

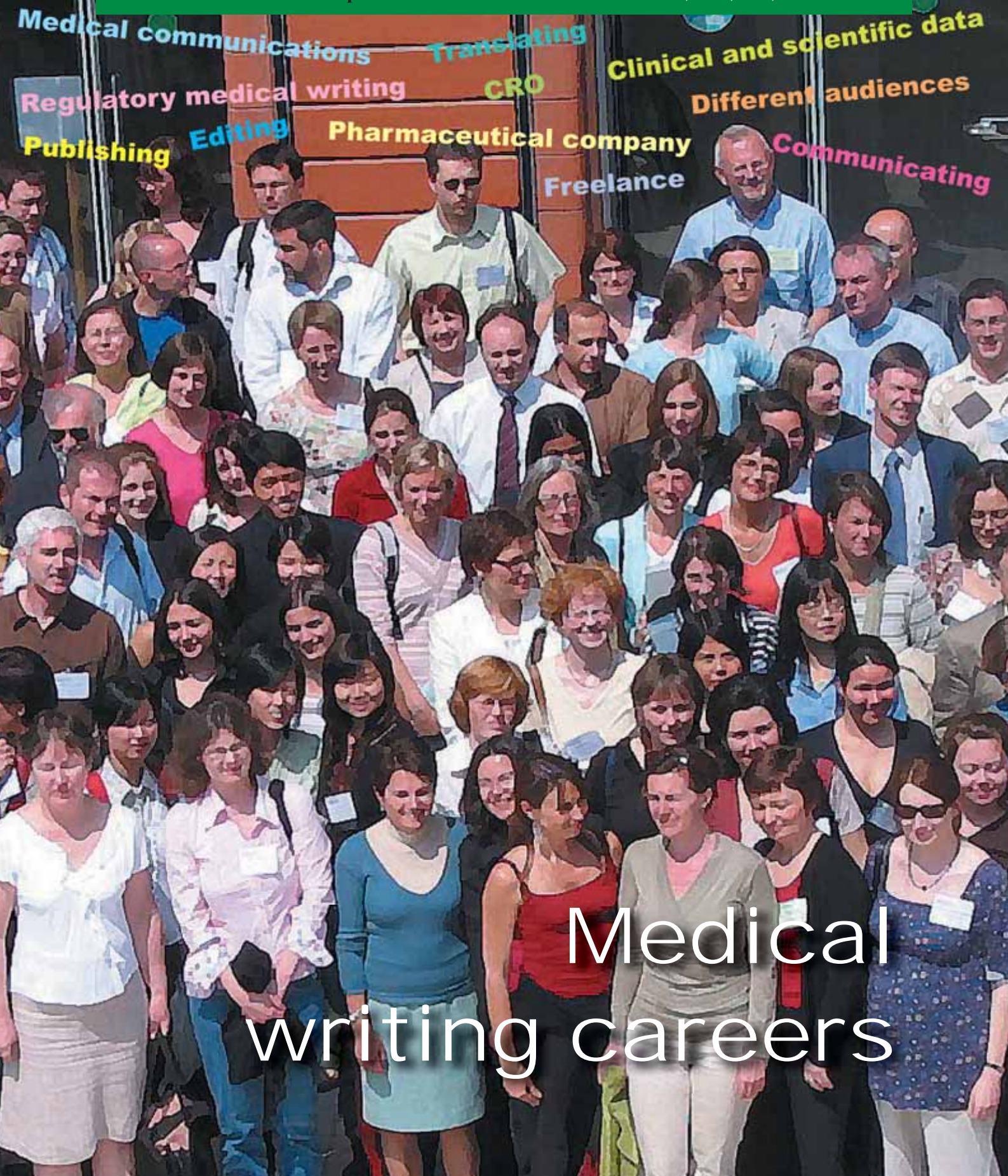


European  
Medical Writers  
Association

# The *Write Stuff*

The Journal for European Medical Writers

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Medical  
writing careers



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## Journal insights

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

Articles or ideas should be submitted to the 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

## Behind the press

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## Disclaimer

The views and opinions expressed in *The Write Stuff* are those of the individual authors and do not necessarily represent those of the European Medical Writers Association or its Executive Committee.

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## Medical writing careers

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## ■ From the Guest Editor's desk



## Medical writing as a career

by Alison McIntosh

I have been a columnist for *The Write Stuff* (TWS) Journal from roughly the time I joined EMWA around 10 years ago, but have managed to avoid 'volunteering' for the guest editorship role. At the EMWA Lisbon conference last year the TWS editorial committee met to discuss possible topics for our journal and from these discussions it was clear that medical writing careers were of increasing interest to the membership.

Although of value to new or potential medical writers, the articles in this edition of TWS should also be of interest to the more seasoned medical writer. The front cover of this edition has a photograph of EMWA delegates taken at the Lyon conference, most of whom fit the job description of medical writer. However, if you had asked each to describe their day-to-day job I guarantee none would have given the same answer. With this in mind, the articles also allow us a glimpse of the multitude of possible career pathways that exist for a medical writer.

### What do medical writers do?

For those of you considering medical writing as your next job it is important to realise that there are a large number of different types of jobs. Deciding on regulatory or medical communications is just the tip of the iceberg. You can work for a small to large pharma company or medical communications agency, in a clinical research organisation, or you can freelance. Each presents a different set of choices and expectations. You can write for different audiences including regulatory authorities, medical professionals and patients, as well as being involved in translating documents into different languages. In each case, the audience must be presented with accurate information pitched at the level of understanding best suited to them.

In her article, Miranda Dini explains about the complexities of working for a healthcare communication agency. For someone who has never worked in an agency environment her article offers insight into what agency life entails. For those considering this area of medical writing she also gives great advice to help decide which agency is right for you. She explains that since their focus can substantially differ, the type of work you might be involved in can vary significantly from agency to agency.

Ryan Woodrow is a freelance medical communications consultant, who some of you might also recognise from his online blogging. He describes his journey from summer job at Astra Zeneca, to medical information, then on to a medical communications agency where he worked for over 10 years before becoming a freelancer. He gives us a taste

of the type of work he is involved in, and explains why he sees social networking as a very important way to obtain work in the 21<sup>st</sup> Century. Read his article to find out more.

In this edition of TWS, Jo Whelan has interviewed a recruitment consultant and from this we have a snapshot of the job market for medical communications. From her interview it is clear that digital skills are becoming an important expertise reflecting the digital approaches used in communicating with specialists, as well as patients and other audiences. This is a fast moving area covering web design and development, together with interactive media and many other new technical areas. For someone entering the medical writing field this is bound to become an area of great importance with a whole different set of skills required. Some forward planning might be required to learn these new skills to give you an advantage over others in this competitive job market.

In his article, Tejpal Grewal, a recruitment specialist, highlights not only what employers are looking for in those applying for their first medical writing jobs, but also gives pointers towards future trends and the type of training and continuous professional development that we must pursue in order to continue to add value to the services we offer. He touches on the scary subject of 'off-shoring' and the challenges this brings with it, offering some sound advice about how to work within the 'global marketplace'. From this I offer my own advice: be prepared for change, and don't bury your head in the sand!

Julia Powell recounts how she travelled from bench scientist to clinical research, and followed this by a stint as a recruitment consultant and outsourcing manager, before she even thought about medical writing as a career. After working in a medical communication company for a number of years she has now become a freelance medical writer and describes how this transition has worked for her.

From Chris Carswell and Keith Evans we hear of the useful role that the medical writer can play in presenting Health Outcomes data. They put the case for medical writers, who might not have written in this area, to develop the new skills needed to write and specialise in Health Outcomes, a topic of increasing importance to the pharmaceutical industry. The issues raised in their article will be explored further at a seminar they are holding during the 32<sup>nd</sup> EMWA conference in Berlin (10-14 May 2011).

In her regular webscout column Karin Eichele provides a number of useful links that will introduce medical writers to the subject of pharamcoeconomics. These websites,

## From the Guest Editor's desk

including a site with information about the value development plan, are a useful starting point to familiarise you with a topic that is, for many, a new and untried area of writing.

Susanne Geercken, one of EMWA's most experienced workshop leaders, recounts how she came to be working in the pharmaceutical industry and explains how her career has evolved. She discusses some of the cultural issues involved in translating a text into several languages and the challenges this often poses. Susanne introduces us to her most recent responsibility as a 'subject matter expert', a role which has allowed her to author medical texts directed at patients.

Susanne Goebel-Lauth works as a medical writer in another area which many of us will be unfamiliar with, the animal health industry and describes the challenges she faces writing for this part of the industry. There are many similarities in the types of regulatory documents that need to be produced, and translated, to obtain a product licence in animal medicine. However, translation for the animal health industry brings with it certain challenges and she helps us to understand why this is a specialised area for translators.

### How do you become a medical writer?

Up to now there has been no set pathway which leads you to the job of medical writer. Most of us currently working as medical writers happened upon the job in a manner similar to "Brownian motion" (see <http://bit.ly/hjbu0Q> for an example of Brownian motion in action).

Many of us become medical writers after spending a number of years as a bench scientist, even completing a couple of postdoctoral posts before plucking up the courage to change careers. Phil Leventhal did just this and in his article he offers tips to help you make the move, if you are considering it, from 'bench to keyboard'.

