission in 2007 reported that women are still not reaching the top of their professions in significant numbers despite more than 30 years since the Sex Discrimination Act 1975 came into force in the UK [1]. This unofficial barrier to advancement in the workplace is described as the glass ceiling. Few of us need to read a report to see the glass ceiling in place; we just have to look around us. The further up a hierarchy you go, the more men outnumber and outrank women.

There are plenty of opinions on why women are less likely than men to progress into senior management positions. One interesting theory is that men and women use language differently and the way women use language puts them at a disadvantage in the workplace. This theory arose from an essay called *Language and Woman's Place* that was written in the 1970s by Robin Lakoff, an American sociolinguist [2]. Lakoff proposed that women's speech can be distinguished from men's speech in a number of ways. She suggested, for example, that women tend to use more tag questions, which means that they add a question such as "Do you?" after a statement. Another of Lakoff's observations is that women use more hedges, which are expressions such as "sort of" or "kind of". Women also tend to apologise more, speak less frequently, avoid coarse language or expletives, and tend to use indirect language compared with men.

Women apologise more, speak less frequently, avoid coarse language and use more indirect language

Gender differences of all kinds seem to fascinate people. During the 1990s, there was a flood of books on how men and women use language differently. John Gray propelled himself into the bestseller list with his book, *Men Are From Mars, Women Are From Venus* [3]. According to Gray, when misunderstandings occur between men and women, this is because men have forgotten they are Martians and women have forgotten that they are Venutians. Obviously this explanation is allegorical; it also becomes rather tedious–as an exercise in summarising, the first chapter of the book tells the reader more or less everything the author has to say. The point Gray makes is that what a speaker intends his or her words to mean may not be what the person of the opposite sex to whom the words are directed thinks they mean.

A more reasoned approach to the study of gender differences in language is provided by Deborah Tannen who is a sociolinguist at Georgetown University. In, *That's Not What I Meant!* [4] she discusses how people from different cultures use language in different ways. Although there are 10 chapters in this book, only one of which examines gender differences in language and social interaction, this is the chapter that attracted most attention. Subsequently, *You Just Don't Understand* [5] focused on why difficulties arise when we communicate with the opposite sex. Tannen has observed that differences in conversational styles between men and women begin in the playground and she suggests that we learn our conversational styles from our peers when we are children. Girls tend to play in small groups or in pairs, have 'best friends', share secrets and use inclusive language such as, "Let's go and show this to her". Much of the time, girls simply sit together and talk. Boys tend to play outside, in large groups that are hierarchically structured. Their groups have a leader who tells others what to do and how to do it, and resists doing what other boys propose. Therefore, boys learn to strive for position in the hierarchy. Boys' talk is referred to by Tannen as 'one-up, one-down' because either the person a boy is talking to is below him in the pecking order (making him 'one-up') or above him (in which case he is 'one-down').

Differences in conversational styles can explain misunderstandings between men and women in their relationships. Using Tannen's model, if Mary has a problem and she chats to her friend Jane about it, Jane might give minimal responses such as *yeah* or *oh* or *mmm* to show that she is listening. Then she might tell Mary about a similar problem of her own. The women are showing empathy with one another and sharing their feelings. If, however, Mary tells Bob about her problem, Bob would be puzzled by Mary sharing a problem with him because this automatically puts her in the 'one-down' position. Why would she want to do this? So Bob is likely to assume that Mary wants a solution to her problem and he'll respond with, "Why don't you do this?" Or "Go and get that", believing that he is being helpful. But his way of speaking causes Mary to feel that Bob hasn't listened and is now bossing her around while Bob is confused and upset because he can't understand why Mary asked him about her problem if she didn't want him to help her find a solution to it. A woman and a man can walk away from the same conversation with completely different ideas of what was said.

Boys' talk is 'one-up, one-down'

In *Talking from 9 to 5*, Tannen takes the argument further and suggests that the different ways in which men and women use language can put women at a disadvantage in the workplace [6]. For example, if men are making a decision about who to promote to a management position, they are likely to misinterpret a woman's indirect way of talking and gaining consensus as showing indecisiveness, inability to assume authority, and even incompetence. However, a woman can be a very strong leader by using a style of asking members of the team for their opinions and giving them ownership of ideas so that they carry those ideas forward. Unfortunately, this can be interpreted by her bosses as evidence that she doesn't know what she thinks should be done and that she is trying to get others to make decisions for her. Interestingly, women who adopt the more adversarial, information-focussed style, described as characteristic of all-male talk, are frequently perceived as aggressive, confrontational, and unfeminine.

Men misinterpret women's indirect way of talking and gaining consensus as showing indecisiveness, inability to assume authority, even incompetence

Tannen also makes the point that female language is 'marked', which is the linguistic term for the way a small addition to a word alters its base meaning. The 'unmarked' form of a word carries the meaning that goes without saying. The unmarked forms of most English words convey 'male' so being male is the unmarked case. To make the word convey female, we have to add endings such as *ess* or *ette*, e.g. actor and actress. Thankfully, we don't have doctoresses or lawyerettes. Women's clothing is also marked. Ten men in a room could all be wearing dark suits, uninteresting ties and dark closed shoes, and nobody would comment on their clothes–men's clothing is unmarked. There is no style that women could adopt that would be unmarked.

Tannen makes no judgement about differing styles; she simply observes them and offers explanations of how men and women can misunderstand each other. She also clarifies that she does not consider that all women use language in one way and men in another but we do tend to use the differing styles.

Female language is 'marked'

So, do men and women really use language differently? Jennifer Coates drew on evidence from anthropology, dialectology, discourse analysis, ethnography, sociolinguistics and social psychology to find out whether the proposed differences are true or myths [7]. She found that women and men do have different strategies in conversational practice and they do have different styles, although there are few differences overall and any differences are small. Women tend to be indirect and to pay more compliments to the other speakers, while men talk more, swear more and use aggravated directives to get things done. Some analysts have labelled all-female talk 'cooperative' and all-male talk 'competitive'.

Deborah Cameron leaves us in no doubt that there are more similarities in the way men and women use language than there are differences. The title of her book, *The Myth of Mars and Venus*, states her position clearly [8]. She cites a meta-analysis of studies that examined gender differences in verbal and communicative behaviour. There was a moderate effect size in favour of women spelling better and smiling more than men. Women self-disclose more than men and men interrupt more than women but the effect size is small. Other effect sizes were either small or close to zero. Cameron re-examines Lakoff's interpretation of tag questions (e.g. "I'll have dinner ready at six, OK?") as showing uncertainty or seeking approval. Cameron reports a study by another researcher which concluded that women use tag questions to facilitate conversation. "This is a lovely room, isn't it?" is another way of saying "this is what I think, now it's your turn to say what you think". Both men and women use tag questions equally to check information. Another study that was conducted in New Zealand did not find any clear-cut differences between male and female communication styles at work–both male and female managers used a wide range of styles.

It, therefore, appears that although there are some small differences in the way that men and women use language, gender alone is a simplistic and inaccurate explanation. As Cameron points out, it overlooks the rather obvious point that communication by definition involves more than one person. "The way I speak to you is affected by the way you speak to me." People with higher status tend to speak more than people of lower status. Relative power has a substantial impact on how people communicate with each other. Therefore, status and power are more likely to explain why one person will use directive language and another will use indirect, tentative language. However, this again is not a simple explanation that can be applied universally. In healthcare, for example, if a physician uses directive language with a patient and doesn't wait for the patient's agreement, the patient is less likely to be compliant with their treatment compared with a physician who gains the patient's agreement by presenting their instructions as suggestions. The physician is not showing lower status than the patient by using indirect speech, he or she is making use of the style that will achieve the desired outcome.

Status and power more likely explain why one person uses directive language and another indirect, tentative language

Historically, language and gender research has been bias towards studying white western middle-class speakers. Cameron reveals that Lakoff's work was based on her experience of observing men and women in her own social >

How women's use of language might be a disadvantage in the workplace

> circle. Other researchers have used relatives, friends, acquaintances and college students [8]. So we can see that this particular field of sociolinguistic research has been very narrow; rather than telling us about language and gender in general, the results tell us about language and gender in white middle-class westerners.

Tannen acknowledges the limitations of gender as an explanation in language use. For example, she admits that Americans tend to be direct and to value directness whereas the Japanese consider directness to be insensitive and uncouth [6]. This does not mean that the American style is 'male' and the Japanese style 'female'. It tells us that gender differences in language use must be seen in the wider context of cultural differences. We also need to consider social differences and status. This brings Tannen back to her earlier work [4] in which gender difference was only one of several categories that might explain why people can misunderstand each other.

Gender differences in language use must be seen in the wider context of cultural differences

None of this helps women to break through the glass ceiling or to explain why women persistently earn less than men for doing the same job [9]. The main objection to the 'no-blame' theory of gender differences in language use is the inference that women need to adapt to the way men speak. The reality is that the workplace is still a male-dominated domain and women who want to progress up the career ladder have to be better at the game than the men around them. Maybe most women simply don't want to play that game.

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"And what do you want to be when you grow up, Emily?"
"A D-cup!"

Women managers: Employees don't like them

McKinsey, management consultants, contend from their research that five of the nine leadership behaviours leading to corporate success are used more often by women than by men. Furthermore these leadership qualities are becoming more important as companies become less hierarchical and adopt more matrix structures [1].

However, apparently their underlings—both female and male—are not so keen on female bosses. In a survey of 3000 employees conducted in August 2010 by the online recruitment firm www.UKJobs.net 75% of the men questioned and 63% of the women said they preferred to work for a male boss [2]. The average worker had had two female and three male bosses. The reasons for the preference for male bosses were that women bring their personal lives into the office, are subject to mood swings, worry about their appearance, are too competitive and talk about staff behind their back, whereas men are straight-talking, have a to-the-point attitude, are less likely to have a hidden agenda, or get involved in office politics.

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Science IS sexist

by Alexandra Jellicoe

I was listening to the British Radio 4 a few months ago and the discussion about gender intelligence lodged in the deeper recesses of my brain unthought-of until recently when I went to see Jocelyn Bell Burnell talking of her 'Eureka' moment. She discovered the existence of neutron stars called pulsars in 1967 and I think she can safely be considered one of England's most pioneering and gifted scientists. I was struck by her comments that she intuitively knew she had discovered these stars months before it was proved. Her colleagues didn't believe her until she systematically followed due scientific process and offered a logical and evidence-based explanation of what she knew to be right.

I posed a question to Jocelyn during her talk. "Do you think that women are more intuitively than logically intelligent and do you think that as scientific research has been designed to only include this logical, evidence based approach, it alienates women?" Her response was that in order for her to be successful in science she became a 'Shemale.'

To be successful in science she became a 'Shemale'

The part of this I find interesting is the role of male and female intelligence and their role in science. 'Masculine Intelligence' tends to describe a step-by-step, logical approach to problem solving and 'Feminine Intelligence' to describe an intuitive approach to problem solving [1-3]. Of course it is possible for a man to have a more feminine intelligence and vice-versa rather than brain power being defined purely by your private parts. Although I think on the whole the general differences in gender still hold true.

This extract from an article written by Coonor [4], 'Understanding the Difference Between Men and Women' is a very good example of the different approach groups of girls and boys use to solve problems. *"Some of the more important differences in approach to problem solving are illustrated by observing groups of boys and girls when they attempt to find their way out of a maze. A group of boys generally establish a hierarchy or chain of command with a leader who emerges on his own or through demonstrations of ability and power. Boys explore the maze using scouts while remaining in distant proximity to each other. Groups of girls tend to explore the maze together as a group without establishing a clear or dominant leader. Relationships tend to be co-equal. Girls tend to elicit discussion and employ "collective intelligence" to the task of discovering a way out. Girls tend to work their way through the maze as a group. Boys tend to search and explore using structured links and a chain of command."*

The whole structure of science is that it is biased towards this more masculine approach to problem solving. You have a professor looking for the truth in his chosen scientific subject and he commands his researchers to solitarily go out, find the answers and report back. As many people may be looking for the same truth, it fosters a culture of secrecy and competitiveness. Your work is only revealed when you have gone through the painful peer review process of publishing in a journal and beaten your competitors to the punch.

The PhD has also evolved into being many years of work focused onto one tightly bound question or hypothesis and a systematic approach of uncovering the answer to this question. It seems that this may also be more suited to the male brain. Men tend to focus on one problem at a time or a limited number of problems at a time. They take a linear or sequential perspective, and view elements in a task as less interconnected and more independent [4].

Extracts from articles written by Coonor [4] and Hennesy [5] further illustrate this point;

Science is biased towards this more masculine approach to problem solving

"Women have four times as many neurons connecting both sides of their brain than men do. Women have more efficient access to both sides of their brain and can focus on more than one problem at one time and frequently prefer to solve problems through multiple activities at a time.....Young girls have often found the conversations of young boys "boring", whilst young boys express confusion at a conversation between 5 girls who may be discussing as many as three subjects at once. [4]

"Women tend to be intuitive global thinkers. They consider multiple sources of information within a process that can be described as simultaneous, global in perspective and will view elements in the task in terms of their interconnectedness. Women come to understand and consider problems all at once. They take a broad or "collective" perspective, and they view elements in a task as interconnected and interdependent." [5]

In other words, the female brain is likely to find the existing scientific research approach dull, dull, dull. It is too >

Science IS sexist

> narrow and systematic and does not maximise the use of the hive of activity going on in a female brain. Men approach problem-solving from a task-oriented perspective while women typically solve problems more creatively.

Women also tend to communicate more effectively than men, talking through issues and show empathy towards each other whereas men tend to be more task-oriented, less talkative, and more isolated [5]. This is something I personally struggled with enormously whilst doing my own scientific research. My own method of problem solving is to talk to as many people as possible about a particular issue to assist in unravelling my own thinking. I choose people with relevant experience whose judgement I trust. Left to my own devices and without access to this tool I find reaching decisions enormously challenging and actually very stressful. I would much rather use the community brain to reach a collective decision to act on rather than have to make autocratic decisions on my own.

Scientific research approach does not maximise the hive of activity going on in a female brain

I can only draw on my own experience as a female researcher but the structure imposed on me in order to succeed in science was not at all suitable. It did not take advantage of my strong instincts to work as part of a team and talk through issues with like-minded and equally focused individuals. It did not maximise the use of my brain which is inclined to multi-task and keen to address a broad range of problems at once. It did not encourage me to use my skills of inclusive and collective decision making in order to arrive at solutions agreeable to many rather than just some.

The structure imposed on me did not encourage skills of inclusive and collective decision making

In my opinion, the scientific process is incredibly sexist and needs considerable reform. There is a reluctance to accept in the scientific community the difference in approach between men and women. There is a well founded fear of stereo-typing which may lead to sexism. But as far as I can see the entire system is alienating to women and therefore sexist anyway.

A group of people researching a broader topic using their considerable communication skills and inter-changing roles as appropriate has as much value as a solitary figure spending a year in the library reading the literature, two years in the lab and another year secretly writing up their results for publication. There is considerable discussion going on as to why we still actually publish research papers. The process of peer review publishing is to some extent outdated [6]. If research is a continual conversation between peers (as I propose it should be) then there is no need for the existing judge and jury system where virtual strangers can decide if your many years of work are a valuable asset to the scientific community or not. This type of reward system is again, I suspect, much more suited to the male competitive ego than the female.

Is there no scope to include this more feminine intelligence? And more importantly, is our society significantly losing out as a result? A survey published in the Guardian [7] revealed that only 4% of women want to be engineers (more would prefer to be a housewife) and only 14% would consider science careers (see box). Perhaps the lack of scope for feminine intelligence may explain why such a small proportion of women even consider science careers much less proactively pursue them. And many who do start a career in research often do not continue after their PhD [8]. The trouble is, in order to find out if there is any truth in this theory we must use science to test it and as it stands, science may be wholly rather inadequate to do so.

The top 10 career choices for school girls
(*Guardian*, 3rd October 2008)

Model:	32%
Actress:	29%
Teacher:	28%
Lawyer:	24%
Journalist:	24%
Musician:	20%
Doctor:	20%
Beautician/Hairdresser:	20%
Scientist:	14%
Housewife:	12%
Engineer:	4%

Note: More than one choice was allowed

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Doctor, manager and mother: An interview with Beate Hanson

by Diarmuid De Faoite

Beate Hanson is the Director of AO Clinical Investigation and Documentation (AOCID), part of the AO Foundation. She is a medical doctor and clinical epidemiologist who also serves as a clinical assistant professor on a masters programme at the University of Washington, USA. She practiced orthopaedic surgery for several years before moving into management. The mother of two children, she is based in Switzerland.

You've managed to make your mark as a woman in the traditionally male areas of surgery and management. To what do you attribute this?

I've always been a very driven and goal-orientated person. This comes from several sources; from my family history, from something inside me, and also from my life-changing injury. When I was 19 I had a motorbike accident with several very severe fractures. I had to spend 1½ years in hospital, and another 1½ years in and out for further treatment. This was my introduction to the world of surgery. In actual fact it was my surgeon and later mentor, Professor Bernd Claudi who was the one who said to me, "So why don't you study medicine?"

Life-changing injury?

Yes. It was touch and go as to whether they would be able to save my left leg. Before one operation I had to sign an amputation consent form. I didn't know if I would wake up with or without my leg so that night I made a decision. If I survive this operation and come out of this whole, I want to help others. This is where my passion for my work sprang from. I want to help others to survive similar accidents, in particular to avoid complications developing.

Did male surgeons easily accept you as a female surgeon?

I think they welcome females on the team as long as they are either students or young assistant doctors. But this changes the more women move closer to a higher position. I don't think they are ready for it yet. There really is a glass ceiling.

What's the best comment you heard made about you as a female surgeon?

When I was practicing, to my surprise, many male doctors thought I was very talented as a surgeon and said so. I brought the female caring touch in just by paying a lot of attention to the ethical and more human aspects of a surgeon's work, e.g. by talking with patients, their relatives and so on.

How did becoming a mother affect your professional life?

I am convinced that if you are a manager or a doctor or if you are in a position where you have to make decisions for other people, empathy plays a big role. And the ability to empathise is something I learn from my children every day.

The funny thing is that this female touch which was viewed as a strength in the medical world is generally seen as weakness in management.

What can be done to encourage more women to choose a career as a surgeon?

To really facilitate them so that they don't have to make the decision between career or family. The work situation in hospitals is different nowadays. For example, in many countries there is regulated work time, even for young doctors. Surgeons (male and female) need to have the opportunity of additional childcare, including overnight, because you still have to do night shifts. Their family situation can be improved by offering nurseries or daycares and job sharing. I think that addressing these issues would increase the numbers of female doctors and surgeons dramatically.

You moved into clinical research. Why did you choose this branch of science?

When I was in the operating room I always thought that I could only help one patient at a time. Thanks to these clinical studies we conduct worldwide, I am part of a team reaching out and helping many more patients around the globe.

The actual incident that made me aware of the great need for evidence-based medicine was when I was party to a discussion about the treatment of a young man's torn ligament. One doctor insisted he had recently read that conservative treatment could also give good outcomes while the other doctor was insisting upon operating. I realised that this kind of information needed to be available to improve patient care. It also led to my studying in the USA because the courses that interested me were only available there. While in Seattle I could also see that women in the USA receive a lot more encouragement to join the workforce than they do in European countries like Germany or Switzerland. >

Doctor, manager and mother: An interview with Beate Hanson

You are a member of a number of executive boards and are often the only woman on them. Advantage or disadvantage or irrelevant?

All of the above. You have to remember that when a man starts a job he generally expects to be working with men. When a woman starts a job she usually expects to be working with men. But a man never really expects to start working mostly with women, least of all to be taking orders from one. So a woman in an executive position is a relatively unusual situation for both men and women to adjust to.

I do think I had to work harder than a man to be accepted. So whenever you are together with people who you've already proven yourself to, then it is fine. The problem is always the newcomers. I find that you have to prove yourself once again as a woman in a way men don't have to. That's my observation anyway.

Interestingly, you can read in the management literature how women are generally focused on the work at hand, while men become absorbed by work rituals such as titles on business cards.

However, one improvement for me in clinical research is that the working hours are more flexible, making it easier to combine being a mother and a professional.

AO Executive Management 2009

How does a woman survive in the executive workplace?

I think it comes back to the question of this advantage / disadvantage. You have to be aware of that. You have advantages as a woman and you have to play that card fair and smart. You have to also be aware that you have a disadvantage—you cannot pretend you are a man because you're not one! So you have to just be a woman amongst men and that's when you'll find the best acceptance. If you are too girly-girly they don't take you seriously. If you are too male, too macho, then they don't either. My experience is 'be who you are' and that's how I think you can be the most successful. Allied to this, you need to believe that what you are doing is right.

Too many women are unfortunately knocked off course by the societal hurdles they face. This could be anything from a particularly biting comment by a male colleague at a meeting, a lack of conviction in themselves and what they are doing, or an inability to find an organisational solution to help them achieve what they want. I realise that I am lucky in that I've faced all these problems but have never allowed them to deflect me from reaching my personal goals.

How is it to manage a division of 25 people comprised mostly of women?

I was trained as a doctor, I was trained as a clinical epidemiologist, but I was never trained to be a manager. At the time I was applying for my current position as a Director, my second child had just been born. However, I knew that this was a once in a lifetime chance to change my career direction.

Perhaps naively, I simply thought that with my clinical background and knowledge of how I manage my family I could do it. Put differently, I knew that it was a case of now or never and I have never been one to shirk a challenge.

With some experience in both worlds now, I think the real difference between surgery and management is that when you've trained in medicine, particularly spending every day in the emergency room and the operating room, it's all about time. You're trained to make decisions. You are even trained how to make decisions by exclusion because you have to come to a quick decision.

The longer I spend in management, the more I think you get further by having concepts. A patient wants you to make a decision for them. Your employee wants to share decisions with you on what's happening. So you need to be more patient and seek 'buy-in' from employees. This has been a learning process for me.

Any final thoughts on the subject of women in the workplace?

I would like to encourage women to be brave and to aim for what they want in the workplace, in life. Everyone makes mistakes. I made many mistakes which came about from engaging in my work with both my heart and my head. But in the end it all works out. And when it does, you won't have to look back with regret when you are older at any missed opportunities.

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Women's Health

by Joselita T. Salita

Introduction

Our society is confronted with many 'women' issues and an equally pressing one is women's health. Two independent comprehensive reports on this topic were published last year: that from the World Health Organization (WHO) which presents a global picture [1] and the other from the Faculty of Medicine Carl Gustav Carus in Dresden, Germany (which will be called the Carus Report in this article) which concentrates on the EU member states [2]. Although the former also covers European women's health issues under the general label of 'high-income countries', I find it interesting to compare specific EU findings against global trends.

Why is women's health important?

More and more evidence shows that being a man or a woman matters when it comes to health. The WHO report states that women are of more particular concern not only because diseases related to birth and reproductive organs affect only women but also because women in many societies have socio-cultural disadvantages. For instance, due to discriminatory practices, they are more vulnerable to communicable diseases, AIDS for one, and have less access to healthcare and other means like education and employment, which limit them to protect their health.

Global health trends

Women live longer than men. In Europe, women live on average about 7.55 years more than men (computed from EUROSTAT Data in [2]) although this gap is starting to decrease. In 2007 there were 155 million more women over 60 years old living in developing countries than in developed countries, so that an increasing life expectancy is a trend not only in countries with good geriatric care. However, "women's longer lives are not necessarily healthy lives". Pregnancy and childbirth carry risks and this is evidently demonstrated in high maternal mortalities recorded in 2004, accounting for the second leading cause of death among women aged 15 to 44 worldwide, 99% of which occurred in the developing world. Although these risks may not be faced by women in the EU member states, the Carus Report mentions that the so-called Healthy Life Years (HLYs), an indicator of disability-free life expectancy, of women across Europe to be slightly lower (75.4%) compared to men (80.4%). This also interestingly leaves the question whether the longer quantity of women's lives are indeed quality years.

Women are at a higher risk than men of developing osteoarthritis, rheumatoid arthritis and osteoporosis; and in later life, are more likely to suffer mental problems than men such as dementia and Alzheimer's disease.

Depression and anxiety are mental disorders by which women are more susceptible to suffer than men, globally. 13% of women are reported to suffer from post-partum depressions within one year of child delivery. 73 million women worldwide suffer a major depressive attack annually. The Carus Report states that the double work load (family and employment) women have may be responsible for this although more research is necessary to substantiate this.

Suicidal behaviour, believed to be closely linked to depression, is a serious public health problem among women. It is the fifth leading cause of death among women in Europe and is also among the top ten cause of death in women between 20 and 59 years old from low- and middle-income income countries. Although mortalities due to suicide are higher in men than in women, women attempt suicide twice more than men (men seem to be more effective in carrying out suicide, see also [3]). WHO associates high suicidal rates among women in the developing world to women's low esteem in the society, sexual abuse, burden of work, violence at home and easy access to pesticides.

Cardiovascular diseases (coronary/ischaemic heart disease and stroke) are no longer traditional 'male' problems nor are they 'diseases of the affluent'. They significantly cause disabilities and mortalities among women in all income groups. In fact, in low-income countries, they have the most significant contribution to mortalities among the non-communicable diseases and for the age group over 60 years old, mortalities in low-income countries due to cardiovascular diseases are twice higher than in high-income countries, currently accounting for 25% of deaths in this group. Lifestyles of women have changed as well in the developing world leading to obesity, tobacco use and hypertension, which are risk factors for cardiovascular diseases.

Cancers claimed the lives of 1 million women in 2004 with 80% of these coming from low- and middle-income countries. In low-income countries, cervical cancer represents the only cancer form to significantly cause fatalities in women. Low cancer survival rate is attributed to late diagnosis, limited access to screening and less effective treatment. In the rest of the world, breast cancer is the most >

Women's Health

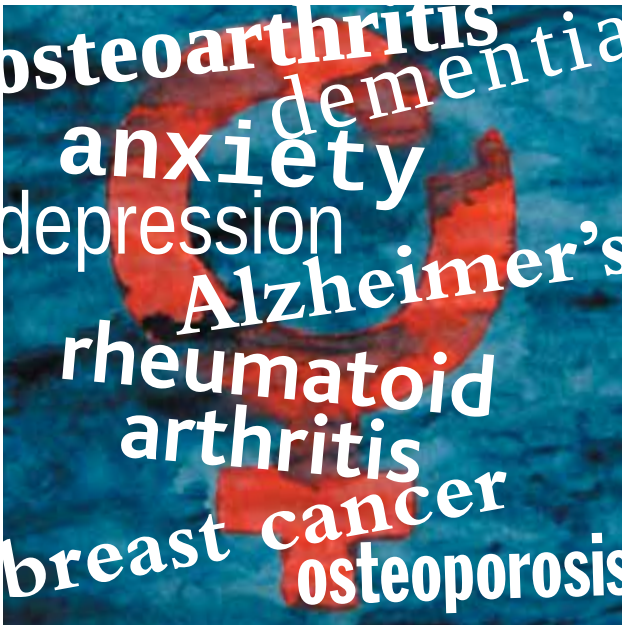
common form of cancer-related deaths. In the EU, mortality due to breast cancer has shown a declining trend due to early detection and improved treatments. Other major forms of cancer-related mortalities among women in Europe are cervical cancer, lung cancer and colorectal cancer.

Differences between global and European health trends

In 2004, about half a million women in developing countries died due to pregnancy and childbirth complications. In Europe, deaths due to these complications have significantly declined in the last decades and still continue to decline. In fact, from 1997 to 2006 there was a decline from 9.32 to 6.05 in absolute maternal deaths for every 1,000,000 live births. The WHO report computes that "an African woman may face a lifetime risk of death during pregnancy and childbirth as high as one in 26, compared with only one in 7,300 women in developed regions". However, the authors warn that the data from the developing world may be unreliable as women in many parts of Northern Africa, East Asia and Latin America have already increased access to health care programmes and awareness of their rights since the 1990s and these must have surely contributed to declines in maternity-related mortalities.

Globally, HIV/AIDS is the number one cause of death among women of reproductive age. This is not so in Europe. Although there has been an increase in HIV reported cases in Europe between 2000 and 2007, there has been a decline of AIDS cases from 20.8 to 9.3 million cases. AIDS is responsible for less than 3% of deaths among women of the EU-member states. There are more men infected with HIV than women in Europe (ratio 2:1), which is also the contrary case in countries like Africa.

Infectious diseases such as tuberculosis and other pulmonary diseases take a big toll on the fatalities of women worldwide. Again, 73% of the data are from the low-income countries and the rest from the middle-income countries. Many women from low-income countries also still suffer from tropical diseases like schistosomiasis, filariasis and nematode infections as a result of poor living conditions and close contact with their infected children. Thousands of women go blind due to trachoma, an easily preventable infectious disease, usually contracted by mothers from their children. In the Carus Report, infectious diseases have an insignificant contribution to mortalities and disabilities of women.



Accidents and injuries are also a leading cause of death and disabilities among women in the world. In low-income countries, 80% of which are reported from South East Asia, fire-related injuries usually associated with cooking and violence at home is one of the eighth causes of this type of mortality. In the EU, fatalities due to accidents and injuries claim about 80,000 lives per year and are the fifth cause of death among women. Most accidents are related to falls and transport. However, European women suffer less accident-related mortalities and injuries than their male counterparts.

Conclusions

The implications and recommendations of both reports are similar: that there is "a paucity of reliable data" and a need for a gender-specific approach not only to address many interesting research-oriented topics but also to create better health policies for the benefit of public health in general. For example, although another independent study shows that there is a 3:1 ratio of women to men affected by migraine [4], data on how this disorder influences European women's health status are scattered. The reports also clearly demonstrate that although commonalities in health trends exist on a global basis, differences arise most likely due to poverty. Although poverty is also a barrier to the health of men, its impact on women may be a lot stronger. This together with the socio-cultural disadvantages women face draws attention that women's health is also a moving social issue. The topic is not just about women and their health but about the world and the call for improvement of data in order to improve health systems is a call to improve the world.

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Ergonomics and the medical writer

by Alice Knight

It would be hard to imagine a world without computers and there is no doubt that our productivity would be a lot lower without them. But widespread computer use brings health risks and users should take steps to reduce those risks.

The *Oxford English Dictionary* defines ergonomics as 'the relationship between people and their working environment, as it affects efficiency, safety and ease of action'.

Ergonomics should not therefore be limited to giving advice on office furniture but should cover all the ways that health can be improved in the working environment.

I have been working as a teacher of the Alexander Technique for more than twenty years, and the main change I have observed over those years is an increase in certain kinds of health problems (shoulder pain, neck pain, headaches, and excess tension in the back, neck and shoulders) among younger people who often appear at first glance to have 'good posture'. This seems to be associated with the enormous increase in the use of computers.

I had never come across such high levels of tension in a group as at EMWA

Thus the demands of working long hours at the computer often take their toll on the physical and mental health of the user. Increased pressure at work in a less than ideal environment leads to unwanted tension and a feeling of being stressed which can then lead to a variety of health problems. I have noticed that when I teach computer users how to eliminate unnecessary neck tension the mere fact of sitting in front of the computer and placing hands on the keyboard appears to rack up the tension in the neck even before any work has been done.

The widespread use of laptops has undoubtedly caused an increase in neck and shoulder problems. It contravenes two of the main principles of healthy working—it encourages a tightening of the neck, and a slumping of the upper spine as the user peers at the screen. It also leads to tense shoulders, wrists higher than elbows and a bending at the wrists in order to use the keyboard. This could be avoided by carrying around an additional keyboard and placing the laptop on top of a pile of books, but that reduces one of the key attractions of the laptop: its portability (Figure 1).

Having looked at the official guidance given by the UK government on health and safety for computer users (www.hse.gov.UK/pubns/indg36.pdf) and the advice given by RSI Action (www.rsiaction.org.uk) on how to prevent repetitive strain injury (RSI) in young people, I can see that there is a large area of common ground in the advice given by the Alexander Technique community and these other advice sources.

Ergonomics should cover all ways of improving health in the working environment

The most basic requirement for improving the working environment is to make sure that the heights of the screen and the chair are appropriate for the user, so that the user is encouraged to have good posture. As far as the Alexander Technique is concerned, the knees should never be higher than the hip joints, the wrists should be below the elbows (or horizontal with the elbows), the arms should not be bent at the wrist, the neck should not be contracted and the head should not be tipped back to see the screen. In addition the feet should be planted firmly on the floor, >

Figure 1. a) Man with a poor posture at a laptop.

Figure 1. b) Man with a good posture when the laptop is adapted.

Ergonomics and the medical writer

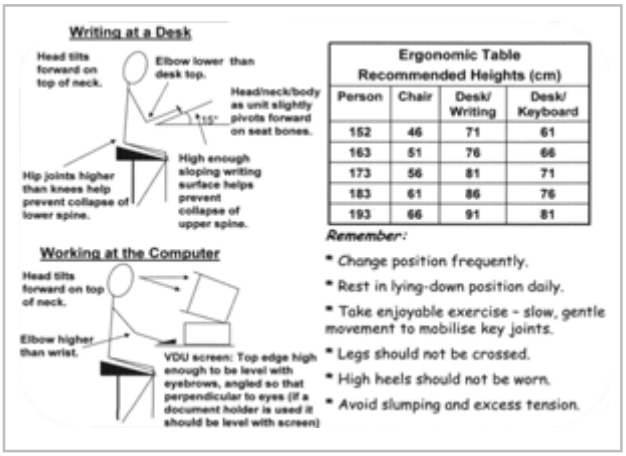

Figure 2. Recommended heights of screen and chair.

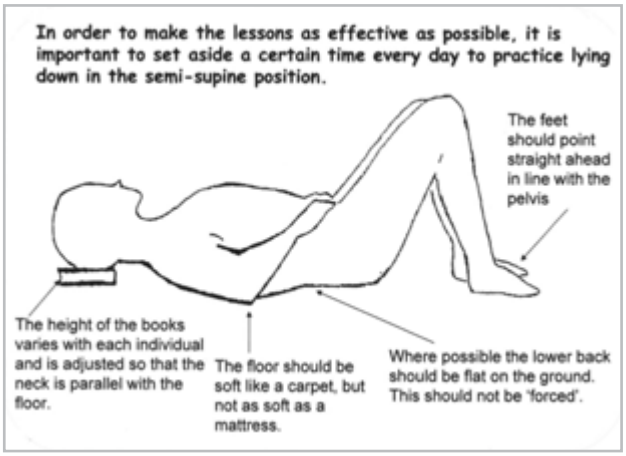

Figure 3. Taking a break lying down in the semi-supine position.

> which means a footrest for shorter people (a footrest can sometimes be improvised by using telephone directories) (Figure 2).

The ideal chair for achieving good posture while working might vary between individuals, but I personally use a Salli saddle chair without a back which looks like a horse riding saddle on top of a conventional office chair base. The saddle chair ensures that the user's legs are kept apart which also helps maintain a good sitting posture, (but of course this is difficult if the user is wearing a tight skirt). The saddle chair has proved to be very popular with dentists who often suffer neck problems from bending over and examining patients. A chair with a forward tilt is often conducive to improving posture and a forward tilt is now a common feature of good office chairs. The seat should never tilt backwards and a forward tilt can be introduced simply by putting a sitting wedge on top of a flat chair.

People will suffer from health problems if they do not take care of their working habits

The physical working environment can only be as healthy as the user enables it to be. No matter how perfect the chair, the alignment with the screen or the lighting to avoid glare, users will still tend to suffer from health problems if they do not take care of their working habits. One of the most simple and yet most difficult measures is to take frequent breaks. Official government guidance is to take frequent short breaks, preferably at least once an hour, RSI Action recommends a few minutes break every half hour and I would strongly agree with these recommendations. One reason why people are so reluctant to take breaks is the apparently addictive nature of working at the computer. From my personal observation, people find it more difficult to take a break from the computer than they used to do when working at a typewriter. As long as the computer is switched on it seems to act as a constant reminder of tasks undone. The therapeutic value of a break will be even greater if the computer is switched off.

What I would advise is that, in your break, you do something really kind to your body and spend ten minutes lying down in the semi-supine position, your head supported by soft books and your legs bent at the knees. This is what we teach our Alexander students: how to lie down in such a way that the spine is encouraged to lengthen and any damage done by working at the computer can be undone. Of course such lying down may be difficult to do in a large open plan office (Figure 3).

Another theme of the government advice is that the computer user should have good posture, it shows pictures of bad posture and again there would be no disagreement with the Alexander community. But the government gives no guidance as to how to achieve that aim apart from making sure that the working environment is well designed. However, we all know that no matter how good the working environment, it does not guarantee good posture. One aim of the Alexander Technique is to teach students how to achieve good posture at work so they do not suffer from excess tension. For some people that can take a long while. An important part of the Alexander Technique is to get people to listen to their bodies—to cultivate their self awareness so that they realise when certain parts of the body are tensing unnecessarily. This enables them to take pre-emptive action to get rid of that tension before it develops into a health problem. If people listened to their bodies more they would realise that they need to take a break to refresh themselves and give them renewed energy, get rid of excess tension and enable them to return then to work more efficiently.

Hot desking and aesthetics are obstacles to a healthy working environment

The ability to listen to one's body can also help people deal with new challenges that they were not specifically trained for. An example would be when someone gets a new pair of glasses. Someone trying on a pair of varifocals should be alert to any neck tension that they might be causing and may decide not to buy them, or ensure that they can be returned if they are not suitable.

So the official government advice, RSI Action and the Alexander Technique agree that your working environment should be organised optimally, you should take frequent breaks and that posture is very important. There are only two points of minor disagreement that I would have with the government guidance. One is that the guidance regards a chair with a back as a necessity to achieve a good sitting posture, whereas Alexander teachers think it is possible to achieve this with a backless chair. The other is that the government thinks that the computer user's arm should be parallel with the floor from the elbow to the wrist, rather than allowing for a slight downward slope of the lower arm as I recommend.

An example of the efficacy of these simple measures can be found in the experience of an EMWA member from Scandinavia, who attended my workshop in 2005. She had suffered from back and shoulder pain, and I found her neck extremely tense. When I met her the following year I discovered that her health problems had vanished. She had followed my advice on the optimal height of her chair and computer screen, she had also practised the Alexander lying down position. The advice on organising the working environment is pretty straightforward and non-controversial, but there are still obstacles to it being adopted throughout the workplace. In a group office framework, unless all the workers have identical body shapes the workstation will probably be slightly different for each worker. That means that hot desking is going to be an obstacle to a healthy working environment. The heights of the screen and chair will have to be adjusted each time a new user starts work. This will take time and work pressures mean that it is not likely to be done. However, requiring people to use identical workstations is similar to forcing everyone to wear standard size 10 shoes. Another obstacle I have come across is the aesthetic one. When I visited a large architectural firm in London and told them what a healthy working environment would look like, they told me that it would be displeasing to the eye and that all work surfaces should be the same height.

If the computer user is self-employed then it should be easier to adopt the work practices that promote good health. But there is still the pressure to meet deadlines that means it is difficult to take the time to organise the work environment and to take the necessary breaks. The important thing here is to realise that taking slightly longer to accomplish a task in the short term will mean less time spent dealing with health problems in the long term.

Alexander teachers, RSI Action and the government agree that it is important that health problems related to computer use should be nipped in the bud and not allowed to develop into serious problems such as RSI. The advice to take early action rather than bearing the pain and hoping that it will go away is vital to ensure long-term health. Although the Alexander teachers' website (www.stat.org.uk) has a first person account of how a student was cured from RSI after taking lessons in the Alexander technique, it is much better to take action well before any serious problems appear.

My first experience as a workshop leader at the EMWA 2005 conference in Malta was that I had never come across such high levels of tension in a group. I attributed this to long hours spent at the computer. However, the experience of my Scandinavian workshop participant shows that medical writers can have the intelligence and dedication to deal with the health challenges posed by working at the computer.

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Alice Knight regularly gives workshops on 'Avoiding Back Pain at the PC: A Therapeutic Self-Help Session Using the Alexander Technique' at EMWA conferences.

Definitions box

Constitutive and inducible

A *constitutive* process is one that carries on without any external influence or signal. An *inducible* process, on the other hand, is one that does not operate unless there is a stimulus or signal. The terms are most commonly applied to enzyme-mediated processes. For example, the system responsible for the production of prostaglandins as part of the inflammatory process in response to trauma involves the inducible form of the enzyme cyclo-oxygenase (COX). However, the synthesis of the prostaglandins involved in the continuous production of the mucus that protects the gastric mucosa involves a constitutive form of COX. In most cases the inducible form of COX is the COX-2 isoform, whereas the constitutive form is the COX-1 isoform.

Most receptor-mediated processes are silent until a molecule of agonist binds to the receptor molecule. This means that the intracellular system to which the receptor is linked receives no stimulus from unoccupied receptors. However, some receptor-mediated systems are constitutive, i.e. the receptor produces a basal level of stimulus to the intracellular process in the absence of agonist. A *full agonist* increases the stimulus to the intracellular process, whereas an *inverse agonist* reduces the stimulus to the intracellular system. An antagonist neither increases nor decreases the stimulus to the intracellular system.

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Newsletters: An invaluable communication tool for clinical trial management

by Monica Ardura and Keith Dawes

Clinical trials are a complex undertaking particularly if multiple trial sites are involved in different global regions. Training for Investigators is normally focussed on the Investigators Meeting, trial initiation visits and at monitoring visits. However, numerous questions arise during the conduct of a trial, along with potential misunderstandings and errors in completing required documentation (such as the patient case report forms). In addition, for complex studies where patient recruitment or treatment is prolonged, or for studies where a rapid recruitment is crucial (such as seasonal studies), maintaining Investigator engagement and motivation is essential. Whilst direct contact with sites is often the best method for dealing with these issues (and the maintenance of question and answer logs), trial-specific newsletters are a common ancillary tool used to communicate changes to Investigators and other trial staff. They are also a good medium for site motivation and can be pivotal in encouraging patient recruitment. Although newsletters are often the task of the clinical monitoring team for a trial (and the trial manager) medical writers can provide excellent support to the clinical teams.

Trial-specific newsletters are a common ancillary tool used to communicate changes to Investigators

Writing and formatting clinical trial newsletters can be an enjoyable task and an interesting alternative to complement more routine medical writing work. They can also help the medical writer understand the course of the clinical trial, which may be very useful when writing the clinical study report. Newsletters can also help establish good ongoing relations with the key players in the study team and are relatively easy and fun to do!

This article will focus on clinical trial specific newsletters; medical writers are also involved in writing and producing other newsletters such as congress newsletters, promotional newsletters or those detailing recent publications (in a particular medical/scientific area). These are not discussed in this article.

Initial steps

Once the decision has been made that a trial-specific newsletter is required, it is essential to develop a template that will be used throughout the trial. The template should be instantly recognisable as being specific for the trial in question. This is normally achieved through branding and the colour scheme. You may also wish to provide the newsletter with a memorable title, based on the clinical trial title. A common publishing software program should be used to create the newsletter template (such as Microsoft Office Publisher, Adobe InDesign, Adobe PageMaker, etc). Using publishing software (as opposed to creating documents in Microsoft Word), means eventual print production will be much easier. In addition, publishing software often has ruler guides (and other useful applications) which mean text boxes and pictures can be easily aligned and moved, making page consistency easier. Microsoft Office Publisher is a very easy program to use and would be a recommendation for beginners (handling text and pictures, menus, styles, formatting and picture toolbars are very similar to Microsoft Word).

The medical writer should request any specific colour brand guidelines to be used for the newsletter. The lead monitor and/or the trial manager will normally be your contact(s). The trial protocol and any sponsor/company or product logos should also be requested. The colour scheme of the template should reflect the brand guidelines or colour of the supplied logos, but garish colour schemes should be avoided as these will deter readers. Suggested regular content for newsletters can also be included in these templates. You may also wish to include a confidentiality clause in the newsletter template. Once a template has been designed and agreed, the key design elements such as colours, body text style, title, and header styles will then remain the same throughout the trial. Some products/medications will have previous newsletter templates that can be easily adapted. At this stage agreements on the frequency of newsletter production, the method of delivery (e.g., newsletters will be printed professionally and distributed to Investigators/sites by post; newsletters will be sent as PDF files via e-mail) and the process for writing content and approving the newsletter need to be made. The length of each issue should also be agreed (normally ranging from 2 to 4 pages; for print production an even number of pages is best).