Internships, once the preserve of young lawyers in John Grisham novels, and the Monika Lewinsky's of this world, is now a term bandied about by ordinary people trying to find a stepping stone in to the job market. On-line discussion forums have numerous questions from people asking about internships; how to find one, are they useful, will they lead to a job? But if you are an employer thinking about offering an internship opportunity, what do you get from it?

It is obvious that if an employer offers an internship there should be a clear, positive benefit, for both employer and internee. This can only come from a well defined series of tasks relating to a specific area of medical writing, and will take time and commitment from the company offering the internship. The expectation of the internee, together with the time and energy invested in the process by them, is not something to be trifled with. An employer offering an internship opportunity should have planned it beforehand, laying out key objectives and should not enter into the commitment lightly. Properly designed and executed, it will open doors for the internee.

Alison Rapley describes her company's experience of setting up an internship for a student programme and Stefanie Kupke the recipient of the internship, describes her

experience and what opportunities this programme has given her. Susanne Geercken also writes about the advantages of accepting translation students on internships which have been offered at her company for around 10 years.

To succeed in the job market today, preparation and forward planning are prerequisites. Anneke Prins describes her route into the field of medical publishing. She not only describes her career path but also gives fantastic and useful advice relating to the application and interview process, as well as confirming how useful her internships have been.

In her article, Lucy Banham describes the route she has followed to become deputy managing editor of the *British Medical Journal*. During her career she has had to learn how to commission, peer review, and edit articles with the aim of learning how to put a journal together. If you think this is the route you want to follow, her article will certainly provide you with much to think about.

Many EMWA members are already familiar with regulatory writing and enjoy the challenges this type of writing presents. For those who are unfamiliar with this area of writing, Greg Morley offers a personal insight into why you might choose regulatory over medical communications as your area of expertise.

### A cautionary tale

I became a medical writer in 1995 and had investigated career changes for at least a year before this, even seeking career advice. After one consultation it was suggested that I use a computer programme which, when fed all the correct information, would come up with the job most suited to my talents. This, I thought, was what I'd been looking for. I answered all the questions and put in all the required information and the computer's ideal job for me was not 'medical writer' but 'travel agent'. I hope this edition of *TWS* does a better job than the computer programme did for me all those years ago!

I would like to thank the contributors to this special edition for giving advice and sharing personal experiences from their medical writing careers. Next time you attend an EMWA conference during the coffee break or at lunch, take time to find out more about the person next to you, ask what does your job entail, and how did you become a medical writer? I think you will be surprised at the answers, if the articles in this edition of *TWS* are anything to go by.

### And finally...

Although I have been the guest editor for this issue, our usual editor Elise has been very much involved. She has reviewed all the articles as well as pulling all the regular features together. Elise is standing down as editor of *TWS* and I would like to thank her for all the hard work she has put in not only on this issue but over the last 7 years. Thank you Elise.

### Alison McIntosh

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## Message from the President



### Dear TWS reader,

by Laurence Auffret

I hope this message finds you well. EMWA's Spring Conference in Berlin (11-14 May 2011) is set to be our largest since the birth of the Association in 1993 and I am really thrilled about it. Germany is a warm host country and it is also home to some of the best medical writers I've ever met.

From Berlin, let's think about Europe, let's think about the world. Where are the boundaries in this ever-connected world?

Our 32<sup>nd</sup> Conference in Berlin boasts several events on the theme of 'globalisation', which is closed to my heart, having worked in 13 countries this year. The Spring Conference is a one-off opportunity to meet up with colleagues from all over the world, share expertise and good practice. Please have a look on the website [www.emwa.org](http://www.emwa.org) to access the full programme.

I also like to think that we still have a lot to connect with. Just register on our LinkedIn and FaceBook sites to participate in industry debates and keep up-to-date with EMWA's

activity. Expressing our opinions in these debates is crucial to furthering the medical writing profession, support EMWA and give strength to our voice in the life science industry.

On supporting EMWA—I have received a number of applications to volunteer for the Association and we would still like to hear from other members too. The Public Relations Officer, the Honorary Secretary, the Treasurer and the Vice-President will be elected during our AGM in Berlin. To stand for election at our next AGM in Berlin, please send me a short presentation via e-mail (400 words) before 15<sup>th</sup> April 2011.

Hope to see you in May in Berlin!

**Laurence Auffret**

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## Meet the EMWA Executive Committee candidates... 2011

EMWA's Executive Committee will be elected based on voting by members. All candidate statements will be provided as part of the Annual Meeting (AM) pack. Candidates will be invited to make a presentation at the AM in Berlin on 11<sup>th</sup> May 2011 at 15.15 hours. After the presentations, a vote will be called and all members present will vote on each position for election. If you will not be at the AM you may vote by proxy by submitting your vote before 15.14 hours on 4<sup>th</sup> May 2011. You will receive details on how to access the AM pack and how to provide your proxy vote in the post in April.

### For the position of Education Officer

Jo Whelan



I have been an EMWA member for about 10 years. I have served on the Education Committee for the last four, and I run two EMWA workshops. I have worked in scientific publishing and medical communications for over 20 years, the last 12 or so as a freelance medical writer. I have gained a

tremendous amount from EMWA in terms of training, networking and making new friends and colleagues, and I'm standing for Education Officer because I'd like to give something back. If elected, my priorities will be to keep the Education programme running smoothly, to ensure that it evolves in response to members' needs, and to ensure that it offers the best possible value for money. I will also do all I can to support workshop leaders, without whom the Education Programme would not exist. I have attended many workshops over the years as a paying participant, and my primary aim will be to ensure that EMWA members have a first rate experience of the training programme when they invest in coming to conferences.

### For the position of public relations officer:

Farid Khalfi



Although I have known EMWA for many years, I joined the association in 2005. I am very impressed by the energy and enthusiasm of people involved in this association committed to training and development. I became a medical writer 13 years ago when I joined a pharmaceutical company, and then a contract

research organisation (CRO) working within a wide range of indications and meeting clients from both small and big companies. I am currently working for a pharmaceutical company specialised in contrast agents. To create and maintain the reputation and positive representation of an organisation or individual is challenging and ever changing and I believe that working in the field of public relations is fundamental. I'm very motivated, proactive, and like interacting with various types of people and learning from them. EMWA is still growing and I want to help in promoting this highly professional organisation. From years of organising medical writing activities or participating in social events, I have learned one very important thing: whatever you do in life, do it with passion.



## Career challenges for medical writers from the recruitment specialist perspective

by Tejpal Grewal

Medical writers have a very important role within the pharmaceutical industry; it is their efforts that document drug development in the industry from the creation of new clinical study protocols to consolidating reports for approval of a new drug, ultimately ensuring that the right information is presented in the right format to prescribers and end users. Even though medical writers are an important piece of the pharmaceutical industry puzzle there are many challenges that new and seasoned medical writer face now and in the future.

Recent graduates as well as industry professionals seeking a career change frequently ask what essential skills are required to establish themselves as a medical writer. Generally, it is not only a set of skills that someone requires but also a specific mindset. A medical writer needs to present complex information both clearly and concisely, therefore effective written and verbal communication skills are paramount to being successful.

No information can afford to be lost in translation or be misinterpreted and it is from the large volume of information that a medical writer must use their knowledge and support networks to decide how to structure and communicate all of the information relevant to the document that they are producing.

In general, employers find that the best medical writers are those that have a passion for their job, or a specific skillset or perhaps experience in a specific therapeutic area. Hence a career in medical writing is best viewed as feeding your interest and thirst for knowledge rather than being a 'decent paying' job. If a candidate can demonstrate a passion for the role and is able to grasp the fundamental parts of what makes a good medical writer they should find it easier to secure that all important first role in the field.

Individuals can further their chances of success by attending dedicated EMWA courses, networking with experienced medical writers, and seeking out internships or placements. Candidates can also spend time researching companies who are developing products in their specialist area, or the area in which they have written their thesis. The need to take a critical view of the work they may have done in their career so far and working out how that might apply to a future in medical writing is very important. With the ever increasing competition from new graduates and experienced professionals looking to get into medical writing it is important that candidates be pro-active and clear about how their skills relate to a career in medical writing.

As medical writers develop throughout their careers they can either become specialists in a few particular areas (e.g. regulatory writing for oncology studies etc.), or they can take on a broader spectrum of work. The advantage of specialisation is the ability to work in areas of genuine interest and the potential to leverage this expertise into a commodity valuable to certain companies. Medical writers in permanent positions may find that they can gain well rounded experience if they work for a clinical research organisations (CRO) or medical communications agency, where there is the opportunity to work on many different projects. After gaining experience in an in-house role, a medical writer has the choice of moving up into management, specialising in a particular therapeutic area, or becoming a freelance writer.

Although a freelance medical writer who is highly specialised can command an attractive hourly rate, they may discover that finding work in a niche area is a challenge without an established network. Becoming a medical writer with general experience means that someone can have variety in their work whilst also keeping work interesting. However, the diversity of work and experience may not allow generalists to keep up with the specialists when it comes to pay rates. A freelance medical writer with a broad range of experience will not find it too difficult to fill their time, but their hourly rate may not be as attractive as that of a specialist.