Newsletter production

For each issue of the newsletter the medical writer develops the content in close collaboration with the trial team. Important changes or modifications to the trial (such as protocol amendments, recruitment drives, and discussion of Investigator questions or common errors) need to be given priority. In some cases, the medical writer will be provided with the draft text that needs to be included in an issue; in other instances a general discussion or

suggestions for content will be made and the medical writer will be required to flesh out the content with individual team members. Suggestions for standard content are provided in the Box below. It is worth noting that newsletters are not discussed directly in the Good Clinical Practice guidelines, but they should be filed in both the site and sponsor trial master files (as they represent relevant communication with the sites). Newsletters should never replace trial amendments and any significant changes in trial conduct that require appropriate regulatory notification.

It is often best to draft and agree the content of the newsletter in a Microsoft Word file before entering the information into the template. This makes it easier for everyone to comment and make changes. When doing this it is good to have an idea of how much content you want to include in an issue (remember you are normally aiming at 2 or 4 pages). The final approved content is then laid out by the medical writer using the standard template and agreed publishing software. This final 'publishing ready' newsletter can then be approved by the trial team. The newsletter is then distributed to the clinical trial sites. Normally, the medical writer is not in charge of print production and distribution, which should be handled by the wider project team (i.e., the trial/project manager and administrative support).

The frequency of each newsletter should also vary strategically depending on the stage of the trial itself. It is often more useful to have rapid issues (monthly) at trial start up (i.e., to address any teething problems or encourage recruitment), whereas quarterly issues may be sufficient during the maintenance period of a long trial.

In summary, newsletters are a common tool used for communicating trial specific information to Investigators, and medical writers can play an important role in producing print quality documents. They are also fun to do and allow medical writers to express their artistic and/or design skills. In addition, they are helpful for understanding the course of the clinical trial, and for establishing good relations with the trial team.

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Newsletter standard content

Note from the Sponsor or Trial Team
A brief text to summarise any relevant trial news.

Trial Team Contact List
Contact details for important trial personnel; can also include vendor contacts and reminders of adverse event reporting procedures.

Trial Progress/Enrollment Update
An update of the current trial enrollment; this can include charts or tables of enrollment numbers, activated sites and the number of enrolled subjects at each site. At first, the number of initiated or activated sites can be provided and later enrollment numbers at each site. A bar chart showing current and target enrollment can also be produced.

Friendly competition can be encouraged among Investigators by highlighting the names of the highest enrollers or by listing the top enrolling sites. Additionally a 'Site of the Month' or 'Congratulations' section can be included to name the top recruiting sites or countries.

Global regulatory updates—giving the status of regulatory approval by country can also be provided.

Note from the Trial Coordinator
The newsletter may include an article or a note from the trial coordinator or the coordinating Investigator of a high-enrolling site, perhaps giving tips on enrollment strategies. The article can also include a brief synopsis of the trial coordinator's work background and a few human-interest sentences about activities and hobbies with an accompanying photograph and/or scanned signature.

Important Tips and Reminders / Frequently Asked Questions / Topic of the Month
Various 'Questions and Answers' or 'Reminders' sections can deal with data entry issues, laboratory or randomisation tips and other subjects (general reminders, reminders on informed consent procedures, protocol amendments, planned meetings, new team members, etc). Common questions from Investigators or trial related personnel can also be addressed.

Case Report Form (CRF) Completion
Including tips for CRF completion or tips on avoiding common queries.

Quizzes
A quiz can be used to stimulate interest and competition (i.e. questions on aspects of dosing or other protocol issues). Recognition can be provided for Investigators answering questions correctly.

Pictures and Team Member Photographs
Pictures are key to drawing the reader's attention and can make the publication more colourful and readable. Using clip art is not recommended when producing a formal published newsletter, but the less formal tone established by clip art may be preferred by some teams. Some sponsors may request to use their own pictures for a particular section of the newsletter. Photographs of trial team members may also be included. For publication purposes, pictures should be of high quality. Low resolution pictures may look terrible when printed. Care must also be taken with copyright. If you are producing a large number of newsletters then consider purchasing a library of suitable photographs/images.

A chance encounter to a successful career—Journey of a medical writer in India

by *Kavita Muchandi*[1]

After completing my MSc in Microbiology in June 2007, I was enjoying the pleasant weather in Bangalore, and was trying to make a decision about whether to search for a position in a multinational company or to go for a PhD. I chose the former and soon found myself attending an interview. My standard answer to most of the questions during the interview was 'I don't know'. The only qualification that the interview panel was happy about was my highly commended MSc thesis. They praised my writing skills and creativity in presenting tables and figures. I left the interview room feeling 'If nothing else at least I am a good writer'. One month later, someone from human resources at the company called to congratulate me on being selected as a 'Medical Writer'. The company was into outsourcing and provided contract services to a global pharmaceutical company, and my job profile was to draft clinical study and pharmacovigilance reports. I was ignorant of this profession.

India's outsourcing market for data management, biostatistics, pharmacovigilance, and medical writing is growing by 21% annually

Clinical research in India

The annual growth of the contract research market in India is estimated to be around 25% [1]. With a highly skilled English-speaking workforce, an infrastructure on par with international standards, and the added advantage of the time zone, India is a favored destination for outsourcing. According to the 2005 Center Watch vendor and outsourcing survey, medical writing was the fourth most frequently contracted service from contract research organisations (CROs); the medical writing market has grown 15% each year over the past five years, to nearly $700 million [2]. The 'offshoring' of medical writing to India started when global pharmaceutical companies began setting up in-house centers in India. This was gradually followed by the entry of CROs and other service providers leading to an increase in outsourcing of medical writing functions. The outsourcing market in India for data management, biostatistics, pharmacovigilance, and medical writing put together is growing at a rate of 21% annually [3]. Today, medical writers in India have taken a step forward towards 'effective medical writing' wherein by producing high-quality documents in shorter turn-around times they facilitate speedy drug submission and approval. India has a pool of qualified, talented, and experienced scientists. Having realised the importance of medical writing in the pharmaceutical industry, I was thrilled to take up this challenging role. Today I understand the importance of good medical writing, and that it can alter the fate of a researched drug product or device.

Skill set of my team

On my first day in the office, I soon realised that my peers came from different academic backgrounds and had diverse experience levels. This diversity helped us, allowing us to leverage on each other's areas of expertise as and when required.

All had a life sciences background, but this varied from microbiology to biochemistry or pharmacology. We also had physicians in our team. The skill sets ranged from writing documents for marketing to writing clinical documents and scientific publications. It was an enriching experience working with this team, and sharing knowledge via presentations on topics such as interpretation of data, statistics, language skills, clinical discovery and basic research.

Medical writing–training and learning

We were in a co-partnership model with our client (multinational pharma) company, where the client provided the functional expertise. This setup was beneficial to us, as the domain experts from the client team guided us through our learning phase.

Then came the nightmare of clearing the competency test to get certified as a medical writer

Our client gave us three months of rigorous training in clinical writing on topics ranging from 'What is clinical research' to 'Medical writing tips'. During the mentoring phase, my mentor used to handhold me in drafting narratives and annual safety reports. Following this came the nightmare of clearing the competency test to get certified as a medical writer. Ten days were given to complete two different documents. Waiting for the results reminded me of my school days. One fine day I got the good news that I had cleared my competency test with a good score and was finally a medical writer.

1 with contributions from Chitra Karanam, Deepa Raj, Kashika Paliwal, Kumaresan Subramanyam, and Rohit Pushparajan

My first document

After all the training I finally began working on my first document; I was thrilled! As I started work on the document, I started to realise the humongous amount of work that goes into writing a document. I learnt that writing a document was not just about writing it; but much more than that. Checking the sentence structure, presentation, and formatting in the document was an important task. The expectation from my client was that I should understand and interpret the data, present it in a comprehensive and logical manner, manage the project, and meet timelines. I felt like a magician wearing 10 different hats.

My client was approximately 6,500 nautical miles away in a different time zone. I was working on a project with team members located in Japan, Europe, and the USA. Initially I found it difficult to schedule a teleconference at a time convenient to all the members. At times, it was difficult to get required responses from the team members within scheduled timelines; neither was it easy to manage differences of opinions between team members in different geographic regions. Waiting for a response for a project with tight timelines was maddening; however, with time I realised that being in a different time zone helped overall: people working across all time zones meant that a document got worked on 24 hours a day, 5 days a week.

Being in a different time zone helped overall: people working across all time zones meant a document got worked on 24 hours a day, 5 days a week

I learnt to juggle drafting, following-up on data from different team members, resolving conflicting review comments, conducting meetings, and managing timelines, and was finally able to complete my first document.

From time to time I heard terms such as 'turn-around time (TAT)' 'service level agreement (SLA)', and 'productivity' being mumbled across the workplace; these terms were unfamiliar to me. My peers told me that a lot of mathematical calculations need to be done to arrive at these 'parameters'. Most of the life science graduates would agree that we are not very comfortable with complex numerical calculations, and I kept wondering 'Do I really need to know these terms? Is it not sufficient that I write good documents and meet timelines?' I tried to keep myself away from these terms until one day my supervisor started explaining to me what they meant and why they were critical to our organisation. TAT is the time taken to complete a given task (e.g. the number of days taken by the writer from the availability of final tables to send the draft out for clinical review). SLA is an agreement between the service provider and its customer, quantifying in measurable terms the minimum acceptable service that is to be provided to the customer. Productivity can be measured based on the number of hours taken to produce a document (e.g. if the allotted hours per SLA to complete a report are 20 and the writer completes it in 10 hours, their productivity is 200% [time allotted/time utilised ×100]).

I was in awe as I listened; I did not know that numbers mattered so much in determining the 'performance' of our medical writing team. I wanted to learn more about these 'parameters' or 'metrics'. Metrics became the basis of performance management, which was transparent within our team.

Metrics in medical writing

In the initial days of my job, I was doubtful if we could ever quantify 'quality' or 'TAT' in a subjective field like medical writing. A few months down the line, and after interaction with people who use Operational Excellence (OE) tools in the outsourcing industry, I could say with a degree of confidence, yes, 'quality' and 'TAT' can be measured. Quality can be measured, based on the number or nature of review comments, number of data errors, etc. Similarly, TAT can be measured based on the time taken from data analysis completed and output tables available to send the first draft out for clinical review. Again, TAT would depend on the complexity of the document; and we could categorise the complexity of documents based on the type of document (e.g. abbreviated report versus full report), the phase of the clinical trial (e.g. phase II versus phase I), study design, endpoints, etc.

I would say that the 'one size fits all' approach may not work well for determining the metrics in medical writing. The measurement parameters need to be customised depending on the nature of the work, the business model, etc. Over time, metrics need to be revisited and refined based on the lessons learned; this is a continuous process–perhaps analogous to the drug development process, where a molecule moves from the laboratory to clinical trials; and findings from clinical trials form the basis for further investigation of the molecule in the laboratory setting.

Quality can be measured on the number or nature of review comments, number of data errors, etc.

Growth in medical writing

We started off by writing simple documents such as abbreviated clinical study reports (CSRs) for terminated phase I studies and gradually moved up the complexity curve to writing regulatory summary safety reports (such as investigational new drug [IND] annual reports, periodic and annual safety update reports), investigator's brochure (IB) updates, investigational medicinal product dossiers (IMPDs), etc. Over time we began writing complex documents such as full CSRs for phase II, III, and IV studies, and complex IBs; and we assisted in preparing regulatory responses. With each new type of document, I learnt a different aspect of medical writing and regulatory requirements; and my passion to learn about drugs and diseases steadily increased. >

Journey of a medical writer in India

My experience as a medical writer

Medical writing is not an easy profession, especially when it is outsourced. I realised that the major challenge Indian writers face, working across geographic regions and virtual environments, is building trust and camaraderie, as we do not have face-to-face interactions with the on-shore client team members. Over a period of time we were able to build that trust by going above and beyond the expectations of our clients and proving ourselves to them. Also we learnt a great deal about people working in different geographic regions. For example, the Japanese always add -san to the name to show respect. We learnt to be well organised, and planned to handle meetings with people across geographic regions. Working as a medical writer certainly has its share of funny moments. I still remember a teleconference involving about 15 people one of whom was breathing heavily into the telephone (completely oblivious to the fact that he/she was not on mute). After about 30 seconds of this when it was getting tough to ignore it and carry on with the call, the host said, "Would Darth Vader get on mute please. The heavy breathing is not helping at all," which brought on a roar of laughter from all on the call.

From my experience I can say that nothing about medical writing is predictable except that we writers have to be extremely flexible, patient, focused, and last but not least 'be open to feedback'. And being skilled in the English language alone, is not all we need to become the best medical writers; to be a good medical writer, we need also to have effective communication, interpersonal and management skills.

Conclusion

Life for me as a regulatory medical writer has been a roller coaster ride with crazy bends and dizzying drops, but with great thrills too. I am certain you will know what I mean if you are also a medical writer. The whole effect is quite overwhelming but there are rewards too; there is a sense of achievement when you finish writing and wrap up a project. We emerge as better writers and managers after every document we write, with new experiences and expertise, and broadened horizons. Personally, I believe medical writing has taught me to be more patient, more flexible, to communicate effectively, and to manage people and conflicts better, which positively influences my personal life too. My journey as a medical writer has been a gratifying experience and I am proud to be a member of this great fraternity of 'medical writers'.

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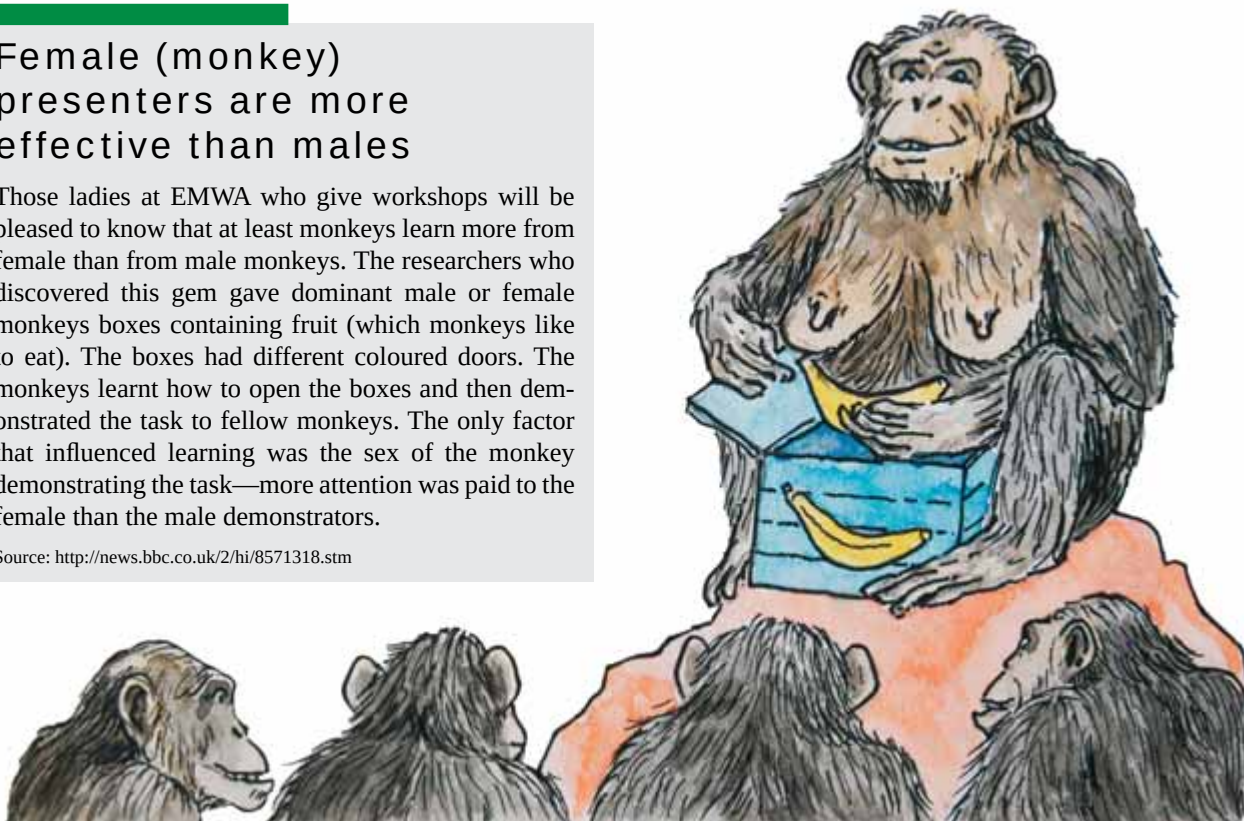
3. The glorious metamorphosis. Compelling reasons for doing clinical research in India [Internet]. http://www.ficci.com/Clinicla-Research-Report.pdf. Accessed 08 November 2010.

Female (monkey) presenters are more effective than males

Those ladies at EMWA who give workshops will be pleased to know that at least monkeys learn more from female than from male monkeys. The researchers who discovered this gem gave dominant male or female monkeys boxes containing fruit (which monkeys like to eat). The boxes had different coloured doors. The monkeys learnt how to open the boxes and then demonstrated the task to fellow monkeys. The only factor that influenced learning was the sex of the monkey demonstrating the task—more attention was paid to the female than the male demonstrators.

Source: http://news.bbc.co.uk/2/hi/8571318.stm



Novel tool constitutes a paradigm: How title words in medical journal articles have changed since 1970

by Neville W Goodman

Increasingly, the titles of medical articles are including words emphasising and probably exaggerating the importance of their subject matter. This, plus an apparent need to impress with long words and often inappropriate metaphor, makes medical writing less good and less honest.

The title of an article is its advertisement: readers read it before reading on or moving on. Certain words, e.g., 'novel' and active verbs [1,2], had been becoming more common in the titles of articles in medical journals, presumably because authors or editors think the articles are then more likely to be noticed.

I wanted to follow this up, to see if the trends have continued, and to find other title words that are becoming increasingly popular with medical authors. I once asked someone why they had used 'haemorrhaged', as in "the rats were haemorrhaged", instead of 'bled'. I was told that 'haemorrhaged' was more scientific. Is there evidence that longer words are preferred to shorter words? Another way to appear in the forefront may be to use words associated with technological advance, or words taken from other disciplines.

I used PubMed (http://www.ncbi.nlm.nih.gov/pubmed) with limits of title field and articles published in English, searching in 5-year periods (1970-74 until 2005-09). For each word searched, I corrected for the total number of articles published, and then scaled that corrected value to the base number, the total for 1970-74. If this corrected prevalence doubled, this is a twofold change. Provided that the base number of any word was not too small, this change enabled direct comparison of the prevalence of any words, and to describe increasing prevalence implies that the increase more or less followed a trend from 1970-74 to 2005-09.

I intended comparing 'new' with 'novel', and the word forms of a number of verbs (infinitive and third person plural, third person singular, present participle, past participle, and associated noun). For long words preferred to short, I chose the verbs 'constitute' and 'represent', which tend to be used instead of 'is' and 'are'. The technical words were 'functionality' and 'tool'. For a word taken from another discipline, I chose 'paradigm', originally a linguistic term. Paradigm is a word that I have already discussed [2]; Atkin [3] noted its increasing use as 'paradigm shift'. In the course of searching these words, I sometimes searched other related words, or phrases containing the words. Nouns were searched in both singular and plural forms.

About 12% of all articles are classified as editorials or reviews. (The percentage is less for the first four 5-year periods, but I don't know whether that is because there were fewer editorials and reviews, or because of non-classification.) For each word, I calculated the percentage of the total number of articles (i.e., 1970-2009) that were editorials or reviews. If the percentage was much greater than 12%, then I presumed the word was favoured by those writing editorials or reviews, and vice versa. I did not explore any time trends for words in editorial and review titles.

PubMed has 'stopwords', which it will not search for. Thus, it is not possible to search for the infinitive form of a verb separately from the third person plural, because 'to' is a stopword.

New is not enough

In 1970-74, 1.9% (over 13000 articles) of all article titles in PubMed included 'new'. In 2005-09, there were nearly 70000 titles containing 'new', but this was still only 2.1% of all articles. 'Novel' has increased from less than 0.1% (573 articles) in 1970-74 to over 50000 titles: a 20-fold rise to 1.56% of all articles. So far in 2010, this has risen to 1.75%, so the trend continues. The increasing popularity of 'novel' is even more in PubMed's core clinical journals (Fig. 1).

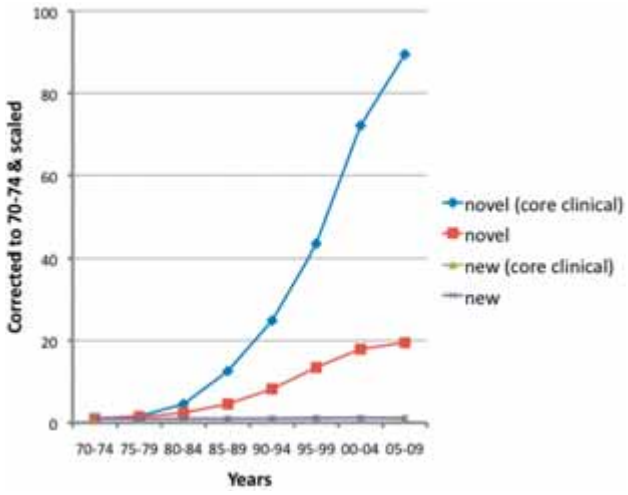


Figure 1 **The prevalence of 'novel' and 'new' in titles of articles published in English and searched in PubMed in 5-year periods, in the whole of PubMed and in the core clinical journals. Number of articles corrected for the total number in each period, and scaled to the 1970-74 value.**

How title words in medical journal articles have changed

> 'Innovative' has increased fivefold since 1970-74. 'Innovation' has increased more than twofold, most of that increase since 2000. Of the seven titles containing both 'novel' and 'innovation' four were published in 2005-09. No one has yet written of a 'novel innovation' but 'new innovation' has an increasing, albeit small, presence.

Fourteen per cent of editorials and reviews had 'new' in the title; 7% had 'novel'. Between 15% and 20% of 'innovative', 'innovation' and 'new innovation' were editorials or reviews.

Actions speak louder; so do longer words

For verbs, I searched, in this order: improve, maintain, prevent, reduce, predict, regulate, stimulate, inhibit, enhance, suggest, excite, suppress, respond and promote. For all of these verbs, the associated nouns are unambiguous (e.g., in contrast to increase, for which 'increases' is both the third person singular and the plural noun). These verbs and nouns are very common title words: over 12% of all titles in 2005-09 contained at least one.

For 10 of the 14 verbs, the third person singular showed the largest increase, and the associated noun showed the smallest, if there was an increase at all. The third person singular increased on average 43-fold; the nouns barely at all (see Fig. 2). The infinitive or third person plural increased 10-fold. (For some reason, the infinitive 'to maintain' was searchable. 'Maintain' and 'to maintain' both increased by the same amount, but I do not know if this equality is generalisable.) The two participles increased between two- and threefold. In 1970-74, the noun form was used four times more than all other forms together; for 2005-09, the other forms had overtaken: 199381 to 198834. The increasing use of the third person singular was even more pronounced in the core clinical journals: on average a 105-fold increase compared with a 43-fold increase.

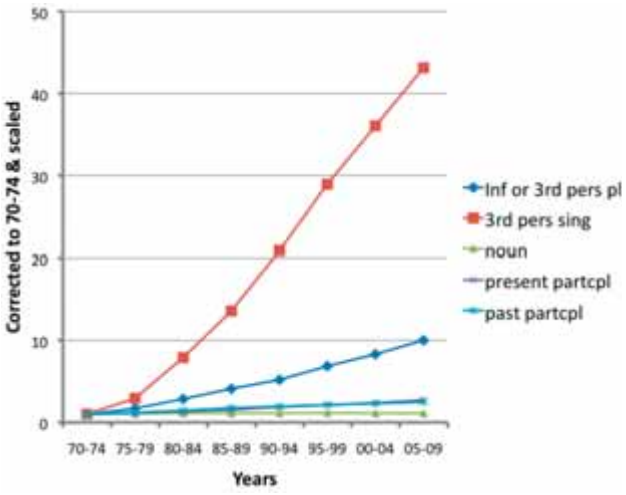


Figure 2 **The prevalence of word forms (see text for more detail) in titles of articles published in English and searched in PubMed in 5-year periods. Number of articles corrected for the total number in each period, and scaled to the 1970-74 value.**

After calculating these averages, I looked at two more verbs, 'occur' and 'treat', and they followed the same pattern.

The pattern for editorials and reviews was different. The third person singular was the least likely form for all verbs except treat: overall, only 1% of titles containing a third person singular was an editorial or review. The noun form was by far the most common; it was 2.4 times more common than all other forms together. The present participle was easily the second most common form in editorial or review.

Diagnose is not as simple, because 'diagnoses' is both verb and noun. The singular noun, 'diagnosis', did not alter. 'Diagnose', 'diagnoses', 'diagnosing', and 'diagnosed' increased three- to fourfold. The additional, adjectival, form diagnostic increased 1.4-fold. But the phrase 'newly diagnosed' increased 17-fold. About 6% of titles containing 'newly diagnosed' was an editorial or review.

'Constitute' and 'represent' are not common title words but their prevalence has increased: 'constitute' sixfold and 'represent' 12-fold. It is not possible to compare their increasing use with any substitute words, and 'is' and 'are' are stopwords. 'Ameliorate' has increased 18-fold. 'Ameliorate' is a difficult word to substitute by a single short word, but 'better' has increased only fourfold. Only 2.4% of titles containing 'ameliorate' was an editorial or review.

Pick a word from somewhere else

'Function' is a common title word: 1.2% of all titles in 1970-74. There has been a steady but small increase to 1.5%: a 1.2-fold increase in prevalence. 'Functionality' first appeared in 1960 and there were two others in the 1960s. There were six in 1970-74, and 664 in 2005-09: a 24-fold increase. 'Functionalities' appeared in 1978, so its 2005-09 prevalence cannot be compared with 1970-74. However, there were 42 in 2000-04 and 112 in 2005-09, which, allowing for the increased number of papers between those periods, corrects to 86.

While investigating 'functionality', I discovered 'functionalization', but this turned out to be a technical term in chemical synthesis.

'Tool' is not a new title word: there were 98 in 1950-54. Correcting to 1970-74, this equates to 301. By 1970-74, there were 430 'tool' (or 'tools'), only a 1.4-fold increase in 20 years. That 1.4-fold increase was repeated in the next 5-year period, 1975-79, and by 2005-09 there had been a sixfold increase. There are big differences between different 'tools': whereas 'therapeutic', 'clinical' and 'research' tools are unchanged; 'prognostic' (up 11-fold), 'screening' (25-fold) and 'assessment' (28-fold) tools are becoming much more popular.

'Toolbox' appeared in 1989, and the 224 (which included three 'toolboxes') in 2005-09 were a twofold increase on 2000-2004. So far, in September 2010, 'toolbox' has increased 1.2-fold on 2005-09.

Seventeen per cent of titles containing 'tool', and 25% containing 'toolbox', were editorial or review.

Atkin [3] noted the increasing use of 'paradigm shift' in 2002, and it increased 1.2-fold between 2000-04 and 2005-09. Whereas 'paradigm shift' didn't appear in a title until 1980-84, 'paradigm' appeared in 70 titles in 1970-74. Its prevalence has been increasing ever since, to ninefold in 2005-09. (I searched for 'paradigm', 'paradigms', and 'paradigmatic'. 'Paradigmatically', the only remaining member of the set that forms the paradigm of 'paradigm' did not appear in a title.)

There was one 'new paradigm' in 1970-74, and 426 in 2005-09: one sixth of all titles containing 'paradigm'. Although small in absolute numbers, the prevalence of 'novel paradigm' in 2005-09 was three times the prevalence in 1995-99. There are five titles containing both 'innovative' and 'paradigm': the first was in 1981, but the others are all after 2000. In 2003, there was an 'innovative paradigm'.

'Paradigm' is favoured by writers of editorials and reviews: 42% of 'paradigm shift' and 34% of other uses of 'paradigm' were in their titles.

Good for medical writing?

These changes in medical article titles in the 40 years surveyed seem to indicate a curious mixture of influences. Those from journalism drive authors to be more direct—to move to using active verbs; and a misunderstanding of scientific style drives them to prefer longer words. These influences are a curious mixture because good journalism avoids long words. If medical authors looked seriously at what makes good journalism, their articles would be a good deal more readable. I suspect that the use of active verbs is not mimicking journalism, but has happened simply because medical authors think that "Newbetalol prevents tachycardias" will attract more attention than "Newbetalol in the prevention of tachycardias".

There seems also to be inflation in authors' descriptions: more and more research is described as 'novel'; and, having latched on to the impressive sounding word, 'paradigm', increasingly that is not enough in itself. Perhaps we can expect "Newbetalol represents a new paradigm for treating tachycardias". 'To innovate' is to introduce new methods, ideas or products, so what message—other than a suggestion of illiteracy—is an author trying to give by writing of a 'new innovation'? There is at least one journal, *Analytical Biochemistry*, whose instructions to authors explicitly state: "In creating a title for your paper, please omit words such as *novel, rapid, improved, simple, sensitive, efficient, convenient, new*. Each is felt to be redundant and actually slows down the reader who is scanning the article titles and wants to know more about the method itself" [4].

Is it medical authors or their editors who are the more responsible? Few journals employ copy editors but, if editors change anything in articles, perhaps it is likely to be the title. The evidence from my survey is not clear on the relative popularity of some title words in editorials and reviews compared with the whole of PubMed. Authors of editorials and reviews (and surely journal editors will be more keen to change their titles than the titles of research articles) do not like the third person singular of verbs. They prefer 'new' to 'novel' (yet like 'innovation'), but they seem keen on 'paradigm' and 'tool'. However, the use of active verbs differs between journals: the *New England Journal of Medicine* has more than the *Lancet* or *BMJ* [5].

Do these changes matter? I dislike them; I think they make medical writing less good, less honest. 'Novel' does not mean 'new', and should not be written in its place. Using the active form of a verb in the title of a research article too often risks exaggeration of the research findings. Writing 'represents' instead of 'is' is polysyllabic fog. 'Functionalities' may be useful to people selling computers, but 'uses' is a better word for the medical author.

'Tools' are hammers and saws: why the need for metaphor in medical titles? A typical title is "Infrared-spectroscopy: a non-invasive tool for medical diagnostics and drug analysis." But infrared-spectroscopy is a method; if anything, it is the spectroscope that is the tool, but that too is the wrong word: the right word is instrument or equipment. These words are longer, but they are the correct ones, and medical journals do not have the newspapers' problem of space, which dictates that 'backs' means 'supports' and 'clash' covers every argument. The first 'toolbox' was "Snake venoms: toolbox of the neurobiologist"; but the venoms are the tools, not the toolbox. Metaphors such as these demonstrate not originality but poverty of expression, which is not good for medical writing.

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Reflections on stability? A 3-year analysis of the EMWA website job postings

by Thomas M. Schindler

This article is based on the notion that job postings on the EMWA website in some way reflect the job market for medical communicators in Europe. Although it is clear that not all medical writing positions will be posted on the EMWA website, positions with an international scope are likely to appear there. A more detailed reasoning why this assumption has some value is available in a previous report by the same author (*TWS*, Vol. 18, No. 2, 2009, p. 124-126). Compared with other means of hiring medical writers, such as the involvement of head hunters, advertisements in print media, etc., a posting on the EMWA website is very affordable and offers the most direct link to the target group of medical communicators in Europe.

Over the 3 years from 2007 to 2009, 82 different companies used this service. They included many large pharmaceutical companies and many of the major contract research organisations (CROs) and medical communication (MedCom) agencies. However, the majority of postings came from small to medium-sized MedCom agencies. Overall, the majority of companies (n=58, 70.7%) had only 1 posting in 3 years, 18 companies (22.0%) posted adverts in 2 years, and only 6 companies (7.3%) had postings in all 3 years of the analysis (2 pharmaceutical companies, 2 MedCom, 1 CRO, 1 recruitment agency).

The number of postings varied substantially over the years (2007: 57; 2008: 68; 2009: 37). While the increase from 2007 to 2008 seemed to signal a broader awareness of the EMWA website, the stark reduction in 2009 is surprising. The lower number of postings in 2009 is most likely due to the economic crisis in the aftermath of difficulties in the financial markets. And indeed, according to figures published by EFPIA (European Federation of Pharmaceutical Industries and Associations, http://www.efpia.org), expenditure for research and development was lower in 2009 than in 2008 and employment in research and development also declined from 113,378 in 2008 to 110,000 in 2009.

Methods

This analysis over 3 years used the same methodology as in the previous report. Copies of the job postings were received from EMWA headquarters together with a list of companies who had posted adverts. Data analysis, quality control, and the writing of this article were performed exclusively by the author.

Companies, adverts, and positions

The number of companies that posted adverts, the number of postings (several companies had more than 1 posting per year), and the number of positions offered (a single posting can advertise several positions) varied over the years.

In 2009, the number of companies that posted advertisements was only 50% of that in 2008. Likewise, the number of positions offered was about 50% of that in the previous year (Table 1). While in the years 2007 and 2008, the proportion of adverts posted by recruitment agencies was fairly constant (16% and 15%), its share increased sharply in 2009 (35%). In most cases, the recruitment agencies specified the type of company they were recruiting for.

Table 1: Companies, postings, and positions offered in the period from 2007 to 2009

	2007	2008	2009
Companies with at least 1 posting	39	50	25
Number of postings	57	68	37
Number of positions offered*	67	88	48

* The number of positions offered is not easily determined as some postings offered "several" positions. In these instances, 2 positions were assumed.

Type of employer

Over the 3 years analysed, the major contributors to the job postings were MedCom agencies, pharmaceutical companies, and CROs (Table 2). The number of job postings from MedCom companies remained on a fairly constant level, while the postings by pharmaceutical companies and CROs became less frequent over the years. Conversely, the proportion of job postings by biotechnology companies increased from 1 (2%) in 2007 to 6 (16%) in 2009.

Qualifications required and types of work advertised

About two thirds of positions offered required a background in a life science or medicine, whereas around one third of advertisers were only interested in the "relevant experience" of the applicants irrespective of their academic background (Table 2). Over the 3 years, there were very few positions for applicants with an arts/humanities background. The proportions of adverts that looked for science graduates and those focusing on relevant experience were similar in all 3 years.

Table 2: Summary of the analysis of postings on the EMWA website for the period from 2007 to 2009

	2007	2008	2009
Type of company*			
MedCom agency	33%	46%	49%
Pharmaceutical company	44%	24%	19%
CRO	12%	10%	5%
Academic	4%	1%	0
Publisher	0	4%	0
Biotech	2%	8%	16%
Regulatory agency	2%	3%	0
Staffing agency	0	0	3%
Other / unclear	4%	5%	8%
Qualification required**			
Life Science / Medical	64%	73%	67%
Relevant experience / unspecified	34%	26%	31%
Language / Translation	2%	1%	0
Medical non-academic	0	0	2%
Types of work**			
Communication	48%	36%	50%
Regulatory	27%	24%	27%
Mixed	21%	23%	13%
Editorial	0	7%	0
Safety writing	0	1%	0
Technical writing	0	1%	4%
Unclear / other	4%	8%	6%
Locations***			
United Kingdom	55%	52%	40%
Switzerland	9%	18%	20%
Germany	9%	13%	18%
France	13%	3%	7%
Austria	0	4%	7%
Ireland	0	4%	0
India	5%	0	0
Unclear / several	5%	1%	4%
Other (<2 or home-based)	4%	6%	4%

* Percentages were based on the number of companies that posted at least 1 advertisement (2007: 39, 2008: 50, 2009: 25).

** Percentages were based on the total number of positions in each year (2007: 67 positions, 2008: 88 positions, 2009: 48 positions).

*** Including only countries with at least 2 positions in any year

Almost half of the positions offered were in medical communications and about one quarter of the postings were looking for writers for regulatory documents (Table 2). About 20% of postings asked for applicants who are proficient in both areas. The proportions of job postings in these different areas of medical writing have remained broadly constant over the years. The demand for editorial skills was also fairly constant: about one third of postings mentioned editing as a task of the job (2007: 33%; 2008: 41%, 2009: 36%). However, the number of postings for editors was low.

When analysed in more detail, it becomes apparent that science graduates have an advantage over applicants with other academic backgrounds in all realms of medical writing. Particularly positions for regulatory writers asked for a background in a life science or medicine (71% to 100% over the 3 years). As might be expected, postings for medical communications positions focused somewhat more on the relevant experience, although even in this area, more than 50% of positions required a scientific background (Table 3).

The proportion of adverts that preferred applicants with a doctorate (PhD) appeared to slightly increase over the 3 years (2007: 27%, 2008: 26%, 2009: 33% of all positions advertised). However, most adverts indicated that the company would also settle for applicants with an MSc.

When a qualification in life science or medicine was required, more than a third of the positions preferred candidates with a PhD (2007: 30%, 2008: 36%, 2009: 39%). When the hiring company focussed on the relevant experience, a PhD was only rarely required (2007: 11%, 2008: 4%, 2009: 13%). Particularly in advertisements seeking regulatory writers, the requirement for a PhD increased substantially over the years (2007: 28%, 2008: 43%, 2009: 54%), while for positions in communications the need for a doctorate remained roughly stable (2007: 28%, 2008: 25%, 2009: 33%). This was also the case for positions offering work in both areas (2007: 21%, 2008: 20%, 2009: 17%).

Most advertisements were for permanent positions (2007: 96%, 2008: 80%, 2009: 98%). While a few postings mentioned salaries in the years 2007 and 2008, none of the postings in 2009 mentioned a salary sum.

Location

In 2007, applicants could choose between 8 different countries. In 2008, the choice was even greater with 10 different countries. In 2009, altogether 7 countries were available as work locations (1 posting offered several locations in Europe). Most positions were located in the United Kingdom, followed by Switzerland, Germany, and France. This result is heavily influenced by the type of work offered. For postings concerning positions in medical communications, most jobs were located in the United Kingdom (2007: 54%, 2008: 70%, 2009: 72%), while jobs for regulatory writers were predominantly located in other countries of Europe (non-UK Europe 2007: 65%, 2008: 64%, 2009: 85%). However, even among the postings for regulatory writers, a sizeable proportion of the jobs offered were in the United Kingdom (2007: 35%, 2008: 36%, 2009: 15%), followed by Switzerland (2007: 6%, 2008: 23%, 2009: 31%) and Germany (2007: 18%, 2008: 18%, 2009: 15%).

Interpretation

The overall number of adverts posted varied greatly over the 3 years. It appears that this variation in volume is due to the economic crisis in 2009. Hence, it is obvious that the number of job opportunities for medical communicators depends rather directly on the economic situation in the pharmaceutical industry. The analysis showed that while >

A 3-year analysis of the EMWA website job postings

Table 3: Breakdown of positions by specialty area and required relevant experience

	2007		2008		2009	
Key area of position posted	Life Science	Relevant Experience	Life Science	Relevant Experience	Life Science	Relevant Experience
Communication	72% (n=23)	28% (n=9)	63% (n=20)	37% (n=12)	54% (n=13)	46% (n=11)
Regulatory writing	83% (n=15)	17% (n=3)	71% (n=15)	29% (n=6)	100% (n=13)	0
Mixed	43% (n=6)	57% (n=8)	85% (n=17)	15% (n=3)	83% (n=5)	17% (n=1)

Table 3 above addresses the question "How many of the communication jobs in year X asked for a life science background?" The total number of positions included in this analysis is smaller than that included in the overall analysis because positions for technical writers or positions with an unclear job profile are excluded. Thus 3 positions for 2007, 15 positions for 2008, and 5 positions for 2009 are not included here.

> the number of postings was variable, the structurural composition of the postings was surprisingly stable. So, over the years, the key users of the EMWA website remained the same, namely MedCom companies, pharmaceutical companies, and CROs. While the proportion of postings by MedCom companies increased, that of pharmaceutical companies and CROs decreased. The increase in adverts from biotechnology companies may signal that some biotechnology products have reached a more mature stage in clinical development.

In regard to qualification, applicants with a background in a life science or medicine have a clear advantage in all areas of medical writing. The demand for a science background was particularly high in positions for writers of regulatory documents, but a science background was also in constant high demand over the 3 years for jobs in medical communication. I venture the thought that the companies may find it harder to teach an applicant the science needed than to train the science graduate in issues of language and style and regulatory compliance. Hence EMWA is well advised to supply trainings in these topics.

The demand for higher qualifications appears to be increasing. In 2009, 33% of positions advertised would have preferred candidates with a PhD. This may mean that the medical writing groups in the different companies are increasingly looking for candidates with higher qualifications to fill their more senior positions. I interpret the wish for a science background, at best at PhD level, as a positive sign for the profession. The science credentials will make it easier for the medical writer to find acceptance among the other members of clinical development teams who themselves have a scientific, medical or mathematical training.

Interestingly the proportions of the different areas of medical writing have remained almost constant over the 3 years, with about 50% of the positions in medical communication and about a quarter of the positions in regulatory writing. The absence of fluctuations might indicate a rather steady demand/supply situation for qualified personnel.

Regarding work location, 2009 was the first year in the analysis when the job postings for the United Kingdom were outnumbered by other European locations. However, still 40% of medical writing positions advertised on the EMWA website were in the United Kingdom. Both Switzerland and Germany have increased their share over the past few years.

Overall, the analysis of the job postings on the EMWA website indicates that the job market for international positions appears to be strongly dependent on the economic situation in the pharmaceutical industry. However, the relative structural stability of the postings in regard to qualifications required and the type of work advertised signifies a stable demand/supply situation for medical communicators in Europe: an encouraging finding for future medical writers.

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Plain language benefits and tips

A recent article gives tips to scientists on how to effectively communicate with the media and the public [1]. Using plain language could help scientists progress in their careers. Research published in *The New England Journal of Medicine* found that subsequent reporting of the work in *The New York Times* increased citations of the research by 73%. Lily Whiteman refers to this report and also describes how the journal *The Cleveland Clinic Journal of Medicine*'s dramatically increased its readership through use of plain language and a popular format [2].

Whiteman's article is posted on Plainlanguage.gov, which aims to improve communication between the American Federal Government and the public. Their section on health literacy is available at: http://www.plainlanguage.gov/popular topics/health_literacy/index.cfm. The site also provides before and after comparisons, including one of an over-the-counter drug label, and a humour section, e.g. "Test results were extremely gratifying" translates as "We are so surprised that the stupid thing works". The resources section is useful for both writers and trainers.

References:
1. Van Eperen L, Marincola FM, Strohm J. Bridging the divide between science and journalism. *Journal of Translation Medicine* 2010;8:25
2. http://www.plainlanguage.gov/usingPL/sciences/whiteman.cfm

Plagiarism: A personal account

Firstly, I must apologise for writing this article anonymously. As I'm writing about my own experience of being accused of plagiarism I would rather not broadcast my identity, for many people believe in the saying that there is no smoke without fire. In other words, I must have done something wrong in order to be accused of such a serious misdemeanour. I shall let you judge for yourselves after you've read this article.

It all started when I was approached by a medical communications company, whom I have worked for sporadically over several years. Their client, a pharmaceutical company, wanted to produce a supplement to a well-known medical journal. So far, so good. The client seemed very young and inexperienced, and wanted me to help pick a few topics of interest within the general subject area. I was happy to do this, and this formed what I would describe as a very brief outline (about three or four lines) on the areas to be discussed for each review. Normally, at this stage, it's a good idea to find potential authors and then draft a much more detailed outline for them to review and comment on before the medical writer writes the first full draft. Unfortunately, I was told that there was no time for an outline stage, so I moved straight to the first draft stage for all the authors that did not want to write their own first draft. Normally I would never do this, and would always insist on a full outline and author approval at that stage. This was my first mistake—and some might say my only one!

"His main concern was that a lot of text has been copied and paste from original articles without you rewrote that parts."