Some generalist medical writers fear that freelancing may not provide them with a steady income. However, freelancing can be lucrative if the freelance medical writer has a very strong reputation in the industry and has built a reliable network of professional connections that can provide an ongoing stream of opportunities. Many people also go down the freelance route as it gives them the flexibility to not only work from home but also to structure their work around their life, and not the other way around as is so often the case. This is a very important advantage for some freelance medical writers and outweighs many of the other considerations.

Even for the most experienced medical writers, the term 'off-shoring' strikes fear into the hearts of all hard working medical writers in permanent positions throughout Europe and North America. With emerging nations such as India producing highly qualified English speaking personnel, some companies have created departments in those areas for the more labour intensive tasks associated with clinical

## Career challenges for medical writers from the recruitment specialist perspective

> research such as data management and medical writing. Companies based in low labour cost countries that specialise in outsourced medical writing services have also emerged and have increased price competition, making outsourcing more appealing to cost conscious pharmaceutical companies or CROs. However, off-shoring does not spell the end for medical writing opportunities in traditional western markets as companies often feel that having in house staff or local freelancers with expert knowledge of their local markets is invaluable. This is especially true for highly specialised medical writers.

The challenges faced by medical writers are more competition for roles and freelance assignments as companies have access to a truly global marketplace. The best way to combat these challenges is for medical writers to understand where they sit in the marketplace and try to develop specialised experience and expertise that adds to their marketability.

There is still a great demand for medical writing expertise in all areas of the pharmaceutical industry globally and the need is unlikely to change in the future. This means that even in testing times a career in medical writing is an excellent option for those who have a genuine interest in the field.

### Tejpal Grewal

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## Useful information about medical writing as a career

EMWA has prepared a careers leaflet designed to help introduce medical writing to those thinking about medical writing as a career option. The leaflet can be downloaded from <http://www.emwa.org/Mum/Career.pdf>

Articles written by EMWA members and relevant to those considering medical writing as a career option are available on the EMWA website. The articles provide both useful information about medical writing and experiences of working as a medical writer <http://www.emwa.org/A-career-in-medical-writing.html>

The third annual edition of the careers guide *From academic to medical writer: A guide to getting started in medical communications*, by Annick Moon will be published in March 2011. It has advice and information for those seeking a career as a medical writer in a medical communications environment and provides a good introduction to what is expected from a medical writer working in this area. The guide contains profiles of medical writers in UK-based medical communications with information relevant to wider audiences. Copies are freely available to download from <http://bit.ly/hhyYQY>.

## In praise of regulatory writing...

A large part of my medical writing career has involved manuscripts and other aspects of medical communications. Such writing, generally aimed at a wider audience, and perhaps involving a certain creative flair, has its attractions. When I explain to an outsider (for want of a better word) what regulatory writing is, the reaction is generally, “Oh, that sounds ...” either straight “boring” or an insincere “interesting”. Both responses, though, are usually accompanied by a quizzical expression that seems to say “Why would you want to do that?”

It's true that there are plenty of ‘boiler plate’ parts to many regulatory documents—the materials and methods section of clinical study reports, for example. A regulatory writer will also often have to be familiar with a bewildering range of internal and external guidelines, which do not generally make for a lively read. And as a regulatory writer you are certainly not encouraged to get too ‘creative’ with the documents you are writing. A regulatory writer will also usually work within the framework of a team, which may seem to further constrain any creative impulses.

So what does regulatory writing have going for it? For one thing, the team-oriented focus of regulatory writing and present its own rewards, such as a sense of belonging, and challenges, such as the need for dispute-resolving skills (or ‘soft skills’ as jargon would have it) and to be sensitive to the team dynamic. Indeed, a couple of articles in the last issue of *The Write Stuff* suggested that the more collaborative approach often taken by women could partly explain the relatively high female presence in medical writing. I don't mean to imply that manuscript writing doesn't involve teamwork or negotiations with the named authors—it clearly does, or at least should from an ethical point of view—I just don't think that the sense of teamwork is so strong with manuscript writing.

Some regulatory documents such as investigator's brochures and their updates involve contact with a wide spectrum of areas, from non-clinical PK right through to clinical drug safety. This can give you an overview of the whole drug development process, unlike manuscript writing, where the focus is usually largely clinical. Other types of document that I find interesting are those used for meetings with the health authorities (briefing packages). Here, a regulatory writer gets a close-up view of the interaction between company and health authority. It is also often quite a challenge to distil tricky regulatory issues into a succinct document that will improve the chances of a successful meeting.

So regulatory writing and communications writing both have their merits (and demerits). Any preference for one or the other will depend largely on the individual. In a way, it is bit like comparing our proverbial apples and pears, something that all types of medical writer are urged to avoid. I personally have got a taste for both.

### Gregory Morley

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## Medical communications: Hot demand for the right skills

by Jo Whelan

*TWS asked recruitment consultant Jessica Guyon, of the UK company Paramount Recruitment, for her view of the job market for medical writers in medical communications.*

### **How would you describe the current job market for medical writers?**

There is a high demand for experienced medical writers within medical communication agencies, but not many medical writers who are actively looking for work. Because of this, when medical writers are looking for work they usually have a large number of companies that they can apply to. However, [in the UK] they may be limited in the locations that they can work (usually North West, South East and London). There are a lot of graduates/new writers (without experience) wanting to get into the industry, but not many entry level roles.

### **Would you say there was a skills shortage when it comes to experienced medical writers? Is there more demand for our services than there are writers to fill it?**

Yes, there are not enough experienced medical writers to fill the number of writing roles available. In addition, there is a shortage of medical writers who have significant digital experience.

### **What skills and experience are currently most in demand in medical writing? You mentioned digital?**

Significant medical communication agency experience, significant medical writing experience, project management, knowledge in specific therapeutic areas. Many companies are moving into digital communications so the number of vacancies is increasing. The skills required are web design/development, interactive media, online gaming, technical skills (flash programming), marketing and advertising.

### **What is the trend regarding salaries? Have they risen much in the last few years, stayed the same, fallen?**

As it is a candidate-short market, the salary for medical writers has continued to increase over the years. In addition, many of the agencies will increase their salaries to compete with other medical communication agencies that are advertising.

### **How do companies regard the issue of flexible working?**

The agencies tend to offer this as a last resort, when they need to fill the position ASAP or when they are having trouble filling the position. Some companies offer home

working and flexible working hours, but this is offered to highly experienced medical writers. There are a lot of experienced medical writers who want a role offering more flexible working or full home working; however, these kinds of positions are not as common.

### **Are companies willing to take on new medical writers with no previous experience?**

### **What advice would you give someone trying to enter the profession?**

Yes, usually the minimum requirement is that they are educated to PhD level. There are not many entry level roles available and there is usually a lot of competition for the position. It is advantageous if the candidate has gained editorial experience, attended an internship in a medical communication agency, gained post doc experience, completed an editorial/ medical writing course or has done a significant amount of scientific writing.

### **Do you have any feel for demand outside the UK? Do you handle many vacancies elsewhere in Europe?**

There is a demand for native English speakers to relocate to medical communication agencies within Europe. However, there are many medical writers within Europe but fewer jobs available to them.

**Thanks Jessica**

Jessica can be contacted at Paramount Recruitment on [Jessica.guyon@paramountrecruitment.co.uk](mailto:Jessica.guyon@paramountrecruitment.co.uk) or see [www.paramountrecruitment.co.uk](http://www.paramountrecruitment.co.uk)

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The illustrations on pages 13, 16, 17, 19, 25, 26 and 28 were designed and produced by Anders Holmqvist ([adobild@yahoo.se](mailto:adobild@yahoo.se)). Anders is a graphic designer, illustrator and photographer based in Lund, Sweden who specialises in providing illustrations for the health and pharmaceutical industry.



## Short-term placements for trainee medical writers

by Alison Rapley and Stefanie Kupke



### The employer view

One of the topics discussed at the EMWA conference in May 2010 was how EMWA could help potential medical writers gain experience in order to launch their career. One possible option is the employment of students for a short period to enable them to gain practical experience in the workplace. The medical writing group at PAREXEL have recently become involved in such a scheme and I would like to share the experience with you.

We were asked to provide a placement for a student currently studying for a BSc in Clinical Research. This qualification is jointly run by PAREXEL Academy in Germany and the University of Wales and covers data management, biostatistics, biochemistry, ethics, clinical research regulations, clinical monitoring and drug development. It also includes a 5-month placement, 4 days a week, in the third year of the course. The course is run from Berlin but a number of the students prefer to be based in an English speaking country in order to improve their English language skills. Students are responsible for their own accommodation, travel, visa, etc. A decent payment for their work and allocation of appropriate tasks is expected whilst the student is on the placement.

Having considered the situation and spoken directly to one of the students we felt that we would be able to provide a job which would have a positive benefit, both to us and the student. This positive benefit for both parties is important because as a clinical research organisation we need to maintain our quality and efficiency whilst also ensuring that we provide the student with a satisfying and challenging job during their stay. We identified several appropriate tasks and Stefanie joined our writers based in Uxbridge in March 2010 to begin her placement.

### What did we learn from this experience?

#### **Be prepared to invest time in the student**

There are administrative tasks involved in employing any new member of staff. In this case additional administration was required to provide the necessary assessments to the university tutor. In addition, any new member of staff needs training before they can carry out the tasks assigned to them and this needs to be taken into account. For this reason placements of less than 3 months may not be a good idea.