Anyway, I researched and wrote two review articles and, with the permission of the medical communications company, another freelance colleague wrote the third as I did not have time to do all three. One of the two articles that I wrote was very well received. Looking at the final version in print now there seem to be very few changes from the first draft. The same could not be said for the other two articles, each of which was drafted by a different freelancer (though the authors did not know this).

I am just re-reading the e-mail now that I got from the medical communications company who acted as a conduit between the authors and myself. Here is the e-mail (my changes in square brackets and names removed, otherwise the rather poor English is unchanged):

"Dear [freelancer],

We just received a phone call from Dr 'P' the guest editor of the [journal name] supplement. He was not pleased the way the articles were written. His main concern was that a lot of text has been copied and paste from original articles without you rewrote that parts. The problem we have now is that we can get in to a lot of problems because this will be seen as plagiarism. You can of course use information from other articles but this information needs to be reworded and not be the same as in the original article.

Dr P is now completely rewriting his article and also already informed the other authors to be careful and read the article very well. Dr P, as well as the other doctors, is a very busy doctor and it is really embarrassing he needs to rewrite the article.

Could you please explain to us what you have done and what exactly happened? Also, we would like to receive a confirmation that after receiving the feedback from all doctors you will make the necessary revisions and will rewrite the parts that are copied and paste from the original articles because this is not allowed and seen as plagiarism as mentioned before.

We look forward to hearing from you soon.

Kind regards, 'E'

"Similarity Index: 30%." I did not know what this meant. Did it mean that my fellow freelancer had plagiarised 30% of the article?

I was shocked as there had been no cut or pasting: that is not the way I work. In fact, to even try to write this way takes longer, and gives far worse results regarding the readability of an article. No half-decent professional medical writer would cut and paste. Anyway, I drafted a robust reply along those lines. It was such an outlandish accusation that I wanted people to realise that I was not going to stand for this sort of nonsense and I was in no mood to be diplomatic.

Dear E

I can assure you that I have not cut and pasted sections from other articles—this is not the way that I write. Dr P must be mistaken. I do, however, paraphrase extracts from other sources and this is called "writing a review", and in all cases the sources were *referenced*.

> Unfortunately, Dr P does not know what plagiarism is: that would be using another source *without acknowledging the reference*. (In any case, I haven't 'cut and pasted', so it is not important to disagree over this definition.) I would be interested to know which passages he is referring to. The only bits that could be construed as being cut and pasted are the tables, and these have to be cited accurately. I am puzzled.
>
> If you would like to read the article through (try it now) you will see that there is a logical flow, and that it reads well. If I had just cut and pasted bits from articles it would not read easily–it can be spotted a mile off.
>
> Dr P doesn't need to rewrite his paper for the reasons he described. I am very angry about what he has said, but I would be happy to rewrite *any* sections that were cut and pasted because they only exist in Dr P's somewhat overactive imagination.
>
> Best wishes
> [Freelancer]

I followed this up with another e-mail saying more or less the same, but emphasising that this was a very serious allegation, the most serious that can be made against any writer, and that he (the author) had better produce some evidence to back-up his statement. What had made me even angrier was that I'd read the article before sending it, and thought that it was amongst my very best work of this type—which made what followed even more surprising. We then heard from the author of the other article. (If you remember, the other freelancer wrote this article, and I should note here that they had done a very good job as I reviewed it carefully before sending it off to the client.) Here is the e-mail I got, again via the medical communications company:

> Dear [Freelancer]
>
> Unfortunately Dr 'B' confirms the same as Dr P. Please find to follow his comment:
>
> Dear Miss E. I had the draft article checked. It fails, and significant portions are not original. I cannot rewrite it in time for July, but I can get it to you end of Aug. It will have to be rewritten as original writing and not copied from other abstracts. I have done extensive work on it but it is not ready and not fully original as of now. I attach the originality report from Turnitin.com, a service that my daughter (high school teacher) uses to check term papers for plagiarism. B.
>
> Do you think, after receiving Dr B's comments you can rewrite the whole article as original writing?
>
> Looking forward to hearing from you.
>
> With kind regards,
> E

This was now a major worry. I looked at the attached report, very briefly, and was horrified to find that it had detected a "Similarity Index: 30%" though I did not know what this meant. Did it mean that my fellow freelancer had plagiarised 30% of the article? This, I knew, was utter rubbish. Needless to say, when I told my fellow freelancer who wrote the article what had happened, they were 'fuming' with anger. The problem was, what to do about it?

Firstly, I looked at this plagiarism report, and noticed that beneath the headline rate of 30% similarity, the software had gone through the whole article highlighting parts of it. These were the parts that it (the software) thought might be from other source articles. As I looked through I realised that only short phrases were being picked out, usually three or four words long. They were usually 'stock' phrases such as "The United States" or "disease prevalence", for example. Then I noticed it had highlighted the entire reference list. As this made-up about a quarter of the length of the review this is where most of the 30% figure had come from. I sent a short reply to the medical communications people to this effect:

> Dear E
>
> I've not had time to look at Dr B's originality report in much detail yet, but on first glance it does not seem to confirm any cut and pasting to me (see section at the end). Most of the percentages he has come up with are probably because of the reference list, and others are fairly common phrases such as "United States"...or "given the burden of..."
>
> I think I need to look into this, but on first glance his report is not backing up what he alleges.
>
> Will get back to you on this.
> [Freelancer]

I next turned to Elise, Editor of *TWS*, to ask her if she knew anyone who could help to back-up my case, as clearly the medical communications people were unquestioning in their belief of the authors and they had failed to put up even the slightest of resistance to their accusations. She very kindly put me in touch with someone she knew (a Professor of Psychology in New York) who is an expert on plagiarism. Happily, he backed us up:

> Hi Elise, this example reminds me of that quote: "stealing from one source is plagiarism, but stealing from many sources is research." This Turnitin report shows instances where short phrases and portions of sentences amounting to no more than 2% or 3% match phrases and sentences found in over 60 separate documents, including student papers. One would have to assume that the 'offending' author took the time to go to each of these sources to selectively misappropriate a phrase or two from each to construct his paper. The more parsimonious explanation is that, indeed, the suspected material are stock phrases (it certainly seems that way to me). There may be a couple of instances that could have been better paraphrased...but, it is a looong stretch to call this plagiarism. Frankly, this situation suggests >

Plagiarism: A personal account

> that the individual making the accusation has merely looked at the overall plagiarism score without a careful analysis of the paper, which to me shows several instances of identical phrases, many of which are merely random or, as the author himself suggests, stock phrases commonly used in that field. What to do about it? Take a few pairs of articles that discuss the same topic and compare them with plagiarism detection software, such Turnitin or Lou Bloomfield's program and see what happens. Invariably, you will find pairs of articles that will similarly share random portions of text made up of short phrases like the case of your author.
>
> Miguel Roig

Well, by now I was hopping mad. These 'authors' had wasted a great deal of my time, not to mention casually wrecking my good reputation in the medical writing and pharmaceutical industry. I was clearly in no mood to take any prisoners, as is apparent when I re-read my e-mail to the medical communications company, reproduced below:

> Dear E
>
> I see that my fellow freelancer has written regarding recent events, and that the essence of her letter is *it's ridiculous to assume that I've done anything wrong and that the authors are damned lucky to have such good reviews to work with as I specialise in this type of work* ([other freelancer] I hope you don't mind me paraphrasing your e-mail in this way). What I find so distasteful is that not only have I been accused of plagiarism, lack of originality and 'cutting and pasting', but that the clinical authors are believed by [the medical communications company] whereas I, a professional medical writer, am not trusted or given any support. Thus, I will deal with their accusations (and Dr B's analysis) *point by point*.
>
> 1. Lack of originality
> The scientific content of reviews, by definition, is not original. Speculations and opinions on these facts may or may not be original. As a medical writer I tend to limit myself to a minimum of speculation an/or opinions, but I have done a fair degree of thinking regarding [topic content] issues and the [specific subject of this review] in particular, and those thoughts that I've incorporated into the reviews are my own. If I bring in other ideas from another source the source is acknowledged. Dr B (who himself appears to struggle with his poor grasp of the English grammar and language in his e-mail—but that is another point) accuses me thus: "... significant portions are not original." His own report (see point 4) shows that this is not the case, and that the only significant part detected as being not original is the list of references.
>
> 2. Plagiarism
> There is no plagiarism. All sources are acknowledged. (See point 4 for proof.) Why would I want to plagiarise? The clinical (i.e. actual author) might have a motive for this, but the 'ghostwriter' does not as I'll achieve nothing, even if I successfully got away with plagiarism. It is in *my interest* to acknowledge all sources—and I have. The software used by Dr B is designed to highlight phrases for the reviewer *to check whether such references are referenced*, not as proof of plagiarism *per se* or even cut and pasting. The clinical authors, and presumably [the medical communication company], don't seem to understand these points.
>
> 3. Cut and pasting
> I don't do it because I don't need to do it—again, there is no reason to do it unless quoting. Sometimes this is a requirement (e.g. quoting diagnostic guidelines for a mental condition) or when quoting exact words from another source (e.g. Bloggs *et al*. in their recent study wrote that "Drs B and P might be good clinicians but know little regarding the practice or theory of medical writing"). I am a professional writer, and I don't need or want to cut and paste long passages of text to write an article. (See point 4 for proof.)
>
> 4. Dr B's 'Turnitin' report
> This person seems to think his report is evidence of lack of originality, cut and pasting, etc. Presumably this is because the 'headline' Turnitin similarity index is 30%. Guess what though? I see from the word count (and also the main text of his report) that he included the references and probably the tables in his 'Turnitin' analysis. The references represent 25% of the word count and, of course, the software has highlighted *all* of these as potentially plagiarised and *only a few isolated phrases within the main text*. Presumably, *Doctor* B is a reasonably clever person, but it is clear that he's unable to use or interpret this 'highschool essay' software. Instead it has provided evidence to support the originality of my draft.
>
> Next, let's look at the main text of B's Turnitin report on his review. In his report the only highlighted text (other than the references) are short phrases–mostly stock phrases that are in common use. For example, "Center for Disease Control and Prevention (CDC)" and "in the United States".
>
> I realise you ***still*** *may not believe me*, as I have offered most of these arguments before, and despite the obvious evidence (supplied, but misinterpreted, by my accusers). Thus, I have taken the liberty of consulting a world expert on plagiarism—Miguel Roig—via a colleague who is a journal editor and European Medical Writers Association committee member. (Please see some of Roig's publications at the end of this e-mail.) He has spent his career researching plagiarism and self plagiarism and I sent him B's report. He writes: "This Turnitin report shows instances where short phrases and portions of sentences amounting to no more than 2% or 3% match phrases and sentences found in over 60 separate documents, including student papers. One would have to assume that the 'offending' author took

the time to go to each of these sources to selectively misappropriate a phrase or two from each to construct his paper. The more parsimonious explanation is that, indeed, the suspected material are stock phrases (it certainly seems that way to me)...But, it is a looong stretch to call this plagiarism. Frankly, this situation suggests that the individual making the accusation has merely looked at the overall plagiarism score without a careful analysis of the paper, which to me shows several instances of identical phrases, many of which are merely random or, as the author himself suggests, stock phrases commonly used in that field."

To sum up. I am very disappointed by [the medical communication company's] lack of support for me. I do not want to receive any further communication on this matter, except an apology from [the medical communication company] who have offered no support to me at all (instead you seem to trust the clinical authors who can barely string words together into a sentence, do not understand what plagiarism is, and who even misinterpret their own report trying to prove overlap of my writing with published sources). Maybe the clinical authors would like to apologise for making such unwarranted and malicious accusation? I'll certainly be letting other people in the industry know about Drs B and P's antics...

[freelance medical writer]

PS. I realise I have not answered your request which was "Do you think, after receiving Dr B's comments you can rewrite the whole article as original writing?" I could, if you wish, reword "The World Health Organization", call the "United States" something else at random, as well as paraphrasing the references (perhaps change a few titles, or change the page numbers)? Would that be ok? I guess not, so my answer has to be no—it is only if I do the actions described above that I will be able to meet Drs B and P's stringent criteria of originality. My flippancy aside, the reviews are already original writing as you should understand now after reading this letter.

Roig, M. (1999). When college students' attempts at paraphrasing become instances of potential plagiarism. *Psychological Reports*, 84: 973-82.

Roig, M. (2001). Plagiarism and paraphrasing criteria of college and university professors. *Ethics and Behavior* (11) 3: 307-323.

Roig, M. & deJacquant, J. (2002). Guidelines on plagiarism in writing manuals across various disciplines. Proceedings of the First ORI Conference on Research Integrity. Office of Research Integrity: Bethesda, MD.

Salhaney, J. & Roig, M. (2004). Academic Dishonesty Policies Across Universities: Focus on Plagiarism. *Psi Chi: Journal of Undergraduate Research*, 9: 150-153.

Torres, M. & Roig, M. (2005). The Cloze Test Procedure as a test of plagiarism: The influence of text readability. *Journal of Psychology*, 139(3): 221-231.

Roig, M. (2010). Plagiarism and self-plagiarism: What every author should know. *Biochemia Medica* 20 (3): 295-300.

[Note: these references were cut and pasted from the internet: clearly a case of plagiarism on my part.]

Well, there you have it. The whole sorry saga. And two, very annoyed and upset freelance medical writers. The medical communications company finally admitted that they were mistaken and I had a (sort of) verbal apology and begrudging acknowledgement that there was nothing wrong with the reviews: "I already explained [Dr P] that other departments also worked with you and that they and other parties were very pleased with the work you provided. Just to let you know that we have no doubt on the quality of work you provided."

However, the authors never apologised (they were probably never asked to). Dr B did send a revised version, and I had a quick look at it. Little had changed, and what few changes had been made (except deleting one table) were always 'presentational' (i.e. slight rewording) and/or fairly random. Unbelievably, given my robust turn of phrase throughout this whole business, the medical communications company was still trying to get me to help the authors! My response at this stage was "Personally, I'd like the whole lot of them (P, B, etc.) out of my life unless they can be bothered to apologise to me." Can you blame me?

"Reader, suppose you were an idiot. And suppose you were a member of Congress. But I repeat myself."

Before I started to write this article I was going to analyse the potential reasons for the accusations and how it might be avoided in future. To be honest though, this would be pure speculation. Originally, I'd thought that the authors might have been caught between disclosure of professional medical writing services in the acknowledgements (I'd included these according to guidelines such as those published by EMWA), and the problem with these American authors regarding the Grassley report, which effectively stifled what Grassley calls 'ghost writing' in top American institutions. (As an aside, this brings to mind Mark Twain's quip that "Reader, suppose you were an idiot. And suppose you were a member of Congress. But I repeat myself.") Now I am not so sure about this as an underlying reason for these authors' actions. To be honest, it may be that one of the authors did not like the main thrust of the arguments I made in the review. Certainly no-one has criticised the scientific content. It seems strange that two freelancers working independently on the same project, albeit for two different authors, were both accused of plagiarism within the space of a few days. In the end though, I thought that it would be best to document the facts of this case and let you, the reader, decide for yourself what might have been going on. To be charitable to these two authors, however, they may not have thought about the profound consequences their rash and unfounded accusations could have on another person's professional integrity.

Note: all of Miguel Roig's publications can be access at http://facpub.stjohns.edu/~roigm/publications.htm

Press release

EMWA's response to "The Haunting of Medical Journals: How Ghostwriting Sold "HRT""

EMWA's press officer, Adam Jacobs, and public relations officer, Andrea Palluch, have posted the following reply (http://bit.ly/d6xjvG) to the above article written by Professor Fugh-Berman in PLoS Medicine (http://bit.ly/aS7q1j). Professor Fugh-Berman replied to the posting and Adam Jacobs commented on her reply as can be seen under 'comments' on the webpage. See also http://linkd.in/anUUAc and http://on.fb.me/gwm0tL

Fugh-Berman's article regarding the ghostwriting of publications about Prempro [1] raises some important points, but unfortunately misses others.

Most importantly, we in the European Medical Writers Association (EMWA) are concerned that she does not mention the significant distinction between ghostwriters and professional medical writers. Ghostwriters are shady individuals who hide from sight, while professional medical writers produce their work in an ethical and transparent manner.

Medical writing is a flourishing profession. Writing assistance in biomedical publications has many advantages but needs to be transparent and ethical.

We have published guidelines explaining what is expected of professional medical writers [2]. Professional medical writers who follow those guidelines would not allow marketing messages to trump scientific accuracy in published papers. In fact, some empirical evidence suggests that professional medical writers can help avoid misconduct. Woolley et al found that retractions of papers from the published literature were significantly less likely to be a result of misconduct when professional medical writers were acknowledged [3]. Further, research recently published by EMWA suggests that professional medical writers may also improve the reporting quality of randomised controlled trials [4].

We in EMWA actively endeavour to raise the profile of the medical writing profession and standards. We therefore believe that there is a clear distinction between ghostwriters who engage in unethical practices and professional medical writers who do not. Fugh Berman's article describes only the bad side of medical writing, without mentioning its positive side, which creates a misleading impression.

We also wish to point out that, although using ghostwriters to insert unwarranted marketing messages into papers is unacceptable, and something we would unhesitatingly condemn, there is no evidence to suggest it is common. Statements such as "Industry-funded marketing messages may infest articles in every medical journal" are therefore entirely speculative and in no way supported by evidence. Although it is clearly very difficult to do high quality research into the prevalence of papers with inappropriate marketing messages, our own experience of writing many papers for many pharmaceutical companies suggests that it is probably extremely rare.

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Ig-Nobel prizes for 2010

The 2010 Ig-Nobel Prizes for improbable research which makes people laugh and then think were announced on 30th September 2010. This year they did not include a prize for literature. The award that I found most amusing (and believable) was that for management. A group of scientists at the University of Catania, Italy showed that organisations would be more efficient if promotions were made at random.

The prize for medicine went to researchers in the Netherlands for discovering that symptoms of asthma can be treated with a roller-coaster ride but I did not find this surprising as since I started running regularly my sinus problems have disappeared. The physics prize was rather nice. A group at the University of Otago, New Zealand, found that people slip less often if they wear socks outside their shoes. And what contribution did UK researchers make to Ig-Nobel science? Swearing relieves pain. All details and references can be found at http://improbable.com/ig/winners/#ig2010

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Good Writing Practice


The idea of an 'EMWA Style Guide' has been proposed and discussed since the early years of the organisation, but a huge range of style guides are available for general writing and writing in the life-science field[1]. Many of these cover the intricacies of grammar and usage with much sound advice; another such style guide is not needed. There is, however, a need for guidance on aspects of writing not covered by existing style guides; this is apparent from questions from clients and at training events with both native and non-native speakers of English. For example, knowing when you can afford not to pay great attention to consistency, when you don't need to toss and turn like Baudelaire hunting for 'le mot juste', or pitfalls to avoid when writing for clinical trials disclosure databases.

We have therefore brought together a group of medical writer and editor colleagues from the EMWA membership to develop a series of articles for a project that we are calling 'Good Writing Practice' (GWP). When giving training events, Alistair often finds himself saying: "… you might call doing that 'good writing practice'…"; hence the name. An example of GWP would be avoiding a dangling clause after a bulleted list by incorporating it into the platform sentence—in other words, being kind to the reader. Not a piece of advice you would find readily in a style guide, but an easy principle to follow to improve the acceptance of your text. Since many writers understandably want 'rules', formulation of at least sensible conventions, if not rules, to make the writing process easier for the writer and the text clearer for the reader might also be appropriate. For example, Wendy recommends using numerals when describing numbers of patients or adverse events because this is what we are counting, and so 'patient' or 'adverse event' becomes a unit of measurement, even if the digit is at the start of a sentence. Maybe we can banish some myths about the use of English and clear up some misconceptions.

The group has had its first round of brainstorming, and we are at present reviewing all ideas and topics suggested. We envisage a series of 10–12 articles and quite a number of boxes spread over forthcoming issues of *TWS*. This may grow into more, of course. At the end of the project, we should have a series of articles that can be published together as an EMWA publication—but that is a long way off.

So what will we be looking at? We are still planning how best to order or group the topics, but 'high-level' ideas so far cover issues such as:

- Positive writing style
- Recognising lost causes and moving with the times
- Avoiding 'over-writing', repetition and redundancy (but also where repetition is desirable!)
- GWP issues specific to freelancers and salaried staff
- Document design and layout
- How to phrase table and figure captions appropriately
- Document quality and consistency
- When consistency is not always the highest priority
- Writing for different audiences
- Cultural issues in medical writing
- Writing habits that annoy the reader
- Formulation and use of checklists to improve writing and editing
- Differences between guidelines and templates
- Use of abbreviations
- Living with formulations that are not perfect but get the message across perfectly well
- Prioritising activities when very little time is available for document review
- Are medical writers and editors also QCers?
- Should the medical writer on the team always be the document owner?

If we feel that a topic is dealt with well enough elsewhere, we will include the topic and provide references.

As we work on each topic, many other issues will emerge. And we are sure that *TWS* readers will also have other ideas after reading this introductory article and the subsequent articles on each topic. If you do have ideas, please don't hold back—**write to us and let us know**. If you are working in the medical communications field and would like to join this project, please also let us know. The membership of the team is not fixed and will certainly have to be varied depending upon its members' commitments over the next few years.

Thanks to Debbie Jordan (freelance), Andrea Rossi (Eli Lilly Italy), Kathy Thomas-Urban (freelance), Susanne Geercken (Pfizer GmbH Germany), Walther Seiler (Bayer Schering Pharma AG Germany), Pamela Haendler (Bayer Schering Pharma AG Germany) for already agreeing to commit time to this project.

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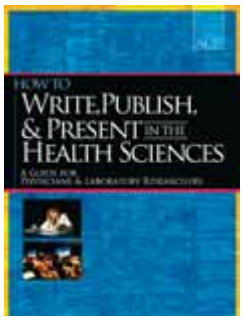
1 See http://www.lib.purdue.edu/vetmed/techwritingtitles.html for a list put together by Purdue University, Indiana, USA. We are not endorsing these publications, just highlighting that many are available.

In the bookstores ...

An easy to read, practical guide to improve your scientific and medical writing skills



Thomas A Lang. How to Write, Publish, and Present in the Health Sciences: A Guide for Clinicians and Laboratory Researchers, 2009, ISBN 978-1934465141. 53.50 GBP. 389 pages.

When we need to comment about statistics we are not overly familiar with, many of us have occasion to reach for another of Tom Lang's books *How to Report Statistics in Medicine*. In his newest book the author has turned his attention to guiding the health scientist through writing, submitting and publishing scientific results in health sciences. The 13 chapters in the new book provide a substantial amount of practical and effective advice for preparing and writing publications, slide presentations, abstract and posters. Each chapter is written in a style that is unstuffy, and easy to read.

Presenting data in a helpful and convincing manner is a key aspect of preparing it for publication. When faced with word limits as well as limits on the number of tables and figures that can be incorporated into your publication, the correct choice of table, figure and graph can be critical for reporting your data succinctly. The correct choice will complement and enhance the understanding of complex data by the reader. In the chapter entitled "How to Display Data in Tables and Graphs" the author helps to highlight the most appropriate format for your data by asking a series of questions about the reasons behind the data presentation. For example, do you want to help readers analyse or reference data? Do you want to show exact values or patterns? To allow you to determine the best way to communicate your data, the answer to these and other questions are fully addressed and explored by the author.

The author also presents many insights into how medical writing has progressed through the years, resulting in guidelines like the CONSORT statement and the uniform requirements for manuscripts submitted to biomedical journals. Guidelines are relatively recent additions to medical writing and the author provides an overview of writing and publishing in medical journals, including a brief history of biomedical publishing that lists key events beginning in 4000 BC and finishing in 2008 AD. Did you know that *JAMA* only began providing abstracts with published articles in 1957?

The debate on ethical issues around publishing research includes knowing the differences between ghost author, guest author and ghost writership, as well as understanding the issues of plagiarism, copyright violations, publication ethics and the practice of 'salami-science'. The background to these and other ethical dilemmas are provided and their importance explained and discussed.

One chapter details important issues involved in preparing drawings and photographs for publication, which can now also cover audio and video clips. Although this can be quite a specialist area and may involve the skills of a medical illustrator or graphic artist, the author should know what will make a good image and also how to complement a presentation or publication. Many helpful tips are provided to help accomplish this. The need to document biomedical images accurately is also addressed, and much practical advice on how this can be achieved is given. Other helpful chapters are dedicated to preparing and presenting slides and posters.

The author has also included a reproduction of "Ten Commandments for Medical Writers." Written in 1957 these commandments should still be pinned above every medical writer's desk and referred to as each new publication is undertaken [1]. The first of these commandments is "Thou shalt not, unless circumstances be extraordinary, release for publication a paper that neither contains anything new nor sheds new light on something old." This book by Tom Lang definitely sheds new light on a subject that is not taught well at university and is a welcome addition which will allow medical writers to improve their medical writing abilities whilst finding out more about their chosen profession.

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Reference:

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An analysis of professional language

Britt-Louise Gunnarsson: Professional Discourse. Continuum, Continuum Discourse Series 2009. ISBN 9780826492517. 27.99 GBP. 288 pages.

Professional discourse plays a great role in modern society. It lies at the heart of the business world and the state. It is discourse that enables the creation and maintenance of organisations and institutions as groups working for common goals. In this book, the expression 'professional discourse' is used to cover TEXT and TALK—and the intertwinement of these modalities—in professional contexts and for professional purposes. In other words, professional discourse

includes written texts produced by professionals and intended for other professionals with the same or different expertise, for semi professionals, i.e., learners, or for non-professionals, i.e., lay people. It also includes talk involving at least one professional to be taken as a synonym of 'paid-work related'. The adjective 'professional' thus covers both skilled and unskilled paid jobs, both doctors and cleaners who work in a hospital, both white and blue colours in a factory, etc.

The purpose of the book is to explore text and talk that occur in different environments to deepen our understanding of what professional discourse is, how it varies and why it changes. A central tenet elaborated in the different chapters is the dual relation between professional discourse and its contextual framework. This relation is analysed as a two-sided complexity, i.e., as both a discourse-related and context-related complexity. As the author claims in this book, an in-depth analysis of variation and change should explore this two-sided complexity and also the dynamic character of professional discourse, how professional language and discourse is continuously contextually reconstructed.

The book gives a broad and multifaceted perspective on discourse in the professions, including law, business, medicine, science and the academic setting, technology and bureaucracy. The case studies presented are based on authentic texts and spoken data, collected within different environments and relating to different domains. The aim of each section is to offer theoretically grounded and systematically investigated answers to questions of relevance for advanced students, practitioners and academic scholars. Each section thus includes discussions of both theory and methodology to provide tools for applications and further studies.

In contrast to most earlier studies on professional language and discourse, the studies presented in this book are innovative in their theoretically grounded and systematically undertaken analysis of authentic data. The theoretical basis of the case studies dealt with in the book derive from a range of disciplines: text-linguistics, pragmatics, genre studies, sociolinguistics, interactional sociolinguistics and sociology, psycholinguistics and cognitive psychology.

What all sections share, however, is the discussion of linguistic variables in relation to psychological, social and societal (related to society at large) variables. Professional language and discourse are viewed as being constructed and reconstructed in relation to contextual frameworks. As the book shows, we reach a deeper understanding of the emergence, development and constant change of professional discourse if our findings are discussed in relation to contexts at different levels: the situated communicative event, the environmental framework (the workplace, the organisation/discipline) and the societal framework (the legal-political, the technical-economical, the socio-cultural and the linguistic frameworks.

Another factor common to the studies is that they are all based on detailed analyses of linguistic data. The book therefore develops and discusses applications of different methodologies: text-linguistic analysis of large corpora, concordance analysis, function-oriented text analysis, psycholinguistic experiments, ethnographic observations, interviews and discourse analysis. Furthermore, several chapters focus on how and why professional discourse has changed over time and how it is likely to change in the future. One purpose of the book is thus to explore the dynamic and complex socio-historical reconstruction of professional discourse.

Medical professionals and applied linguists interested in medical discourse will be mostly interested in Chapters 4 and 5. Chapter 4 is concerned with the socio-historical construction of medical discourse. Medical articles from three centuries—the 18th, 19th and 20th centuries—are analysed and discussed in relation to three stages: a pre-establishment stage, an establishing stage and a specialised stage. The multidimensional methodology is used in the Chapter to analyse changes in text patterns at cognitive, pragmatic and macro-structural levels. The Chapter also discusses changes in linguistic expressions of evaluation over time. Chapter 5 focuses on the non-verbal (i.e., visual/graphical) representation of 90 scientific articles within technology, medicine and economics from 1730 to 1985. This Chapter is also concerned with the construction of scientific discourse, in this case with a focus on graphic representation, formulas and tables.

All in all, and drawing largely on her own extensive research that spans the last three decades, Professor Britt-Louise Gunnarsson has produced an account of professional discourse in contemporary Europe that is, in the renowned applied linguist John Swales' parlance "*fresh, lucid and uncluttered*".

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A menu on display outside a mountainside lodge on the slopes of Mont Blanc at Mer de Glace (a glacier with a tourist-accessible ice cave) above Chamonix, France. Photo kindly provided by **Jack Aslanian** (jaclanian@earthlink.net)

Webscout

Chronic disease management

by Joeyn Flauaus

Chronic diseases such as cardiovascular diseases, diabetes, cancer and chronic respiratory diseases, are diseases that are lifelong or recurrent conditions that can be controlled but not cured. Chronic diseases affect the population worldwide as they are one of the leading causes of deaths worldwide, i.e. representing 60% of all deaths (source WHO). Most of the chronic diseases are so called non-communicable diseases (NCDs) meaning they are not contagious (e.g. asthma, diabetes). These diseases often require long-term treatment.

Many areas of medicine have undergone great change within the past years due to increased knowledge about clinically related symptoms and overall development in medicine. Therefore, management of many diseases (e.g. infectious diseases, metabolic diseases) has changed. Disease management means a coordinated approach to educate patients about their condition (e.g. by the physician), to improve compliance with drug intake as well as certain lifestyle changes. Especially the management of chronic diseases such as diabetes, high blood pressure, COPD, and asthma requires a lot of effort and discipline from patients.

Diabetes rates are rising worldwide and healthcare costs are exploding, which is increasingly affecting the economy in many countries. Therefore, patients need to learn a lot about the importance of discipline, persistence, and motivation in managing their disease. Diabetes can be well controlled if patients follow certain steps such as monitoring of blood glucose levels, exercising (weight control), eating healthily, regular visits to the physician, taking drugs as instructed (compliance), and taking care of the body. Foot, eye, skin and dental care are of utmost importance for a diabetic (**http://www.hpb.gov.sg/chronicdisease/diabetes/control_takecare.htm**). Compliance in these special patient groups is often very low as they don't see the immediate impact of their carelessness. However, this can lead to major problems and prolonged hospital stays if wounds are not healing for example. It is amazing how patients can improve their quality of life and general condition when they stick to a certain disease management regimen. Drug intake can be reduced tremendously if patients start to exercise and loose weight.

In today's world, it is relatively easy to manage a disease as a lot of information and training programmes are available online. Everyday technologies like Internet, e-mail, mobile phones etc., should be used to facilitate the self-management of chronic conditions.

The ultimate goal for patients with chronic conditions is to make it clear that they are responsible for their health and to show them how they can influence their quality of life!

Below I have put together a selection of websites related to the topic of chronic disease management. These provide some insight about the complexity of chronic diseases, the global distribution and the possibilities of disease management.

World Health Organization (WHO):
http://www.who.int/topics/chronic_diseases/en/
This website bundles various information on chronic diseases. You can find general information including fact sheets and multimedia features. The WHO action plan for the prevention and control of NCDs is also provided.

The economic burden of chronic disease:
http://www.chronicdiseaseimpact.com/
The research findings of the study "An Unhealthy America: Economic Burden of Chronic Disease", which was carried out by the Milken Institute, are presented with interactive charts. The results show the enormous financial impact of seven common chronic diseases (i.e., cancers, diabetes, heart disease, hypertension, stroke, mental disorders, and pulmonary conditions chronic diseases) on the US economy. Data can be reviewed by various categories like geographic region, type of disease or risk factor. Even though the data are representing the conditions in the US, the research findings are a good indicator for what we can expect in Europe in the next couple of years.

Centers for Disease Control and Prevention:
http://www.cdc.gov/chronicdisease/index.htm
Comprehensive information for the general public on Chronic Disease Prevention and Health Promotion are provided.

Recommended reading for those who are especially interested in this topic:

The Chronic Disease Crisis: a white paper by Jerry Halberstadt, New Technology Publishing, Inc./Healthy Resources: **http://www.healthyresources.com/editorials/crisis/**

If you find a website that should be mentioned in the next issue, please e-mail me at: Joeyn.Flauaus@sanofi-aventis.com. Any ideas for the next issue, comments or suggestions are also welcome.

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Prioritising systematic reviews and more on ghostwriting

by Nancy Milligan

This edition of journal watch focuses on two 'Policy Forum' articles recently published in *PLoS Medicine*; the first concerns the status of systematic reviewing and the second offers further debate on the issue of ghostwriting and drug promotion in publications.

The importance of up-to-date systematic reviews

According to an article by Bastian, Glasziou, and Chalmers, keeping up with information in healthcare has always been difficult and is affected by two main problems: an overload of unfiltered information and a lack of open access to the information most relevant to the well-being of patients [1].

The authors gave an overview of the history of medical publishing and argued that indexing of medical literature in the late 19th century and the development of systematic reviewing and meta-analyses in the 1970s and 1980s were the major milestones in medical communications, achieved in response to a growing number of clinical trials being undertaken and the need to synthesise the accumulating research evidence. By the end of the 1980s, regularly updated electronic publication of systematic reviews, meta-analyses, and bibliographies of randomised trials began which then provided a model for the inauguration of the Cochrane Collaboration, an international, independent organisation dedicated to the preparation, maintenance, and dissemination of accurate, up-to-date systematic reviews of the effects of healthcare interventions.

The authors went on to suggest that since the middle of the 20th century the number of clinical trials has continually risen, and a plateau in growth has yet to be reached. The number of systematic reviews has also increased in recent years; however, growth of non-systematic or 'narrative' reviews and case reports has been even greater, and the emergence of journals which publish non-systematic reviews has outstripped the growth of systematic reviews. Bastian, Glasziou, and Chalmers suggested that only a small number of trials are being analysed in good, up-to-date systematic reviews, which they say makes it difficult to identify the information most important to clinicians, patients, and policy makers.

The authors suggested that a number of steps need to be taken in order to rectify the current situation: first, we need to prioritise effectively and reduce waste in the production and reporting of research evidence; second, we need leaner and more efficient methods of staying up-to-date with the evidence (for example, new methods to reduce the effort of updating reviews, a way to provide an assurance to clinicians and patients that conclusions are not out of date, and methods to ensure that systematic reviews are placed clearly in context of other research); and finally, we need more international collaboration which could result in better use of resources for systematic reviews. The article also gave an overview of one such collaboration, initiated by the German Institute for Quality and Efficiency in Healthcare (IQWiG) and including a number of other organisations such as the Cochrane Collaboration, Duodecim, the Scottish Intercollegiate Guidelines Network (SIGN), and the National Institute for Health and Clinical Excellence (NICE). Called 'KEEP Up', the collaboration was formed in an international meeting in Cologne in November 2009 and aims to provide a platform for tackling practical and methodological issues involved in keeping up-to-date with research evidence.

More recent debate on ghostwriting

The issue of ghostwriting continues to be a divisive topic in the medical press, as demonstrated in a recent article by Fugh-Berman (and the subsequent response by EMWA) on the ghostwriting of publications about the menopausal hormone therapy Prempro [2].

In an article titled 'The haunting of medical journals: how ghostwriting sold HRT', Fugh-Berman used the specific example of the pharmaceutical company Wyeth using the US medical communications company DesignWrite to suggest that industry uses ghostwriters to insert marketing messages into articles published in medical journals. She argued that various ghostwritten articles, reviews, and commentaries have been used to promote various unproven benefits (e.g. prevention of cardiovascular problems, dementia, Parkinson's disease, vision problems, and wrinkles) and downplay harms (e.g. risk of breast cancer) of menopausal hormone therapy and to cast any competing therapies in a negative light. The author also offered a number of other examples of ghostwriting being used to promote drugs. In conclusion, Fugh-Berman suggested that medicine, as a profession, should take responsibility for the situation, and that academic institutions and medical journals should take a hard line on ghostwriting to ensure that 'unscrupulous relationships between industry and academia are avoided rather than courted'. >

Journal watch

> Adam Jacobs, EMWA's press officer, and Andrea Palluch, EMWA's public relations officer, submitted a response to the article on behalf of EMWA. Briefly, they suggested that Fugh-Berman's article raised some important points, mainly that using ghostwriters to insert unwarranted marketing messages into papers is unacceptable, while missing others, most importantly that there is a clear distinction between ghostwriters, who engage in unethical practices, and fully acknowledged professional medical writers, who should produce their work in an ethical and transparent manner. Jacobs and Palluch went on to offer some evidence suggesting that, in fact, professional medical writers can help avoid misconduct [3] and may also improve the reporting quality of randomised controlled trials [4]. They also suggested that Fugh-Berman made some entirely speculative claims in her article which were in no way supported by the available evidence.

After a response by Fugh-Berman essentially pointing out that medical writers who work for industry do not control the final product, rarely see their names on their work, and the publications they produce reflect the marketing goals of industry; Adam Jacobs again responded with the following points: that it is indeed correct that medical writers can only advise and cannot dictate and control the final product (which should lie with the named authors), that medical writers frequently see their names in the acknowledgements sections of papers, and that papers in which marketing messages have over-ridden scientific considerations is not an inevitable consequence of being paid by industry. Fugh-Berman submitted no response to this.

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Wives, mothers and medical writers

When I first wrote my first piece for *The Write Stuff* in 2007 [1], little did I know that I would inadvertently become a sounding board or worse—an inept adviser—for women who were in the same boat as I was. Since 2007, I have been contacted by e-mail by no less than 10 women who, for one reason or another, got 'inspired' by that article. The first 3, I replied to in rather lengthy e-mails, which I stupidly forgot to save. At the 4th inquiry, I decided to change my strategy and replied "Sure, I'd be happy to try and answer your questions. Give me a call and let's talk." That way, I could share whatever little pearls of wisdom I had while folding the laundry. This approach scared off 3 who didn't take up the offer of a phone chat but I was able to talk to 7 and even met 1 personally. Table 1 gives a rather scanty summary of whatever data I could gather.

TOTAL NUMBER	**10**
Lost to follow-up	3
Phone call stage	7
Networking stage	5
Face-to-face meeting	1
DEMOGRAPHICS	
Swiss: Non-Swiss	1:6
Moms of little kids	6
Trailing spouses	6
EDUCATION/EXPERIENCE	
PhD	6
MD	1
Previous medical writing experience	2
Academic experience	6

CURRENT STATUS*	
Job in pharma industry	3
Job in research	1
Freelancing/job hunting	2
Job hunting	1

*based on last correspondence

During the 'phone chats, the most common questions asked were:

- How is the medical writing job market in Switzerland/Europe?
- How do I get into the medical writing field without any experience?
- How feasible is freelancing?

I must admit that I don't have any consent whatsoever from these women to use their data here and I hope they will excuse me for this. I assure them that their identities will remain a confidential. I also cannot claim that these women are a representative sample of *The Write Stuff* readers. What I can say from these data however, is that there are lots of well-educated women out there who got into the role of stay-at-home mom and trailing spouse and are now trying to find their way out through medical writing. This is a real waste of skills and talent if the job market does not give these women a chance to get into medical writing, with or without previous experience.

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Reference:

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Out on our own

We had an excellent turnout at the Freelance Business Forum at the Autumn Conference in Nice this year. More than half of the 45 delegates who attended were new members. Alison MacIntosh very kindly took the minutes which will be appearing in the March issue.

The two contributions we have in this issue are concerned with a topic that has been discussed in this section and elsewhere in the journal before—the topic of acknowledgment of contributions to publications by editors and medical writers: Both strongly express a point of view that we don't often come across in this discussion.

Before adding a few words about that, I (Alistair) would like to take this opportunity to thank Sam, the Freelance User Group and all those who have contributed to this section of *TWS* very much for their support and contributions over the past few years. I have decided to step down as freelance coordinator after 8 years, and I will be handing over the reins to Sam. The Executive Committee has asked me to coordinate the EMWA subcommittee that will be collaborating on the MSc in Medical Writing at Innsbruck University in Austria, and I decided it was time for a change.

We have also decided to retire the EMWA Freelance mailing list and shift all activities for freelance representation to a Web 2.0 platform such as Facebook or LinkedIn. Further details will follow.

Now, on to acknowledgements. The discussion in the Freelance forum has so far centred on acknowledgement of editors or authors' editors, who are often freelancers and do not usually fulfil the Good Publication Practice requirements to be authors, but do make a significant contribution to papers, especially when working with authors whose first language is not English. In a past issue, Karen Shashok described why she thinks that editors and authors' editors should always be acknowledged. She will only take on jobs if this is agreed in advance. But she does realise that this is often not an option for those dependent on the income. In this issue, Paul Woolley tells us the unfortunate story of a freelance writer and a salaried writer who found themselves in very awkward situations because they had been acknowledged on publications. The awkward situation was very much worse for the freelance writer than the salaried writer. Paul comes out very firmly on the side of those who believe that any publication written, edited or contributed to in any way by a freelance medical writer for a commercial organisation should, if the writer so wishes, appear without the writer's name so that they cannot be pressured to act against their principles, and to protect their professional—and ultimately—private interests.

Rosemary Bischoff feels that the responsibility for acknowledgements lies with the authors of a publication and is not the writer's or editor's problem. A far greater problem for her is that large international editing and writing companies sometimes also own publishing houses that publish articles they produce in medical journals they publish and that this conflict of interest is not acknowledged.

If you have found yourself in the situation of any of the writers in Paul's article, you might like to let us know how the situation arose and what the outcome was so that others can benefit from your experience. Or you might disagree with Paul or Rosie and want to tell us why. Whatever your opinion, please let us know—Sam will be very grateful to hear from you.

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The acknowledgements dilemma: The right to anonymity

by Paul Woolley

In a recent issue of *The Write Stuff* [1], Karen Shashok points out that the increasingly frequently heard calls for contributions made to published articles by medical writers and other writing professionals (including translators and editors) to be acknowledged in print are sometimes to be welcomed, but only sometimes—and she gives reasons why in some instances such calls should be resisted. She describes correctly the possible impact on a freelance medical writer's reputation (and therefore later income) that could arise when the writer is acknowledged in an article for which he/she only provided an initial draft, and the quality of which has suffered greatly in subsequent revisions to which the writer was not party. Indeed, a few years ago there was just such a case, in which a medical writer was pilloried in the national press after she had written the draft of a scientific paper, the contents of which were slanted by persons with a commercial interest [2, 3]. >

The acknowledgements dilemma

> In my view a lot has gone wrong with the "Great Transparency Debate", and this is partly driven by the fact that its impetus has stemmed largely from medical writers who are employees of large companies by whom they feel, and maybe are, collectively under-recognised (see the collection of articles in an earlier *The Write Stuff* [4]). I do not wish here to present a detailed critique of the arguments and counter-arguments that have been brought to bear on the issue. Rather, I should like to focus on one point that to my knowledge has been omitted totally from the debate to date: Can the acknowledgement of a medical writer itself lead to malpractice of any kind? I believe that it can, and have indeed experienced it. However, while the medical writer with employee status is more or less immune from this, the freelancer can be put into an impossible position.

Here are a couple of scenarios from the world of clinical writing (pseudonymised, of course, in strict compliance with reporting standards).