#### **Plan the tasks you are going to provide the student with in advance**

There were a number of administrative tasks which could be taken on by the student, such as coordination of meetings, updating of meeting minutes, and organising travel arrangements. It was important that these remained a small part of the job as they did not provide any opportunity for training in medical writing.

We knew that there would be a number of clinical study appendices required during the time Stefanie was with us. This was something she could be trained to complete relatively easily and it would allow her to become familiar with the different types of documents that need to be included with a clinical study report. This became one of her main tasks during her placement. We also knew that there would be many patient narratives to be written. Although this medical writing task needed more oversight from a qualified medical writer it did provide the student with useful experience in another area of writing.

Overall, a balance needed to be struck between tasks which involved a significant amount of training and oversight such as patient narratives, and those more routine tasks such as collecting appendices material and standard administration which could be taken on after minimal training.

#### **Ensure the student understands the role they are taking on and that it is what they want**

Stefanie was very keen and enthusiastic about her role with us. We had a clear picture of the training she had already received during her course and her previous experience and knew that this would be relevant to the tasks we had assigned. It would not have been successful if the student did not have some previous experience or understanding of the pharmaceutical industry and the clinical trial process.

#### **Would we do it again?**

The short answer to this is yes. We plan to continue our collaboration with the PAREXEL Academy and University of Wales. With appropriate planning and the right candidate, the experience can be beneficial to both sides. We also have the satisfaction of knowing we are training medical writers for the future and putting something useful back into the profession.

## Short-term placements for trainee medical writers

## The student view

**What did you hope to get out of this placement?**

After much consideration, the PAREXEL Medical Writing Services was the most appealing opportunity for my work placement because I wanted to gain first-hand experience within scientific writing and also improve my knowledge of clinical trials.

I became interested in the documentation of clinical research trials from roles previously undertaken within other clinical research organisations, thus I was looking forward to gaining further insight into the many different types of documents required for clinical trials including protocols, patient information sheets and clinical study reports.

I was hoping to benefit from close client contact and the opportunity to work as part of a team, collaborating with colleagues and external experts from many fields of clinical research, such as clinical, statistics and project management.

**Did it meet your expectations; if not, what else would you have liked to have been involved in?**

The work placement gave me new prospects and influenced

me in my future career choices. I was impressed that medical writing can be such a fascinating field.

In general, I was pleased with what I learnt during the placement. I would also have liked to have been involved with the preparation of patient information sheets and other sections in a clinical study report. I appreciate this requires more experience and hope over a longer period of time this would be feasible under the supervision of a professional medical writer.

**Would you recommend this as training for a medical writing role?**

Yes, I would recommend this as a programme to career starters in medical writing. Depending on the level of prior experience in clinical research I would consider this especially useful for young professionals. It provides an excellent opportunity to learn the basics of medical writing within a short period of time.

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"How do I get from here to there?"

© Renée Albe





## Planning a career break into medical publishing

by Anneke Prins

Breaking into the world of medical communications requires a bit of determination, a bit of knowledge, and the ability to identify useful transferable skills. After graduating I spent some time as a post-doc researching plant response to environmental stress and then tried my hand as an English teacher. However, I realised neither of these felt quite right. So I decided to marry my enthusiasm for science with my love of communication, and started looking for a job in the world of medical publishing.

As a graduate in genetics, I decided to shift my focus to plant molecular biology in my postgraduate studies. My PhD was a particularly rich mine of experience, and I owe a lot to my two fantastic supervisors. Many of the skills I learned as a PhD student have been invaluable in my pursuit of a career in medical communication. For example, knowing how to plan and prioritise experiments helped me to organise my work schedule. Keeping a neat and detailed lab book helped me to present my work clearly and taught me to keep excellent, up-to-date records. Many PhD students complain about extra duties required of them, such as helping to peer-review papers, giving lectures, or marking papers, however these tasks prepare you well for the publishing world. Writing papers, having them peer reviewed, and peer reviewing them in return teaches you what journals want. It also gave me an appreciation for the peer review process—something that's essential in ensuring the quality of publications.

***Postgraduate studies are a rich source of transferable skills***

Science isn't all I'm interested in, though. I was raised fully bilingual with Afrikaans and English as my mother tongues, and have always had a strong interest in languages. I spent some time teaching English both in China and London, obtaining the Cambridge Certificate in English Language Teaching to Adults (CELTA). While it strengthened my understanding of the nuts and bolts of English (something which is always useful in a writing or editing environment), it was also an opportunity to improve my creativity. Using the language you're teaching to teach that language is an exercise in creative thinking, but also a superb opportunity to really analyse how you communicate with another person. Teaching people from a wide range of backgrounds also helped me to practise my communication skills. However, I realised that I just wasn't cut out to be a teacher and took some time to identify where I really wanted to steer my career.

My first love has always been science, so I decided to explore careers that would employ both my love for science and my passion for communication. I spent a few months working my way systematically through "How To Get a Job You'll Love" by John Lees—a book that guided me through important questions about my career and where I want it to go. In my opinion, this is one of the most important parts of career change: taking the time to revise your own interests and identifying your key motivations. All my answers pointed towards a career in medical communications, and so I started looking for a vacancy. I registered at a number of recruitment agencies. I ensured that I called agencies instead of e-mailing them, as a lot of exploratory e-mails seemed to 'get lost'. A good recruitment agency will identify your key skills and try to find a job that perfectly suits you. Unfortunately a lot of agencies only seem to recruit people who already have job experience, but if you look around, you will definitely find some that have entry-level positions. A recruitment agent will support you each step of the job application process, preparing you for your interview and giving you information about the company at which you're interviewing.

A recruitment agency helped me obtain my first interview in medical writing. The application process included a very thorough four-part writing test, after which I was invited for an interview. I prepared for the interview by practicing a number of standard interview questions, but also a number of competency-based interview questions. All of these are

***Take the time to identify what motivates you, and go for the job you really want***

readily available on the Internet, and are invaluable. Many of them require you to explain a situation where you applied a specific skill. For example "How do you organise your schedule?" might be a question asked to determine whether you would be able to cope with more than one project at a time; "Give us an example of a situation where you worked under pressure" might be asked to see whether you can work to tight deadlines. A good way to answer these questions would be to describe briefly an appropriate situation you faced before, tell the interviewer what actions you took, and conclude by giving a positive result.

Make sure you know what the key skills are for any job that you apply for—these are usually highlighted in the job specification. It also boosts your confidence to think

## Planning a career break into medical publishing

of examples where you applied these skills in your career in the past. Even if the interview doesn't go that well, use the contact time you have with people who are in the industry to improve your knowledge of the work of medical writers. In addition, prepare some questions to ask the interviewer—some specific to the company, and some more general. "Why do you like working here?" is a good one. If an interviewer can confidently tell you why they love their job, this is a good sign that it could be a good company to work for. If an interviewer gives you a good, comprehensive reply then you can use this information for future interviews as well. This can be especially useful if you are changing career—having someone else state why they find their new career rewarding can help to crystallise your own motivations for changing yours. If you get feedback after the interview, be sure to address the issues the interviewer has raised.

As a PhD student I gained some experience in writing through writing papers and a thesis, but what I lacked was experience of medical writing and a general insight into the world of medical research. In order to tackle these weaknesses I did three things: I started reading medical research papers and blogging about recent medical breakthroughs, I read books about pharmacology and medical writing, and I secured two internships—one in medical writing and one in publishing. Writing the blog improved my knowledge of current hot topics in medical research, while the internships improved my knowledge of both medical writing and the field of publishing.

After four months I found work as an editorial assistant at a large publishing house, working on a group of journals that contain medical reviews covering the pharmaceutical pipeline. My job involves identifying peer reviewers and

inviting them to review papers. I also have to chase up overdue reviews and check that the reviews submitted are thorough enough for the commissioning editors to make a decision. My experience as an intern at a medical communications agency has been invaluable in this position, as

### ***Get a foot in the door by doing internships or by blogging online***

it has helped me to quickly recognise the type of study a paper is based on, thereby speeding up the peer review identification process. I really enjoy my job, as it exposes me to cutting-edge medical research and gives me a thorough insight into the 'other side' of paper submission.

I can highly recommend working in medical publishing as an alternative career in science. It exposes you to the very latest of research, while allowing you to progress within a well-structured career. Working in medical communications is challenging, but finding a job that gives you a buzz is worth it.

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### ***Show you have the key skills required for the job, or you're willing to learn those you lack***

## Theme of the June issue of TWS

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](mailto:claudia.frumento@t-online.de).

As always articles (between 1000 and 2500 words) or short reports (between 100 and 1000 words) 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 the editor at [editor@emwa.org](mailto:editor@emwa.org)

## TWS editorial meeting in Berlin

Participants at EMWA's 32nd Conference in Berlin are invited to take part in the TWS editorial meeting which is open to anyone who is interested in contributing to or helping with the production of TWS. Volunteers for guest editing, writing articles (100 to 2500 words), copyediting or proof reading are always welcome. The meeting is also an informal forum for giving board members your comments and making suggestions for themes and content of future issues, or for letting us know how you think the journal might be improved. Drop into the meeting at any time.

The meeting will be held at Adel's Hotel, Berlin from **13.00 to 15.00 hours on Wednesday 11<sup>th</sup> May 2011** in the Granat Room on the Upper floor.



## See you in Berlin?

See [www.emwa.org](http://www.emwa.org)



## From CRA to sexual medicine: My career in medical writing

by Julia Powell

My first experience of writing anything longer than a student essay was the writing of my PhD thesis; an experience I certainly did not enjoy. I had decided that the isolation and frustrations of scientific research at the bench were not for me, but as I was being funded by a government studentship, and in the absence of an alternative career path (or source of income), I felt obliged to continue. Towards the end of my research a fellow PhD student told me about his girlfriend's new job as a Clinical Research Associate (CRA), which sounded fabulous—a magical mix of scientific research (without the lab work) with the chance of a good salary and company car. So I decided that I wanted to be a CRA, and getting my priorities right I booked some driving lessons! I was also determined to finish my thesis before starting a job as I was reliably informed that with very few exceptions (Brian May from Queen being a recent notable one), not writing up straight away meant that you were very unlikely ever to do it, even though writing became a chore alongside my driving lessons and hunt for the dream job.

### Student to company car driver

I was fortunate to be offered a job as a CRA with the Swedish company Astra Pharmaceuticals (before the days of their merger with Zeneca) in their UK marketing office. At the time they only employed PhD graduates as CRAs because a PhD was seen as an essential foundation for project management responsibilities. I was awarded my PhD and driving licence within days before starting the job in late 1993 and received my longed-for company car. It turned out that I had joined the company at a fortuitous time. Astra's Losec (omeprazole), launched in the late 1980s, was working its way to becoming the world's best-selling prescription drug and consequently there was plenty of money for running the Phase III and IV trials that I was working on as well as generous amounts for training and other perks. The job was everything I had hoped it would be.

I was able to adapt my experience of running experiments in the laboratory to planning and running clinical trials. For those of us working in hospital-based research, each CRA was responsible for one or two clinical trials at a time and took on all associated responsibilities from writing the study protocol, designing the CRF, organising supply and packaging of drugs, recruiting investigators, dealing with ethics committees, monitoring the trial, writing the clinical

study report (CSR), as well as writing journal manuscripts and any conference abstracts and posters. It was total immersion from day one and all had to be done in accordance with GCP as well as Astra's own meticulous high standards. It was certainly a great way to learn the job. My first project was running a clinical trial on inflammatory bowel disease which had hospital sites all over the UK and the Republic of Ireland, so I was darting about in my company car as well as enjoying the halcyon days of British Airways champagne cream teas on short-haul flights in business class (with the added bonus of Air Miles). I truly loved my job!

I felt a sense of ownership and pride in the clinical trials that I was running and gained expertise that I still find valuable today.

### Onwards and upwards

I worked my way through gastrointestinal, cardiovascular, and respiratory clinical trials amongst others and also progressed up Astra's career ladder (and company car grade). I became a regional clinical research manager, responsible for a team of CRAs and project managers in the South of England. I also became field-based and had my first taste of life working from home in our tiny house in Berkshire.

This was in 1997 when the Internet was in its infancy and broadband only a pipe-dream. Wads of paper memos were just about being replaced by intra-company e-mails. To communicate with Astra's intranet I had to switch off my home phone to use a dial-up modem and listen to all the clicks and whistles as it sent and received a few e-mails in the time it took to boil a kettle and make a cup of coffee—and drink it too. On the other hand, working from home then did not have today's bombardment of e-mails and the temptations of shopping websites and all the other interesting diversions on the World Wide Web.

However, as is often the case with career progression, I had been promoted away from the things I really enjoyed, which was the sharp end of running clinical trials and had ended up spending a great deal of time managing budgets and people. I managed to retain responsibility for writing manuscripts and overseeing other writers which I particularly enjoyed. Having responsibility for reviewing documents written by others allowed me to see that writing (especially manuscripts) was a particular skill that didn't necessarily go hand-in-hand with other technical skills.



## From CRA to sexual medicine: My career in medical writing

## A baby, recruitment and more babies

My life changed when our first baby arrived in 1998 and after a generous Swedish-length maternity leave which gave me plenty of time to think, I decided not to go back to AstraZeneca (the merger had just happened) and to look for something part-time that involved less travelling. Sadly, I handed back the keys to my company car and approached ClinPharm, the CRO and recruitment agency who had found me my first job at Astra, hoping for a part-time position somewhere. However, I actually ended up accepting a job as a ClinPharm recruitment consultant and outsourcing manager.

ClinPharm were sold to the US company United Healthcare, and morphed through several names, whilst I diligently carried out interviewing, profiling and match-making for many types of jobs in the pharma industry. The company was unusual in carrying out face-to-face interviews with as many potential candidates as possible rather than relying on CVs and telephone interviews. The information gleaned had to be summarised into a succinct profile which highlighted the candidate's strengths whilst being honest and realistic—not forgetting that a candidate could ask to read their own profile at any time under the data protection act! It was often the profile that would persuade a client to interview a potential candidate rather than the typically British understated CVs that most people produced.

This was also the first time I encountered medical writing as a distinct job, rather than something that was done as part of another job. From then on I kept medical writing in the back of my mind as a possible future career.

Much of my time was spent interviewing and providing careers guidance to would-be CRAs or similar (“wannabes” as we called them), with no previous experience. However, it was also common to be faced with a vacancy that proved to be very difficult to fill. It was puzzling to me that whenever we advertised a vacancy for an experienced medical writer, we were inundated with CVs from “wannabes” and also from freelance writers, but only very rarely was an experienced applicant actually looking for a permanent job and they were almost inevitably too expensive for the client.

I thoroughly enjoyed working in recruitment, but also missed being more closely associated with clinical research. There were many occasions when I was tempted to apply for one of the vacancies I was trying to fill, but like most other working mums, I was torn between developing my career and spending time with my young family—we had two young children by then. I finally gave up my job entirely when we had a third baby and moved some distance away to Kent for my husband to take up a new position as a university lecturer. Having three children aged four and under made childcare prohibitively expensive, so I took a career break and immersed myself in motherhood for a while.

## Back to college again

Once two of my three children had started school I started to think about re-establishing my career and improving our family finances, but for the first time in my life was suffering from a huge lack of self-confidence. Unless you have been in this situation it is hard to imagine how it feels. I felt that my skills were out of date and that the world of clinical research had moved on without me, although I later discovered that this was not so. What had changed hugely though was the way people worked, thanks to the very rapid development of the Internet around that time. The Internet had gone from being a lunchtime distraction for those lucky enough to have access at work, to being the mainstay of how people worked in just the very few years that I was away from it all.

As a way of easing myself back into the world of work I started a short part-time course in European business and e-commerce at Canterbury Christchurch University. I began to relish the time I could spend learning new skills and brushing up old ones as I slowly regained some confidence and began to think about what sort of job I could do that would fit around school hours. I had been thinking about medical writing for some time, but felt too out of touch and still lacking in confidence to strike out on my own as a freelancer. It was then that I had a lucky break. I was idly flipping through the local paper at college one coffee break when a job advert with a job description written just for me (or so it felt) jumped out at me from the page. A local medical communications agency was looking for a medical writer with a PhD and experience of the pharmaceutical industry to work part-time, flexible hours either from home or in the office. The advert said that the company specialised in urology, which I did not have any particular experience in, but nonetheless I completed the writing test and interview and was stunned to be offered the job.

Looking back now it is hard for me to understand the lack of confidence that I had in my own abilities at the time, but I really did feel that my career was on the shelf and that the company was taking a gamble offering me the job. I had clearly forgotten my own earlier experience of how hard it was to recruit a medical writer. It was only later that I learned that this was the company's second attempt to recruit a new writer, the first advert having failed to attract a suitable applicant.

## Sex in the pharmaceutical industry... or pharmaceuticals in the sex industry

It turned out that ‘urology’ had been used largely as a euphemism in the job advert in place of ‘sexual dysfunction’. The success of Pfizer's Viagra for erectile dysfunction had led to a massive expansion (I must now apologise in advance for this and all other unintended double entendres—a hazard of writing in this field) in potential products for ‘diseases’ related to sexual function, such as premature ejaculation and female sexual dysfunction. Alongside the more classic urological disorders such as incontinence, I found myself attending meetings and writing about the sorts of things people don't normally discuss in polite company and became a mine of information to my friends! >

## From CRA to sexual medicine: My career in medical writing

- > I also discovered that a good sense of humour was the way to survive when so far out of my normal comfort zone.

There are many difficulties with running and reporting clinical trials in such a 'sensitive area', such as the reliance almost exclusively on patient-reported outcomes and the lack of agreement as to what is 'normal'. Many sexual disorders do not yet have clear disease definitions that are acceptable to the regulatory authorities, creating an extra hurdle to be crossed for drug developers. Whilst many of these issues are unique to working in sexual dysfunction, others are relevant to any emerging or newly identified disease area or pharmaceutical target.

I was thoroughly enjoying being back in clinical research, and now focusing on medical writing. I continued to have the occasional self-doubt when faced with something new, but actually enjoyed every new challenge. I started doing more regulatory writing (including contributions to FDA submissions for the first time) alongside the mainstay of conference abstracts, posters, journal manuscripts and review articles and also overseeing the work of more junior writers. I also joined EMWA and attended my first EMWA conference.