1) Solly Schreiber is a medical writer working for the contract research organisation CRObar. A while ago, in a project sponsored by the dermatological company SkinFul, he wrote a protocol for a clinical trial to test a salve for chapped fingers. Now, CRObar is working on the design of a study to test another salve produced by a competing sponsor, the company SkinFlint. Indeed: to acquire the project, CRObar boasted to SkinFlint about their medical writer with experience in that very indication! Unfortunately, SkinFlint is a start-up company with only little medical experience. So one day, shortly after a meeting to decide on details of the study protocol, Solly Schreiber gets a confidential 'phone call from the friendly project manager at SkinFlint: "We haven't been able to decide about the inclusion and exclusion criteria—can't you just copy them from your earlier study?" This of course throws Solly into a severe conflict of duty, as he is bound over to maintain confidentiality regarding SkinFul's project, but at the same time he is required to be as helpful as possible to the new client SkinFlint—and of course he cannot afford to have any complaints about his "lack of co-operation with a client" flying about.

However, the solution for Solly is relatively simple: He stonewalls for the moment, and reports the matter to his superior, who together with Solly makes the—rather obvious, but apparently necessary—decision that SkinFul's protocols cannot be copied-and-pasted over to SkinFlint. This verdict is passed back tactfully to SkinFlint's project manager as a medium-level company decision based on CRObar's inviolable confidentiality policy. In the upshot, Solly will doubtless channel his general experience into giving SkinFlint a high-quality protocol anyway, a good time will be had by all, and face will be lost by none.

2) Molly Schreiber is a freelance medical writer and works for various companies on all sorts of different clinical documents, including published articles. She regarded it as a minor personal triumph when an article that she had helped to prepare, describing a revolutionary new treatment developed by the Apeutics company, was published in the top-ranking international journal *The Syringe*. The article was based on a clinical study carried out and reported by Apeutics; Molly's job had been to turn the 150-page clinical-statistical report into a 6-page publishable article. Thus, none of the ideas were her own, and she was quite properly not included among the authors, who were researchers at Apeutics. However, Apeutics were happy to acknowledge her expert contribution to preparing the manuscript, and in any case *The Syringe* requires any such contributor to be named in print.[1]

Imagine then Molly's pleasure when, some months later, she was rung up by a research director from Therapacity Ltd., a firm of which she had not previously heard, and complimented on her well-presented and excellently written *Syringe* article! She was even more gratified to be told that her obvious expertise in the field made her a clear choice as external medical writer for a very similar project that Therapacity were developing. However, at the introductory meeting on Therapacity's premises it became clear that her real qualification was not, as she had been given to understand, medical experience or writing skill, but something else that was in far higher demand and far shorter supply at Therapacity: She knew what was going on at Apeutics—and was expected to pass on this inside knowledge.

This put poor Molly into a terrible dilemma, one that her employee cousin Solly would never have experienced. If she agreed to work for Therapacity on their terms, she would have to break her obligation of confidentiality towards Apeutics. Being an honest person and committed to ethical professional conduct, Molly could not contemplate this. However, by pulling out of the prospective collaboration with Therapacity, she would make it obvious—even if unspokenly so—that she saw through their idea and was not willing to play along. The price of doing this was clear to her: Never any chance of any—even straight and ethical—work from Therapacity, ever again![2]

I am not going to continue the story, and indeed I do not know how Molly resolved the dilemma, if ever she did. I can think of no solution. In consequence, I can only recommend that any publication written, edited or contributed to in any way by a freelance medical writer for a commercial organisation appear without the writer's name. This can be agreed in advance with the person or firm out-contracting the work. If the intended journal requires medical writers to be mentioned by name, then the medical writer should think twice before accepting the task.

1 As an aside: This violates the conventional wisdom that contract researchers—be they companies or one-person shows—do not name one client to another unless this is agreed (e.g. 'reference clients' for promotional material). The tales of Solly and Molly make it clear why this principle should be adhered to.

2 Of course, the result would have been the same for Molly if Therapacity had decided that she was probably in cahoots with Apeutics and should not be approached anyway—an equally real disadvantage of being named as a co-contributor.

The ethical basis for this is fundamental: the ideas and other intellectual input for anything I produce as a medical writer must come from the named authors, who by signing the paper take full joint responsibility for its content (see Rosie Bischoff's powerful arguments for this in *The Write Stuff* [5], which apply just as much to publications as they do to other clinical documents). Tasks involving scientific input from the medical writer, for which he/she might reasonably claim co-authorial responsibility and credit, are a different matter altogether; in my own view, that is hard-core ghost-writing and in itself unethical. Loss of income? Tough. Perhaps I might end with another real-life story. It concerns the freelance medical writer Dolly Schreiber, who one day received an e-mail that contained a stack of results along with a request to perform a literature search, write an introduction and turn the whole thing into a well-paid-for Ph.D. thesis. However, for a dilemma drama the storyline is rather thin: without hesitation, Dolly adopted the time-honoured advice of Nancy Reagan and just said "no". Sometimes you've got to.

What do we learn from the tales of Solly, the employee, and Molly, the freelancer? First of all: by being named, both writers come under pressure to betray confidential information. Secondly, however, for the employee there is an easy way out while for the freelancer there is none: the employee can take refuge behind the employer, while the freelancer, placed under such pressure, has to choose between unethical behaviour and loss of a client. The former choice, one would hope, there is no question of; the second can represent a substantial personal sacrifice. The only protection against this is the option of anonymity.

Doubtless, 100% transparency is a good thing when it promotes ethical behaviour; here I argue that there are situations where its effect is the reverse. If a medical writer is expected not to divulge a client's confidential information, then surely the medical writer has every right to insist on the confidentiality of information about the writer him-/herself. Guidelines and rules should reflect this; regrettably, many of these are at present, for the reasons set out above, biased towards the needs and situation of the medical writer with employee status and are weighted against the (ethically acting) freelancer.

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The acknowledgment debate and why medical writers are not the real problem

There are 2 aspects to this debate that irritate me, but unfortunately I also feel that my present position as a medical writer does not qualify me to be part of the solution. I will explain why.

While employed by a pharmaceutical company in an earlier life, I authored a number of scientific papers in my own name. I was always acutely aware of the need to be as impartial and as fair as humanly possible but I was also aware that I found myself in a dilemma. However, I have to quickly add that in those days, before the advent of 'publication strategies', I never experienced any pressure from my employer to slant my writing. From the very beginning of the current acknowledgment debate it has bugged me that medical writers seem to be the ones who are expected to take the issue seriously, even at the expense of jeopardising business should a customer not want to acknowledge us. Surely the responsibility for this debate HAS to be with the authoring community and their employers. I have not followed things very closely but as far as I am aware, this group have remained resoundingly silent. Up to now I have been reluctant to engage with the debate as I simply do not see it as our problem. As with the issue of responsibility for regulatory documents, which lies squarely with the sponsor, the responsibility for acknowledgments in publications, in my view, lies squarely with the authors.

However, I do feel there is potentially a threat to scientific impartiality in another area where acknowledgement is of far great importance than the odd unmentioned medical writer. The problem involves the business models of some large international companies offering professional editorial support, publication planning and medical writing to authors. These companies typically promise that customers will have 'the solutions they need, when they need them, and in the media best suited to their requirements'. The last promise is the problem. A conflict of interest must arise when these companies also own or partly own whole publishing houses, prominent amongst whose products are medical journals, even medical society journals. It is routine practice not only to offer authoring services to pharmaceutical companies but also for them to directly submit the paper to a journal in joint ownership with the very same writing services company. In view of this ownership connection, I have to ask myself how seriously can we take the impartiality of editorial boards? I think it would be hugely important not only to acknowledge the medical writer, but also to mention that the medical writer's employer is in joint ownership with the publishing house that is publishing the journal in question. Not only medical writers but also medical communication companies and publishers should acknowledge their professional connections.

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Editor's note: A similar problem of ties between authors and the journal/editors has been addressed by Peter C. Gotzsche in an answer to a comment on research on mammography. See http://www.bmj.com/content/340/bmj.c1241.long/reply#bmj_el_234237

Biomedical publishing shorts

Conflicts of interest: Journals should also disclose their sources of income

Journals have various sources of income that have a conflict of interest potential. Publication of industry-sponsored randomised trials for instance has been shown to increase journal impact factors and they are also a source of income from selling reprints to drug companies. Andreas Lundh and colleagues used PubMed and tax information to investigate citations from industry-supported trials reported in 1996-1997 and 2005-2006 in six leading general medical journals and the influence on the journal impact factors. They found that industry-supported trials received more citations than other types of trials and excluding them from the impact calculation lowered the impact factor. The explanations for the increased citations are that the trials are big, drug research is known to increase citations and sponsoring companies use various strategies to increase awareness of their studies (including ghost authored reviews that cite them). Higher quality of industry-sponsored trials might be another explanation but there is little evidence to support it.

The researchers also asked each journal editor about the journal's income from industry sources. Only the *BMJ* and *The Lancet* provided this information, which for reprint sales was 3% and 41%, respectively. Other journals might have even higher incomes, e.g. *New England Journal of Medicine* which publishes the most industry-supported trials and refused to disclose reprint sales income.

The researchers concluded that as publication of industry-supported trials is associated with an increase in impact factor and sales of reprints can provide substantial income for the journal "journals should live up to the same principles related to conflicts of interest as those that they require from their authors". They also suggested that further studies be conducted into income from advertisements which could be another source of conflict of interest as it is known that when The *Annals of Internal Medicine* published an article critical of industry advertisements it lost approximately US$1-1.5 million in revenue.

Source: Lundh A, Barbateskovic M, Hróbjartsson A, Gøtzsche PC. Conflicts of Interest at Medical Journals: The Influence of Industry-Supported Randomised Trials on Journal Impact Factors and Revenue – Cohort Study. Available at: http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000354

Worth reading

A recent article published in the *American Journal of Medicine* by Obman EM, Roe MT and Armstrong PW titled " Public sensationalism and clinical trials: how to address the challenges of science?", which proposes the establishment of an effective data safety monitoring board, is worth reading. Available at: http://www.amjmed.com/article/PIIS0002934309011504/fulltext

Hunting down clinical research data—Not yet a problem of the past

Yet another example of publication bias in clinical research has recently been reported in the *British Medical Journal* [1,2]. During the production of a health technology assessment (HTA) report on antidepressants, detective work by the German HTA body, the Institute for Quality and Efficiency in Health Care (IQWiG), revealed that most of the evidence on reboxetine, a selective norepinephrine reuptake inhibitor, was actually unpublished. The drug manufacturer, Pfizer, initially refused to provide the unpublished data but relented after massive public pressure. Analysis of the full data set showed that published data overestimated the benefit of reboxetine and underestimated harm. In fact, reboxetine showed no benefit over placebo. Although doubts had previously been raised about the effectiveness of reboxetine and application for approval was rejected in the United States in 2001, this was the first publicly available analysis of a comprehensive data set, even though the drug has been marketed in Europe for 13 years. After reviewing the IQWiG report the Federal Joint Committee, the German statutory health insurance system's main decision-making body, excluded reboxetine from reimbursement in September 2010, but the decision is not yet legally effective.

The reboxetine case highlights the problem faced in post-approval drug evaluations: in contrast to the submission of clinical trial data to regulatory authorities, manufacturers are generally not obliged to provide such data to HTA bodies. As a consequence, subsequent health policy decisions may be made on the basis of biased evidence, resulting in suboptimal health care for patients and a waste of resources. Furthermore, clinical practice guidelines are also generally based on published literature, resulting in potentially inappropriate treatment recommendations.

The effects of publication bias have been known for decades. The United States has played a leading role in solving the problem by introducing the FDA Amendments Act of 2007, which regulates trial registration and reporting of results on a publicly accessible platform (www.ClinicalTrials.gov). Although the law does have loopholes, for example, in not applying to older drugs, it is a pivotal step to full transparency in clinical research. In contrast, developments in Europe have been lagging behind; even though initial legislation was issued in 2004, mandatory online publication of trial results has been delayed and is still not legally effective. Individual countries such as Germany are now introducing their own laws, but such measures cannot replace a comprehensive, worldwide solution. In addition, neither the European nor German plans cover medical devices. Finally, existing regulations do not solve the problem of selective outcome reporting; this requires registration of full study protocols and any amendments, as well

as statistical analysis plans. The extensive media coverage of the reboxetine case and the reaction of health policy decision makers will hopefully maintain the momentum and speed up the implementation of legislation on the mandatory publication of all results of clinical trials.

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What about female authors of medical papers?

A study of papers published in the *Wiener Klinische Wochenschrift*, a middle European peer-reviewed general medicine journal, posited that the gender imbalance in academic medicine is reflected in scientific publication. Although about 50% of students accepted for medical schools throughout the world are females, this percentage is not reflected among high positions held in hospitals and university departments.

The study looked at papers submitted to the journal between 2001 and 2009 and found that the percentage of female authors of original papers had increased and is now about 30% (in paediatrics it is 50%). Rejection rates of papers with male and female first authors were the same but those from females tended to be rapidly rejected more often. Interestingly these rejections were more related to the poor presentation than to poor science, which led the investigators to suggest that women do not present their work as well as men—because they are less careerist and less self-promotional. There were more women first authors in multidisciplinary papers than in monodisciplinary papers—perhaps indicating that women are more willing to work in teams.

Further findings were that very few review papers and editorials were authored by women, hardly any female reviewers were used (although their reviews were better) and only one member of the editorial board was female.

The paper concluded that although the increase in female student intake to medical schools is beginning to come through in the publication of medical papers, journals can do more to encourage women. They can seek out women reviewers and board members and also solicit review papers and editorials from women.

Source: Heckenberg A, Druml C. Gender aspects in Medical publication—the *Wiener Klinische Wochenschrift. Wiener Klinische Wochenschrift* 2010;122:141-145

Fascinating skepticism

Skeptic is a nice website (http://www.skeptic.com) for a questioning mind and it covers some fascinating topics of science. The site is run by The Skeptics Society, which promotes science and critical thinking. Its mission is to serve as an educational tool for those seeking clarification and viewpoints on controversial ideas and claims. Rather than a position, skepticism is described as a method that requires compelling evidence before a claim can be believed. However, belief can always only be provisional because facts in science are subject to challenge. The site has various forums, podcasts, lectures, geotours you can book onto, a reading room with a comprehensive, free resource of articles relating to science and skepticism, and a magazine which you can subscribe to. The cover story of the magazine in October was 'Ignorance of bliss' by Steve Salerno with the introduction "we still know so little about happiness—except that we're supposed to pursue it". The topic of happiness in the workplace is also covered. The magazine includes a regular column 'bad language' and book reviews.

The distinguished lecture series, which can be bought on DVD, includes such titles as 'How the economy works: confidence, crashes, and self-fulfilling prophecies', by Roger Farmer, 'Natural experiments of history', by Jared Diamond and 'On fact and fraud: Cautionary tales from the front lines of science', by David Goodstein. In this Goodstein describes not only fraudulent science but Bednorz and Müller's discovery of high-temperature superconductivity that turned out to be real. Sample lectures on evolution and climate change can be downloaded.

Maggie Thatcher and her vegetables

It is said the British Prime Minister Margaret Thatcher was once in a restaurant with her cabinet. The waiter asked her if she wanted steak or fish. "Steak of course," she replied. "And for the vegetables?" "They'll have steak as well."

Words, Grammar & Co

Suspected to be related

I don't wish to dig too deep into the causality discussion, just look at the ungainly way some concepts are expressed in subject narratives. I have previously written about 'unlikely', viz. that it is not appropriate to say *event X was likely related to drug X—likely* must be followed by *to be* (as must *unlikely;* this may be turning into a lost cause). Several of my clients have stopped assessing adverse events with 'definite, probable, possible, unlikely, remote, not related' (or similar unnecessarily complex systems) and very refreshingly have switched to dichotomous 'suspected' or 'not suspected'. Whilst this avoids the 'likely' problem, it has unfortunately led to such awkward linguistic acrobatics as:

- *The causal relationship (between headache and drug X) is suspected to be related/not suspected to be related.*
- *Headache is/was (not) suspected to be related (to drug X).*

I am ashamed to say that I also frequently find these bad examples on CIOMS forms from English-speaking countries. The second sentence is more acceptable than the first, but more acceptable than both are:

- *A causal relationship is/was suspected between headache and drug X.*
- *No causal relationship was suspected between headache and drug X.*
- Or, to personalise things a little: *The investigator/reporter suspected/did not suspect a causal relationship ….*

Definitely wrong are the following (which I haven't yet seen on CIOMS forms from English-speaking countries I am relieved to say):

- *The causal relationship between headache and drug X was unsuspected.*
- *There was an unsuspected causal relationship between headache and Drug X.*

These both mean that there WAS a causal relationship and that it was unexpected.

Worst-case assessment is often used for causal relationships, which means that if a case is not assessable because there is too little information, a causal relationship is 'suspected'. This should not, however, be expressed as follows:

- *This case is suspected to be related due to insufficient information.*

This is one sentence I will never agree to as a lost cause, and will always insist on something similar to the following, even though they are longer:

- *The sponsor considers that there is insufficient information to assess this case and therefore suspects a causal relationship with Drug X.*
- *In the absence of adequate information for proper assessment, the sponsor suspects a causal relationship with Drug X.*

Infernal prepositions

I sometime wish that English were a highly inflected language to deal with all those grammatical cases that we use prepositions for. But it isn't—and anyway, we'd have to learn all those endings, and you can bet your life that there would be loads of inexplicable exceptions.

Mary Smith in (or should it be *of* or *from*?) London asks: *My question relates to the use of 'in' versus 'for' for patients. There seems to be a tendency in medical writing to accept the use of 'in patients' regardless of context, i.e.,* (not my comma! AR) *'Wonder drug can have a beneficial effect on quality of life, especially in patients with such and such symptoms.' Given that 'in' means inside, enclosed, or surrounded, I prefer to use 'for patients' in this context, on the basis of 'for' meaning affecting or relating to. It seems that we develop cars for people to drive—but drugs 'in' patients to take? I just wondered what your feelings were about this.*

The problem here is that prepositions have a core meaning, but very quickly deviate from this when collocated with verbs and in phrasal verbs, and they also vary according to the nouns they precede, even if the nouns have the same or a very similar meaning or can be categorised as the same thing (nobody says ***at*** *morning*, but we all say ***at*** *night*. Consider also that we say *She arrived* ***on*** *the morning* ***of*** *5 February* but ***in*** *the morning* ***on*** *5 February).*

Mary says that *in* means 'inside, enclosed, or surrounded'. But this is only its core meaning. What about *in advance* and *in favour*? No core meaning left there at all, and on top of that, it is inexplicable why *in* is correct—it just is. Or, take *up*. In *I went up the stairs*, *up* has its core meaning of indicating ascent. But this is nowhere apparent in *I looked the correct spelling up*. In fact, if you used a book, you would probably be looking *down* while looking things *up*.

Now, on to patients. If you give a patient a drug that was developed *for* patients, the drug usually enters the patient's body (topical preparations also enter the body) and acts inside them, so I am quite happy to write that something was tested *in* patients and that it is intended for use *in* patients with a certain disorder. *Findings in patients* moves a little away from the core meaning, but the results still came from something being applied in the patient's body (and this even applies to mental suggestion, of course), so I am also happy with that.

Mary gives the example: *Wonder drug can have a beneficial effect on quality of life, especially in patients with such and such symptoms* and says that she would rather write *especially* ***for*** *patients with such and such symptoms.* I would certainly spontaneously write *in* and would most likely correct *for* to *in* if editing this text.

What do other readers think?

The WOCBP test

Ladies! Read through this (exclusion criterion from a report on—wait for it—an anti-hay fever drug) and see whether you are a WOCBP.

Women of child-bearing potential (WOCBP), defined as all women physiologically capable of becoming pregnant, including women whose career, lifestyle, or sexual orientation precluded intercourse with a male partner and women whose partners had been sterilized by vasectomy or other means, unless they met the following definition of postmenopausal: 12 months of natural (spontaneous) amenorrhea or 6 months of spontaneous amenorrhea with serum follicle stimulating hormone (FSH) levels >40 mIU/m or 6 weeks post surgical bilateral oophorectomy with or without hysterectomy or hysterectomy or were using one or more of the following acceptable methods of contraception: surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: intrauterine device (IUD), male or female condom with spermicidal gel, diaphragm, sponge, cervical cap).

Well—are you or aren't you? Even if you are, and disregarding the silliness, errors and inconsistencies in the above text, all it means is that you belong to the group of:

Women who may have become pregnant not using specified acceptable methods of contraception.

And these 13 words are all you need to put in your report (instead of 128) under 'Exclusion criteria'.

Our readers deserve every break we can give them!

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Safety uber alles?

The Brits are reportedly crazy about 'uber' without the umlaut 'ü'. Aside from the highly popular and complimentary 'uber-babe', 'uber-Boss, uber-Guru and uber-charming' are also becoming part of the hip lingo [1], spoken or written. In this usage, 'uber' is synonymous to 'ultra'.

Then there is the less politically correct phrase 'uber alles' (as in "Deutschland über alles") which English speakers use to mean 'above everything else.' It is controversial because of its strong association with the German National Socialist Party and the Aryan superiority ('Germany is above all') principle. The phrase was later on popularised by the rock group Dead Kennedys in their song "California uber alles."

The urban dictionary however has a different take:
"uber alles (correctly written in German 'ueber alles') has nothing to do with the Nazis, but was a line of a poem written in 1841 which was used for the German National Anthem. It does not translate as 'above all' (that would be 'ueber allen') but rather 'more than anything else', as in 'ich liebe Dich ueber alles in der Welt' (I love you more than anything else in the world). A misleading translation was purposely chosen by the Allies during the second world war for propaganda purposes." [2]

I am no linguistic expert, neither in German nor in English so I can't really vouch for Urban's translation but it got my German husband thinking that maybe he need not feel embarrassed when singing his country's national hymn after all.

In any case, the terms 'uber' and 'uber alles' seem to be rapidly getting integrated into the English language. I can almost imagine a future generation of medical writers writing about the 'safety uber alles' policy of the EU's uber-regulatory agency on our quest for the 'uber-effective' anti-cancer drug.

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The great typo hunt

Copyeditors and medical writers are not normally considered potential candidates for changing the world but have you ever thought you might like to do something to change the world? Jeff Deck and Benjamin Herson, two copyeditors, thought of one way that they might be able to do this. They set off on a journey across the USA with their red pens and a mission to correct typos in public signage. You can hear an interview with them at http://www.radionz.co.nz/national/programmes/ninetonoon/20100915

The most common typos they encountered were misplaced apostrophes and errors in the use of double letters, e.g. dining spelt dinning. When asked what they considered to be the cause of the errors they replied that most arose through bad proof reading but poor grammar education in schools was also a contributing factor. With thanks to Neville Goodman (nevwgoodman@mac.com) for alerting *TWS* to this interview.