As I gained experience as a medical writer and in time became Head of Medical Writing, I also began to think more about freelancing. I had worked on contracts alongside freelancers and had also met a few through EMWA. I also had the good fortune to live very near to Margaret Bray (in fact we had sons in the same school class), who has been an EMWA member and freelance medical writer for many years. I started quizzing Margaret and other freelancers about the business side of things and began to realise that working freelance made good business sense. Also, as my three sons were progressing through primary and on to secondary school and my husband was now doing a long daily commute, I found that I needed a greater level of flexibility to support them and their burgeoning social/sporting/musical lives.

### Taking the leap into freelancing

Financial pressures and personnel changes at the agency I was working for provided a further incentive. I finally made the leap and left my paid job to become a freelance medical writer in 2009. In doing so I left behind the career

structure and progression, pension, private healthcare, IT support, paid-for training courses, generous expenses, staff Christmas party, company car, business travel etc. that working as an employee can provide (actually most of that was just wishful thinking!). I attended the EMWA conference in Frankfurt just after making the decision, with some of the old self-doubts creeping in, but Margaret introduced me to some seasoned professionals and I felt a new enthusiasm after some morale-boosting chats (or maybe it was the wine).

In some ways it was an easy transition for me as I already had my office set up at home and a supportive family, but I was contractually prohibited from approaching (or poaching) clients from my previous company, so the biggest challenge for me has been generating new clients and contracts. My EMWA freelance listing has certainly helped, although I have had more work via personal recommendations and other sources. After a slow start, the work started to come in and has continued to flow, although not always in the steady way that I would like. I had the pleasure of my first invoices being paid and the frustration of having to chase overdue ones.

I have had the opportunity of working in some new and interesting therapeutic areas and sometimes also producing types of documents that I hadn't written before, such as sales aids and marketing support materials.

Freelancing has enabled me to work with some great people, although due to the powers of the Internet, I have hardly met any of them face to face. One company even sent me a bouquet of flowers and bottle of champagne after I took on an urgent last-minute project for them and worked through the night to complete it. It just so happened to be one of my first ever freelance projects and I was trying to make a good impression, which clearly paid off as I have had plenty of repeat business from them. I have also had a few more challenging projects, but I am learning how to be more challenging myself when necessary in order to clarify details and expectations upfront.

### On reflection...

Writing this article has made me reflect on my career and the choices that I made in a way that I haven't before. I know now that pursuing a career as a medical writer was the right choice for me, but total immersion in clinical research as a CRA and project manager gave me an insight into the generation and reporting of clinical data that continues to be invaluable to me. My move into freelancing has enabled me to earn more money for working fewer hours, generally with a good work-life balance. The feeling of empowerment and freedom that has come from being my own boss is liberating and right now I can't imagine wanting to do anything else.

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## Freelance Medical Communications Consultant: “So what exactly does your job involve?”

by Ryan Woodrow

“So what exactly does your job involve?” is the question that I get asked often by friends, family and even every now and then by my wife of 10 years. To be honest, I still find this question somewhat difficult to answer, because the truth is my job varies tremendously from day-to-day. My standard answer is usually “I help pharmaceutical companies to communicate about their drugs to doctors”. This usually suffices as an explanation and people generally quickly switch the subject to avoid listening to the technicalities.

While this explanation is short and sweet it is also tremendously superficial. In any given day I can be a writer, a marketer, a PR consultant, a meeting facilitator, or a strategic advisor. As a freelancer, I am also required to be a book keeper, a social media expert and much, much more. This huge amount of variation, together with the ability to keep up to date with science, is why, after 15 years I am still passionate about working in medical communications.

I understand that many EMWA members are from a background of clinical and regulatory writing, and that medical communications may be somewhat of a mystery. Well “med comms” agencies traditionally support pharmaceutical and biotechnology companies in three key areas:

1. Publication planning, including the development of clinical publications and congress presentations in close conjunction with authors and in line with Good Publication Practice
2. Thought-leader educational programmes, including the delivery of live scientific meetings such as advisory boards, satellite symposia and standalone meetings. This includes generating all the scientific content of the meeting (from slides to programme books).
3. Production of an extensive range of other educational materials for healthcare professionals including slide kits and monographs.



However, there are many other areas in which medical communication companies can and do provide support, for example they provide clients with marketing and strategic consultancy (e.g. development of product positioning and messages), develop e-solutions (e.g. web strategies and other tools using new technologies), and provide competitor intelligence to name a few. Essentially, any time that a pharmaceutical company wants to communicate about their products, then a medical communication company could have some role. An excellent careers guide available about medical communications can be found at the following link: <http://bit.ly/hOd0iQ>.

So how did I ultimately end up as a medical communications freelancer? Well, I started working for AstraZeneca during summer holidays at university doing mainly administrative work, but at the same time learning a little

***The huge amount of variation and ability to keep up to date with science is why after 15 years I am still passionate about medical communications***

about what the company did and why. Two of these summers were spent in the Global Medical Information Group in the company, which from day 1 struck me as being an interesting place to work. The group was focused on providing medical information about the company's drugs to healthcare professionals, which

involved writing Q&As, position pieces on particular issues and other documents. I was fortunate enough to gain a job in this group in 1996 after my BSc without the need to do a higher degree. I subsequently worked in the medical information department at Roche. In both these roles, I was required to provide information to internal teams or to healthcare professionals on a number of drugs in written and oral format. This taught me two very important lessons that have stayed with me throughout my career in medical writing/medical communications:

1. **Research skills and filtering key information about complex therapy areas.** The ability to quickly drill down to the key information about a drug or therapy area, without getting bogged down by unnecessary detail is of considerable importance to medical writers. Most writers do not work in the research area that they specialised in at university. For example, a microbiologist may be expected to write about oncology. We are often required to pick-up on a new drug or therapy area in a short time frame involving days or weeks.



## Freelance Medical Communications Consultant: “So what exactly does your job involve?”

- > **2. Attention to detail and scientific accuracy.** Ensuring scientific accuracy is of fundamental importance, and is perhaps one of the most important skills of a medical writer. In my medical information roles, it was essential for information sent to doctors and pharmacists to be accurate. Mistakes could have led to drugs being misused or worse still possible legal action. Similarly, in medical communications, mistakes could lead to drug companies getting into hot water with the FDA and other regulatory agencies, as well as earning the mistrust of healthcare professionals.

Ten years ago, I felt it was time for a new adventure and I began looking for a career offering plenty of variety, but which gave me the opportunity to do more of the thing that I enjoyed doing most: medical writing. After looking around, I felt that a career in medical communications was for me and I joined a large medical communications company in Cheshire as a medical writer. On a personal level, working for a relatively large company provided a number of benefits including:

- A clear career pathway
- A large variety of work in different areas
- Good mentorship and investment in training
- Robust, tried and tested procedures
- Plenty of like-minded people to share experiences and best practices
- Financial stability with less of a risk of redundancies

Each of these benefits may be of more or less interest to different people. For quite a number of prospective employees, the clear career pathway is particularly important and this is where medical communications can offer new recruits a great deal. The typical pathway for a writer entering “med comms” is as follows:

1. Associate Medical Writer
2. Medical Writer
3. Senior Medical Writer
4. Editorial Team Leader (for people wanting to take on management responsibilities) or Principal Writer (for people preferring to remain on the writing/delivery side)
5. Senior editorial management (e.g. Editorial Director, Editorial Unit Manager or Vice President Medical and Scientific Services)

As you become more experienced, and your career progresses you learn new skills and take on additional responsibilities. Typically these include reviewing the work of more junior writers, delivering scientific meetings without support of colleagues (e.g. satellite symposia), leading teams from an editorial perspective (i.e. becoming the main point of contact for clients), providing clients with strategic advice and recommendations, and even working on pitches to win new work for the agency. There is also the opportunity

to mentor more junior team members and take on line management responsibilities. All of this helps to ensure that the job remains varied and exciting. I was fortunate enough to progress throughout this career pathway.

A few years ago, I felt it was time for me to try working for myself as a freelance medical communications consultant. It certainly was not an easy decision as you have to prise yourself away from the benefits of being in employment (regular wage, holiday and sick pay, pension etc.) and grapple with the risks of whether you feel you will be able to get enough work to pay your bills. You also have to deal with the niggles of setting up book-keeping, finding yourself an accountant and marketing yourself—something that I think we scientists can struggle with. Another drawback for some people is that you lose the social element of working with and around other people. However, there are also many rewards. I guess the main one is that you are your own boss, and can generally decide what work you take on, your working hours and when you take holiday. In my case this flexibility is important as I have three young children and I definitely see them more now that I am freelance. Additionally, you can potentially earn more than you would within an agency if you are able to find regular clients.

I have been lucky enough to have gained relatively long-term contracts (each lasting 3-6 months) over the past 2 years with several companies, including directly with one pharmaceutical company. Aside from over Christmas, I can't think of a time that I have had 2 weeks off!

If I was to answer how I have been able to find and maintain work, my top three tips would be as follows:

1. **Don't become a freelancer too soon.** In my case, I had over 10 years of medical communications experience before I started working for myself. This means that I have a wide range of experience of working on different projects and therapy areas. It also means that I have considerable experience in providing strategic guidance and finding solutions to particular problems. This all helps you to be able to market yourself to would-be clients. Finally, and most importantly—the longer you have stayed within agencies, the more people you know. Being connected certainly helps to find work. A lot of getting work is about being connected, which brings me on to...
2. **Get connected and social network.** Most of the work that I gain is from people and companies I know already. However, I get contacted probably about once a week from other companies enquiring about my skills and availability. Almost certainly for me, most of this traffic comes via LinkedIn. If you are considering going freelance then putting your profile on LinkedIn is

*The longer you  
have stayed within  
agencies, the more  
people you know*

*Unless you can be  
found easily online  
you will almost  
certainly miss out  
on opportunities*

## Freelance Medical Communications Consultant: "So what exactly does your job involve?"



a 'must have'. You can find mine at: <http://uk.linkedin.com/in/ryanwoodrow1>. You can increase your profile on LinkedIn by joining appropriate groups (e.g. the EMWA group) and writing helpful replies/insights in response to questions. Twitter is also a great resource for getting your name recognised, as is blogging. As an example, I wrote an article on my own blog about the point of Twitter for medical writers, which can be found at: <http://bit.ly/fiI4UJ>. A freelance friend of mine also gains a considerable amount of work via Facebook (he has a page for his company). The point is that unless you make sure that you can be found easily online then you will almost certainly miss out on opportunities.

3. **Be seen as more than just a writer.** In my case, I work in close collaboration with agencies and am generally seen as one of the team internally and externally by pharmaceutical clients. As a consequence, my day-to-day work involves much more than medical writing. I help deliver meetings (e.g. advisory boards and symposia), review work, provide consultancy, as well as deliver slide kits, publications and other written materials. I appreciate that this may not appeal to everyone, but working as part of the team rather than as a traditional freelance writer (called on periodically when the agency is stretched) means that work is more constant and you are more valued. The best way to achieve this is to demonstrate to an agency that you may already be working for that you know the therapy area well, that you are a good writer and that you have the skills needed to operate as part of their team. If you are already freelance, try asking your existing client if you can become more involved in the team by attending team meetings, reviewing work, etc.

So, what's next after being a freelance medical communications consultant? Well I sometimes think about what I might be doing in 10 years time, and the truth is I can't imagine being in a different role. I thoroughly enjoy my job and the key to this is because no day is ever the same. Each day I am writing or communicating about something different, and in doing so I am learning about something new. Who needs more than that?

#### Ryan Woodrow

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## The politics of infectious names

Richard Horton, editor in chief of *The Lancet*, has apologised for the name New Delhi metallo beta lactamase-1 (NDM-1), which appeared in a report in *The Lancet Infectious Diseases* journal. NDM-1 is a gene carried by bacteria that makes the strain resistant to carbapenem antibiotics. The name New Delhi was given when it was identified in December 2009 in a Swedish national who returned to Sweden for treatment of an antibiotic-resistant bacterial infection following unsuccessful treatment in India. The study published in August 2010 in *The Lancet* was conducted by a multinational team and examined the emergence and spread of bacteria carrying the gene. Among other countries cases have also been diagnosed in the UK and Canada. India's medical fraternity were infuriated by the report in *The Lancet* because of potential damage to their growing medical tourism industry. They contend that there is no evidence that the gene originated in India and have defended the standards of treatment in Indian hospitals. Indian politicians have even suggested that "malicious propaganda" is involved. The lead author of *The Lancet* study, who is based in India, has said he does not concur with the advice given in the report that people should avoid having elective surgeries in India. However, Dr Samlee Plianbangchang, WHO's regional director in the area, has stated that the resistance of the bacteria to almost all antibiotics was "largely due to the incorrect use of medicines, including use for too short a time, too low a dose, inadequate potency or for a wrong disease". An editorial in the March 2010 issue of the *Journal of Association of Physicians of India* supports this view pointing a finger at the widespread misuse of antibiotics in the Indian healthcare system and lack of control of prescription of antibiotics by doctors.

The incident gave rise to discussion on the World Association of Medical Editor's listserver ([www.wame.com](http://www.wame.com)) including whether it is an editor's role or remit to censor science and discovery. One editor thought Richard Horton had done a disservice to the richness of medicine with his apology by "crumbling at the first hint of controversy", while others considered a superbug should not be named after the city/country in which it is presumed to originate. Should the Spanish flu of 1918 be renamed?

Sources: <http://bit.ly/eK9ThE>  
[http://en.wikipedia.org/wiki/New\\_Delhi\\_metallo-beta-lactamase](http://en.wikipedia.org/wiki/New_Delhi_metallo-beta-lactamase)

## How to spell a common word

Just in case you did not know:  
<http://www.d-e-f-i-n-i-t-e-l-y.com/>



## Is agency life for you?

by Miranda Dini

Pharmaceutical and medical device companies continue to develop new products to meet the need for new or improved ways of treating our ageing population. As a result, the need for effective communication of healthcare information—whether it aims to educate about diseases or products, and targets consumers, healthcare providers (HCPs), investors, payers or other stakeholder groups—continues to grow exponentially. And so, too, has the number of healthcare communications agencies established to serve this need. It's hard to put a finger on exactly how many healthcare communications agencies there are in the UK, let alone in Europe, but the last issue of *Communiqué*, a bi-annual industry guide, had 54 agencies listed.

Medical writing in a healthcare communications agency offers a unique set of benefits and challenges. Many people fall into agency life without having heard of it as a career option until they're interviewing for a role. A straw poll of the medical writers in my agency, AXON Communications, indicates that they heard about this career option from a variety of sources, including friends or family, adverts, recruiters, careers magazines, and a talk at university about careers away from the lab. Yet healthcare communications remains a bit of a black art to many—or at least a very challenging cocktail party conversation when trying to explain succinctly to friends what you do for a living!

Working at an agency allows you to leverage complementary skill sets relating to a love of the science, a desire to communicate effectively and an interest in creative problem-solving. It also requires an awareness and acceptance of the business and commercial aspects of the pharmaceutical/device industry, as well as working in a client-service environment. In an agency, meeting deadlines and delivering projects within budgets is almost as important as the quality of the deliverable itself—sometimes you have to submit a project before you would optimally want to. To some degree, all of these aspects may require a compromise in how you might otherwise deliver a project in a different (i.e. university) setting.

Healthcare agencies come in all shapes and sizes, but there is one consistent thread you can generally pull through all of them—a similar personality type chooses agency life:

- Fear of boredom/seeking variety
- Driven to learn
- Works best under pressure

So what does a career in a healthcare communications agency offer that other medical writing options may not? Diversity is probably at the heart of it. Diversity in the form of clients, types of projects, and roles and responsibilities. Most agency medical writers will have a variety of clients or 'accounts.' Depending on the agency's structure, the number of permanently assigned accounts can range from 0-6. This variety ensures that agency staff can have very diverse experiences relating to client relationships, account considerations (strategic, types of projects and audiences), and internal agency structures.

### Client relationships

One of the most exciting elements of working in an agency is becoming a trusted advisor to your clients. Individual clients provide different experiences and learnings you can take to another client. For example, some clients view their agency teams as partners and include them in strategic discussions and decisions, while others prefer to have their agencies in more of a tactical role, delivering quality work based on outlined specifications.

Some clients prefer to have direct interactions with physician experts or advocacy groups themselves, while others will delegate this to their agencies. Sometimes agency responsibilities will not be decided by the individual lead client, but by the client team, which can comprise a medical, marketing, clinical, communications, digital, market access, and market research expert, among (many) others.

Finally, each pharmaceutical company has a different set of parameters for their agencies to consider. This can relate to preferences for utilising digital vs traditional media, and whether the corporate culture is conservative or bold when it comes to communications, to name just a few.

This diversity in possible client relationships supports the understanding that there is no 'hard and fast' rule in advising your clients, but rather a host of considerations in offering valuable and pertinent advice.

***Agency work offers diversity in clients, client relationships, types of projects, and roles and responsibilities***

***The joy of agency work is that what is defined as 'medical writing' can mean a host of activities***



## Is agency life for you?

## Strategic communications

There are many strategic considerations when developing communications programmes with your clients. For example, some diseases are recognised as a significant health concern, so the focus may be on increasing awareness of recognising complications. Other diseases may require communications support to educate HCPs or consumers to recognise symptoms, or the benefits of early diagnosis or clinical interventions to slow progression. There will also be significantly different strategic considerations based on where a product is in its lifecycle (e.g. if it is launching in 2 years and the focus is on raising awareness of the need for this product in a specific indication, or if it has been available for 5 years and now needs to demonstrate long-term outcomes and relevance in other indications).

Medical writers can also be involved in strategic commercial decisions, such as effectively positioning the product through communications, as compared with its competitors and/or in consideration of the client's portfolio of products.

All of these strategic communications will be grounded in the science, based on accurate and timely reporting of data, in support of the Good Publication Practice, and in consideration of local and international regulatory guidelines.