Daft words: Oxford University Press's word of the year

Oxford University Press's word of the year is 'repudiate'. The following is from its press release announcing the decision:

"An unquestionable buzzmaker in 2010, the word refudiate instantly evokes the name of Sarah Palin, who tweeted her way into a flurry of media activity when she used the word in certain statements posted on Twitter. Critics >

Words, Grammar & Co

> pounced on Palin, lampooning what they saw as nonsensical vocabulary and speculating on whether she meant "refute" or "repudiate."

From a strictly lexical interpretation of the different contexts in which Palin has used "refudiate," we have concluded that neither "refute" nor "repudiate" seems consistently precise, and that "refudiate" more or less stands on its own, suggesting a general sense of "reject." Although Palin is likely to be forever branded with the coinage of "refudiate," she is by no means the first person to speak or write it."

Who can be whose?

It just did not seem right to use 'whose' to refer to a coagulation factor in "Human coagulation factor IX (FIX) is a vitamin-K-dependent coagulation factor whose absence or dysfunction causes hemophilia B." I wanted to change the text to "Human coagulation factor IX (FIX) is a vitamin-K-dependent coagulation factor, the absence or dysfunction of which causes hemophilia B". But the late placed relative pronoun is a mouthful compared with the neat use of 'whose' so I turned to Oxford Fowler's Modern English Usage1. Fowler scoffs at those who consider 'whose' can only refer to people and the suggestion that it should be forbidden as a relative pronoun for the inanimate, to quote "The tabooing of whose is on a level with that of a preposition at the end of a sentence: both are great aids to flexibility; both are well established in older as well as in colloquial English." So 'whose' it is.

Are they comparable?

'Hedging' can be a problem in scientific writing if an evasive word is chosen under a false conception of its meaning. Take comparability studies where one thing is compared with another. When the study is complete the conclusions often state that A and B are comparable. This is not much of a conclusion because almost anything can be compared with anything else. There's an English expression that implies you cannot compare apples with oranges. But of course you can as scurrilously explained in the article 'Apples and oranges—A comparison' http://improbable.com/airchives/paperair/volume1/v1i3/air-1-3-apples.html. What the conclusions to the comparability studies should state is that A and B are equivalent or similar—no pussy footing about with 'comparable'.

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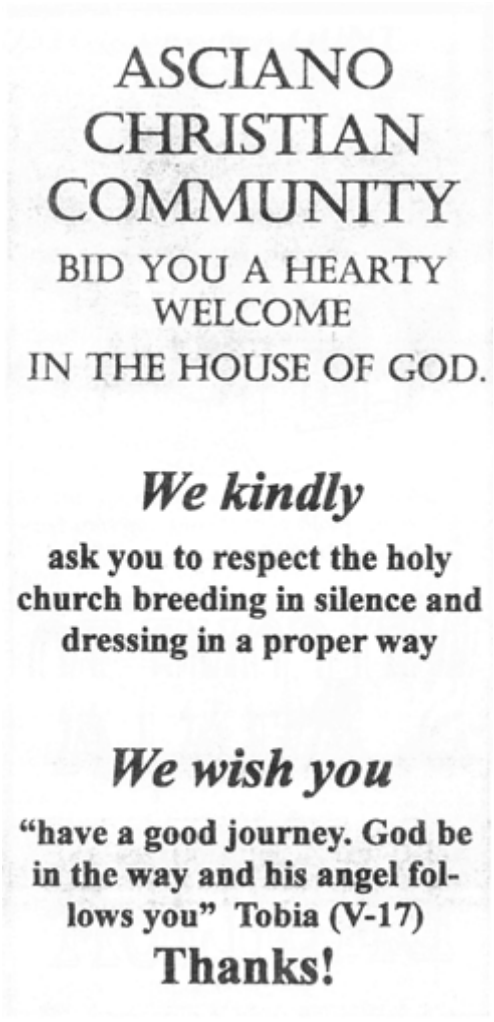
1 second edition, Oxford University Press Oxford, New York



Breeding in silence

It is well known that particularly the Catholic Church likes us to procreate to our biological maximum, but actually in the church? The second problem I have is that personally I have always found it exceedingly difficult, not to say highly inefficient, to breed while properly dressed. Thirdly, breeding in silence really does take away some of the fun. Finally, to 'wish me a good journey' and then 'God be in the way' sounds somewhat malicious. Is it a warning that I am going to be stuck behind a large procession of pilgrims on foot for the next 20 kilometers?

Found in a brochure distributed to visitors at the door of a church in Tuscany. I am still trying to work out what they might really mean.

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Evaluating the Evaluators

The European Medicines Agency (EMA) was born as a network of national drug agencies back in 1993. The European Union (or European Community as it was back then) was growing both geographically and in the extent of its powers. Central to the whole project was the idea that Europe should be a single market, with no internal trade barriers. To help achieve this in the pharmaceutical sector, the Europe-wide agency was launched. It was now no longer necessary to deal with numerous individual national agencies when marketing centrally approved drug products.

It is perhaps testament to the success of the EMA that, while Euroskeptics have railed against a wide range of European institutions and laws, I don't recall the agency ever being the object of their wrath. What's more, the recent high profile cases of drugs that have been withdrawn due to safety concerns have largely been perceived as the result of deceit by big bad pharma rather than failure of the EMA (or other regulatory agencies).

The Ernst and Young Audit

Not only has the EMA avoided the ire of Euroskeptics, many actually think the EMA has worked surprisingly well. Despite the messy looking organisational chart (the figure shown is considerably simplified), the bureaucratic meltdown that might be expected from such a system hasn't happened. Nevertheless, the European Commission, to whom the EMA reports, has embarked on a transparency and accountability drive (perhaps to win the hearts and minds of its citizens, whose faith may be flagging...). As a result, the Commission ordered a report by Ernst and Young to evaluate the "...effectiveness and the efficiency of the system dedicated to the provision of marketing authorisations for human and veterinary medicinal products...". The findings make for interesting reading.

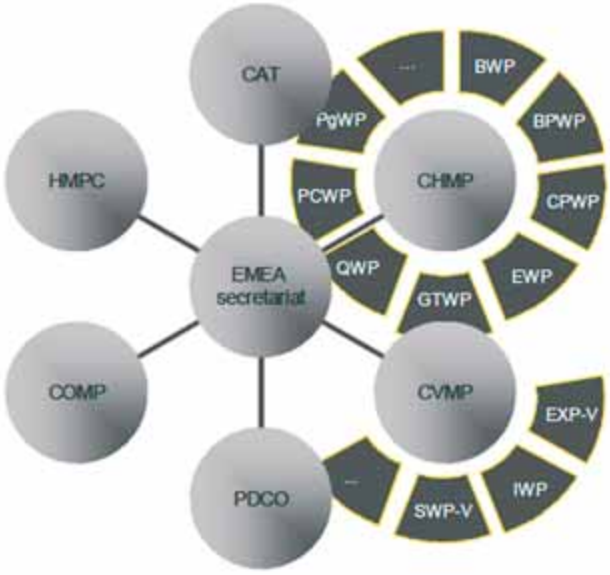

Figure. **Not rocket science but rather a schematic representation of the organisation of the various committees of that report to the EMA secretariat. Source: Ernst and Young report[1]. CAT: Committee for Advanced Therapies; CHMP: Committee for Human Medicinal Products; COMP: Committee for Orphan Medicinal Products; CVMP: Committee for Veterinary Products; HMPC: Committee on Herbal Medicinal Products; PDCO: Paediatric Committee. Only standing working parties are shown. Note that as an additional layer outside the various working parties, there are scientific advisory groups. Other figures such as rapporteurs are also omitted.**

For example, as mentioned above, the EMA is really a network of National Competent Authorities (NCAs—currently 44 in total). Interestingly, these agencies consider that they benefit from participating in the network in terms of expertise and knowledge gained. This two-way benefit is perhaps unusual (I can't imagine many national institutions, especially in the UK, claiming they can learn from a European counterpart). It is also important if we remember that most applications do not actually go through the central route but rather follow the mutual recognition procedure, where the NCAs play an important role. Interaction with the EMA surely goes some way to ensuring a consistent standard for such applications.

Committees and their functions

The EMA has many committees, although the CHMP (Committee for Medicinal Products for Human Use) is the main decision-making entity (for human medicinal products). The workload of the CHMP is already high and still increasing, so the creation of two dedicated committees to deal with referrals and generics has been suggested. Certain committees have already been created to deal with emerging needs. The COMP (Committee for Orphan Medicinal Products) has generally been considered a success, although there may be issues about funding (the committee relies heavily on the involvement of NCAs, who may not feel sufficiently well compensated for their efforts). Trends towards so-called personalised medicine by targeting very specific patient populations could increase the workload further and put further strain on the system.

Another committee singled out for discussion by the report is the Paediatric Committee (PDCO). After recent changes to try to ensure that drug development caters to the needs of children, drug companies are now obliged to present a Paediatric Investigation Plan (PIP) or argue why their drug would not be appropriate for paediatric use to get the necessary exemption. The PIP is assessed by the PDCO but some stakeholders expressed concern to the auditors that, years later, the final opinion of the CHMP might call into question the clinical plan approved by the PDCO. Drug companies do not welcome an added uncertainty in their drug-development programmes.

Strengths and weaknesses

Despite some of the potential problems outlined above, in line with my personal opinion and that of others, the report suggested that the EMA works well, balancing the need to protect the public from unnecessary risks while at the same >

For regulatory writers

time making the latest innovative medicines available to the public. The CHMP itself receives input from working parties (see figure), whose members are generally appointed by the NCAs. As an additional layer of expertise, there are scientific advisory groups, sometimes established on an ad hoc basis to provide support in a particular area. These groups often include academics and people from industry. This somewhat diffuse arrangement has been identified as a potential source of outside influence. On the other hand, it could also be a source of strength as the people in these groups are often at the forefront of research in their particular field and so can provide a knowledgeable and up-to-date input into the decision making processes (though the committees have the final word). This is particularly important in fast-moving areas such as advanced therapies. Another potential benefit of the scientific advisory groups is their views bring diversity to the table, helping to break a dynamic where decisions are made by a core group of like-thinking regulators.

What the EMA doesn't do...

Finally, the audit report touches on comments of some stakeholders about what lies beyond the scope of the EMA: pricing and reimbursement policy, and control of whether the approved drugs actually reach the market. On the last of these points, the EC Regulation that consolidated the EMA includes a so-called sunset clause that obliges centrally authorised products to be placed on the market within 3 years of approval.[2] However, the clause does not force a marketing application holder to make the drug available in all European countries, thus denying many European citizens access to potentially beneficial drugs. Such decisions are presumably the result of economic considerations, with larger markets more likely to be profitable. Pricing and reimbursement policies in individual countries may also help determine profit expectations and hence the decision to go to market in a given country. Whatever the reasons for this patchy availability of some products, it is unfortunate because it means the EMA, through no fault of its own, is failing in its original aim of providing a market for drug products free of internal barriers.

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We've begun to raise daughters more like sons... but few have the courage to raise our sons more like our daughters.

Gloria Steinem

1 Evaluation of the European Medicines Agency. European Comission. January 2010. Available at http://ec.europa.eu/enterprise/dg/files/evaluation/final_report_emea_january_2010_en.pdf

2 Regulation (EC) No 726/2004. Article 14(4-6). Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF

This photograph of a notice at a dodgems track was kindly provided by **Neville W Goodman** (nevwgoodman@mac.com)

German or English? Kindly provided by **Ursula Schoenberg** (u.schoenberg@t-online.de).

Gained in translation

Science at the multilingual crossroads

"We believe that the privilege of being native English speakers comes with a responsibility to help EIL[1] colleagues with their English."

John R. Benfield in *Chest* 2006;129:1728–30 [1]

For the modern-day researcher, English is the only way to gain wide visibility and actively participate in international scientific discourse. English is used by the most widely read and cited scientific journals. According to one study, the proportion of English publications in the area of chemistry increased from 54% in 1970 to 82% in 2000 [1]. The proportions of English papers originating in countries with official languages other than English also increased. For example, the share of English papers authored by French scientists increased from 16% in 1970 to 93% in 2000 [1].

Between 2003 and 2005, the *Journal of Thoracic and Cardiovascular Surgery* received 59% to 63% of its manuscript submissions from authors whose native language was not English, and the experience of the *Annals of Thoracic Surgery* was similar [2]. In both journals, the acceptance rates of manuscripts authored by non-native English speakers has been reported to be essentially the same as that for native speakers.

1 EIL, English as an international language

While most non-native English scientists do not appear to question the prominent role of English in today's world of science—for most of them, the use of English in scientific discourse was a given when they embarked on their careers—the requirement to publish in a language other than one's mother tongue does present yet another hurdle to getting one's research published. One way to overcome this is to increase the awareness of the Anglophone world of this extra effort. Yet another is to increase funding for science translation and editing.

Brian Budgell and his team have developed an impressive spectrum of methods and tools to assist non-native speakers of English in getting a handle on the linguistic challenges of science publishing. Last issue's translation section introduced one of their projects, i.e., the Springer online concordancer. Here's more on how it all started and where it's headed—the potential synergies between EMWA and the Centre for Biomedical and Health Linguistics are obvious and waiting to be exploited.

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1. Sano H. The world's lingua franca of science. *English Today* 2002;72:4.
2. Benfield JR, Feak CB. How authors can cope with the burden of English as an international language. *Chest* 2006;129:1728-1730.

Centre for Biomedical and Health Linguistics: Helping non-native English speakers get a grip on the lingua franca of science

by Brian Budgell

How and why we got started

The Centre for Biomedical and Health Linguistics began approximately 6 years ago in Japan as an informal collaboration of friends who were all involved, one way or another, in helping Japanese students and colleagues deal with the challenges of biomedical English. The spectrum of our activities ran all the way from teaching biomedical terminology to first-year health sciences students to collaborating on biomedical research and co-authoring research reports. All of us were struck by the ineffectiveness of language education in Japan, and we wanted to do something about it, beyond the piecemeal help that we were providing to individual colleagues or small groups of students. Additionally, those of us who were working in undergraduate education saw considerable room for improvement in assessment processes. The upshot of this was that we began working together to create teaching and testing resources that addressed our common needs. Initial efforts were based on our collective intuition of what constituted good biomedical English and good teaching practice. However, it was not long before we began to question the validity of our own methods. We wanted to solve real-life communications problems, not just add more noise to the confusion of language sites on the web and language textbooks.

www.bmhlinguistics.org >

Helping non-native English speakers get a grip on the lingua franca of science

> Those of us who speak English as a first language may not fully appreciate the challenges facing those who come to English as a second language. Nor are the societal costs of language barriers well understood. Most biomedical research papers are now authored by writers whose first language is not English. These writers are under considerable pressure to publish in English to reach the widest possible audience through high impact journals. This practice produces a hollowing out of the biomedical knowledge base within their own language, since one would not normally publish the same material in both English and a second language. This then puts additional pressure on students and young researchers to study in English. Studying for a graduate degree, or conducting post-graduate research is hard enough in one's native language, let alone in a foreign language. Thus, our collective experience in Japan was that language issues were a significant barrier to education and international collaborations. Furthermore, the interval from completion of research to publication was substantially prolonged. This could harm authors by eroding the novelty of their work. It also meant that the translation of research findings into improvements in health care practices was delayed. The outcomes of such delays are real and meaningful – increased suffering and death. Hence, effective communication within the biomedical publishing field is not some kind of luxury; it is an imperative.

What we do and how we do it

Thus, to improve our own efficiency, the next step in our development was to look at the methods that corpus linguists use to characterise language. A corpus is an electronic collection of literature assembled with the intention of representing a body of language. For example, we chose the five most widely cited journals in midwifery and perinatal care to represent the language of this domain, rather than trying to collect every minor journal in the field. After formatting and archiving, all of our electronic corpora are then compared, using specialised software, to a reference collection of modern general English to identify words which occur statistically more often in the domain or discipline under investigation. We next filter out rare words or words which are not widely dispersed across the literature. From this we arrive at a list of keywords—over represented words—which are likely to have special meaning within or significance to the language under investigation. We can also automatically identify commonly recurring phrases employing keywords, and words which commonly occur in the company of these keywords.

"Those of us who speak English as a first language may not fully appreciate the challenges facing those who come to English as a second language. Nor are the societal costs of language barriers well understood."

When we adopted this strategy, our thought was that with these standardised methods we could identify the language that users genuinely needed—the keywords and phrases, and the grammatical conventions which set biomedical language apart from general English. In short order, therefore, we found ourselves involved in three parallel activities: identifying the languages of biomedicine and health, developing learning resources and developing a valid assessment tool (the Test of English for bioMedical Purposes - TEbMP) to measure communicative competence. Over time, colleagues from Malaysia, China and Australia joined us, as they were facing similar challenges in their own countries. In Malaysia, most university entrants are very good speakers of English as a second language. However, the transition to a third language, biomedical language, often presents unexpected difficulties. China is a special case where a historical burden of isolation has impeded communication on many levels. In Australia, overseas students represent a substantial proportion of health sciences and biomedical students. In fact, they are very important to the financial stability of Australian universities and in some instances this has lead to recruitment of overseas students without adequate consideration given to their language needs.

Developing and analysing corpora

In the early days of our collaboration, some of us were lucky enough to receive financial support from our universities, permitting us to develop and analyse a number of corpora—collections of literature representative of particular disciplines. Initially, we looked at the languages in three areas: nursing, public health and midwifery. The findings of these studies were incorporated into our teaching and testing resources. Additionally, the publication of these results probably helped us to obtain a larger grant which has funded further research and resource development. We now have an additional half-dozen corpora in various stages of analysis, a respectable web site on which to post our resources, and about a dozen peer-reviewed research publications and conference presentations. These are all 'points on the board' with our respective universities, but more importantly we can see the results of our efforts in the achievements of students and colleagues. We are therefore very grateful to the EMWA for the opportunity to engage a wider audience of stakeholders, some of whom we hope will become collaborators.

Developing learning resources

Medical writers, editors and translators might be interested in the actual word and phrase lists which have been generated from our various corpora. These are posted under our *Biomedical Language* directory and will give a good idea of the terms which are favoured by the different disciplines. Our online concordancer, also accessed via our

Helping non-native English speakers get a grip on the lingua franca of science

> "We often encounter instances where a phrase or sentence is grammatically correct and accurately conveys the writer's meaning, and yet it still doesn't sound right to the completely fluent user of the language."

Biomedical Language front page, permits users to search our corpora for authentic examples of word and phrase usage. This tool may help to identify preferred phrasings and will assist editors and reviewers in determining the 'attestedness', or prevalence in the authentic literature, of unconventional turns of phrase. Attestedness is an important issue for advanced language learners and editors. We often encounter instances where a phrase or sentence is grammatically correct and accurately conveys the writer's meaning, and yet it still doesn't sound right to the completely fluent user of the language. In these cases, being able to demonstrate to the writer that their phraseology is unconventional vindicates the advice of the editor and gives the writer confidence in the editorial process. In addition to our concordancer, other open-access tools are under development and will be posted to our site once testing is complete.

Under our *Learning Resources* directory are a number of short courses which were originally targeted towards non-native English speakers, both students and researchers in the health sciences. However, even accomplished writers and editors may find these pages illuminating. Regrettably, much of the popular advice that is offered to biomedical writers these days is based on conventions from general English—in some cases quite archaic English at that. By way of example, the avoidance of self-reference, especially 'I' and 'we', and the high prevalence of the passive voice are, given the culture of science, appropriate in biomedical writing and to be encouraged. This might not be so in general English, but in mastering any language, including biomedical language, we want to study it as it is, rather than as we might wish it were.

Developing TEbMP

The *Test of English for bioMedical Purposes (TEbMP)* is actually our oldest project, and is probably our most ambitious. Experience has shown that health sciences and biomedical students for whom English is a second language struggle with reading and writing regardless of performance on standardised English tests. Similarly, health professionals for whom English is a second language often encounter difficulties in communicating with their patients and colleagues, despite having met benchmarks for general English fluency. Clearly, popular tests for assessing competence in the languages of the health sciences and biomedicine are not making the grade.

As the name suggests, the Test of English for bioMedical Purposes is designed to assess competence in the authentic languages of biomedicine and health. Test questions are based on our corpora and are designed to evaluate competency in the domains of reading comprehension, writing, listening and speaking. At this point, test questions have been piloted and validated with student cohorts in Australia, Canada, China, Japan and Malaysia. Our hope and intention is that, for entrance into biomedical and health sciences programmes, this test will replace or supplement tests of general English. The test may also find application in assessing the language abilities of health practitioners moving into an English speaking environment.

How we became involved with Springer

The ethic of studying authentic biomedical language and then emulating the most effective conventions is gaining currency. We are most pleased that a number of biomedical publishers have approached us for guidance on the development of learning tools for their own stakeholders. Having worked previously with Springer, among the many editors of their *Encyclopedia of Neuroscience*, we have been able to make connections with their e-products division and collaborate or consult on interesting and enjoyable projects. Our colleagues at Springer have also been very generous in providing access to their archives for the purposes of our linguistics research, which has resulted in the publication of a highly useful biomedical concordancer produced by Springer—www.springerexemplar.com. This resource is based on the enormous archives of this publisher and is undergoing continual refinement.

For the future

The Centre for Biomedical and Health Linguistics has been a collaboration of like-minded volunteers since its inception. Our intention is to continue to seek financial and in-kind support so that we can conduct important linguistic research, make the findings and applications of research freely available, and develop open-access resources for all stakeholders with an interest in improving communicative competence within the domains of biomedicine and health. A significant challenge at this point in our development is rising above the background noise to be recognised as an exceptional and credible source of reliable information on the lingua franca of biomedical and health communications. To stay true to our objectives, we also require feedback from our stakeholders, and objective measures of the effectiveness of our efforts. All of this will take many hands, and we hope that some of our colleagues in the EMWA will enjoy working with our organisation.

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