## Types of projects

The joy of working in an agency is that what is defined as 'medical writing' can mean a host of activities. On any given day at my agency, for example, where we have an integrated offering of both medical education and public relations, a medical writer could be helping an author develop a primary publication for a highly regarded peer-reviewed publication; working with a lead investigator to develop slides for a medical congress; investigating and distilling for colleagues the mechanism of action of a new type of drug; writing a pamphlet for parents on what their children might expect from taking a medication; attending and writing a report from a meeting with an advisory panel of physicians; attending a strategy meeting with a client team and writing key messages about their product; developing a document to support responses to questions from the media; working with an advocacy group to develop a website to educate the public about the symptoms of a disease; writing a script that will be developed into a video about the importance of early diagnosis; developing a continuing educational programme for nurses; or conducting research to better understand what roles different HCPs play as part of a care team. While this list may seem incredibly varied, it is actually just the tip of the iceberg when it comes to the variety of activities that define the role of a medical writer.

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***An exciting element of working in an agency is becoming a trusted advisor to your clients***

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## Considering your audience

One of the most interesting aspects of medical writing at a healthcare communications agency is the opportunity to develop targeted communications for specific audiences. It is important to have an in-depth understanding of which type of HCP becomes involved at each stage of the diagnosis and/or treatment decision-tree for the product or disease/condition you are supporting (e.g. general practitioner, specialist, nurse, pharmacist), and what types of information will be most relevant to each. Layer on top of this how the style, tone and content of communication will need to vary for these different groups, as well as the preferred vehicle (medical congress, publication [online or print], educational initiative, press release, digital training, etc), and you have an intriguing set of questions to answer before you even start typing your first sentence.

There are other groups, as well. Consumers, which can encompass patients, caregivers or parents and children, are a growing audience who want accurate and understandable information. And payers have a completely different set of communications considerations.

## Considering which agency is right for you

Most of the aspects of healthcare communications outlined above will be relatively similar regardless of which agency you are working for. The commonalities are that you will have clients, accounts and audiences to consider. You'll also be part of a team, and collegiality is important. However, beyond that, your day-to-day role and your

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***Your day-to-day role and longer-term career path can vary widely by agency***

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longer-term career path can vary quite widely by agency. For example, some agencies will support predominately global accounts, which generally develop the strategy and framework for commu-

nications, which are then executed at a local country level. Others will specialise in local (country) or pan-European activities, which is often more tactical. An additional and growing area of expertise is in emerging markets, with agencies investing in gaining experience in communicating in markets where healthcare communications is a nascent area. Some agencies will specialise in one or a mix of these types of activities, while others will cross the entire spectrum.

Another consideration might be your interest in specific therapeutic categories. Some agencies have therapy area teams, where the writers are dedicated to investing significant time and energy into expertise in a single disease area—and then developing relationships with the leading physicians, and maintaining an in-depth knowledge of the related medical congresses and journals, hot topics, key studies, outcomes parameters, etc. At other agencies, medical writers might work across a variety of disease areas, which provides more variety and opportunities for learning, but simultaneously allows for less of a 'deep dive' into an area of expertise.

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## Is agency life for you?

- > Some agencies will have product teams, where medical writers work consistently alongside project managers and strategists to support their assigned accounts. Other agencies will instead have a pool of writers who are not dedicated, but instead support different accounts based on deadlines, expertise and staffing needs. Or, you may work at an agency where, as you gain seniority, you may support specific challenging projects or situations for a period of time and then move on.

Roles and responsibilities are another aspect to weigh; how do you want to spend your days, and what are your goals for your longer-term career path? Some agencies have a clearly defined split between medical writers and account handlers, which is appealing to individuals who want to concentrate on communicating the science effectively, while letting colleagues consider the how, when and why a project is delivered to the client. At AXON, staff can choose to be pure writers or split their time between medical writing and project managing if they wish. This means that not only are writers in direct contact with clients, they may also be involved in leading the internal account team, developing and managing budgets, or driving overall strategy for the account, if this is something that interests them. It's important to know what your preference is when looking at agencies.

## Final thoughts

Clearly there are numerous considerations when contemplating a medical writing career at a communications agency. If I could offer a few caveats, it would be to first ask yourself the following:

Do you believe that most of the following define you: dislike being bored, crave constant learning, work best under pressure, enjoy solving puzzles, and able to multi-task? Do you operate best on your own or as part of a team? Would an average day at work being described as 'fast-paced,' 'varied' and 'both challenging and rewarding' be something that appeals to or frightens you? Are you comfortable with something that is deadline-driven and not always a 9-5 job?

When looking at specific agencies, make sure you consider what types of projects motivate you. Once interviewing, ask about the training/coaching/mentoring and overall support you'll receive, and possible career paths.

And take my word for it, if you do choose this exciting career option, recognise that you may never be able to clearly elucidate what it is you do when questioned by friends, family or certainly customs after a long-haul flight!

### Miranda Dini

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### Definitions box

## Standard deviation and standard error

These two statistics often cause confusion. Standard deviation (often abbreviated to SD) is a statistic of dispersion—it describes the variability in a given data set—whereas the standard error is a statistic of precision—it describes the precision of the calculated sample parameter. The SD provides information about how much variation there is in a set of data (e.g. a sample drawn from a population). Although standard errors can be applied to a range of parameters (e.g. medians, proportions, odds ratios), they are most widely applied to the mean. In this circumstance the proper terminology is *standard error of the mean* (SEM). The SEM gives information about how accurate the mean you have calculated is.

The SD applies only to normally distributed values (i.e. Gaussian populations) and is defined as the root-mean-square of the differences between individual measures and the mean. It is really the average difference from the mean. Simply calculating the average difference will give a value of zero as there are as many negative differences (i.e. less than the mean) as there are positive differences. The minus signs disappear when the values are squared. So, to calculate the SD you determine the mean, then

work out how much each value differs from this mean. Square each of these, add the squared values up and divide by the number of values. This value is the variance. Take the square root of this and you have the SD.

Like the SD, the SEM also only applies to normally distributed values, although in certain circumstances that are beyond the scope of this article it is possible to use SEMs for non-normal data. If you repeatedly take small samples from a population (and here, 'population' means all the examples in the universe) and calculate the mean value of a particular property for each small sample ('sample mean'), you will find that these sample means differ. In fact, if the value you are measuring is normally distributed in the population, then the sample means of this value will also be normally distributed. The SEM is simply the SD of the sample means about the population mean. It is therefore critically dependent upon the number of measurements you make, which is one of the reasons why SEM should never be cited without a value for  $n$ . The SEM can in fact be calculated from a single sample of values taken from the population.

What is often forgotten is that confidence intervals (e.g. the commonly used 95% CI) are calculated from the SEM. The CI for a mean is the SEM multiplied by the  $t$ -value for the sample size and the percentage probability required. For  $n=5$ ,  $t$  is approximately 2.6 for  $p=0.05$  (i.e. 95%); when  $n$  is large ( $>25$ ),  $t$  is approximately 2.0.



## Becoming a managing editor

by Lucy Banham

How do you become a managing editor? I'm not quite there yet. I've been the deputy managing editor at the *BMJ* (*British Medical Journal*) for just over two years. I'm not sure it's every child's dream to do this job (I wanted to be a pop star), but if you enjoy communication and making things happen it provides plenty to get your teeth into.

As a young person I had a wide range of interests and wasn't sure what to do when I grew up. I did a combination of arts and science A levels to keep my options open. Up to the week of submitting my university application form I'd planned to do English or music, but at the last minute was persuaded that a science degree would be more practical. I think I caved because I thought a scientist would have a better chance of saving the world. I went to study biology at Manchester University, where a tutor helped me publish my first article in a science magazine.

***I was thrown in at the deep end, helping to set up a new journal almost from scratch***

On leaving university I was aghast at the idea of further study—I was desperate never to set foot in a lab again. But after a few months of freedom and pennilessness I realised my college advisers had been right: I now had the skills to get a job. I became a research scientist in a Manchester NHS hospital studying allergies. Writing and presenting reports on our work was a part of the job that I enjoyed at least as much as running the experiments. I wondered about a career in science communication, but it took a while before I was confident enough to take the plunge.

A move to London for personal reasons provided the impetus for change. I got a job as an assistant editor with an innovative medical publisher. I have to admit that I was initially slightly embarrassed to be abandoning my specialist skills to take on what I saw as basically 'just an office job'. I quickly realised I had a lot to learn. London office culture was very different to that of the laid back laboratory. It was a buzz to be around motivated people who took what they did seriously, but it took me a while to get used to the pace.

I was thrown in at the deep end, helping to set up a new journal almost from scratch. Suddenly I was expected to know how to commission, peer review, and edit articles, work to a bossy publication schedule, and operate a very complicated photocopier. I somehow survived this crash course in publishing for the very inexperienced, and after a year I became editor of another of the company's journals.

A lot of the copyediting was outsourced to freelancers, but luckily one of my managers was kind enough to teach me some of the basics. I realised this was something I enjoyed that came naturally. But I wasn't sure I could make a real job out of it—another manager advised me that copyediting was a dying art in the age of online publication.

That may be true, but luckily some publications—even online ones—still have standards. My next job was as an assistant editor at the *Lancet*, a medical journal so famous that even my parents had heard of it. I underwent a terrifying year of intense on-the-job training in which I learned to pick different types of articles apart into tiny pieces and put them back together better than before, in elegant plain English. Training as a copyeditor is pretty harsh because it's such a critical process; I emerged battered, but indelibly competent. I learned why house style is a good thing, even though it seemed to be there simply to make my life a misery. My understanding of healthcare and research also developed. Over the next five years my focus expanded from the minutiae of editing to the overall process of putting a journal together; I enjoyed figuring out changes, deputising for the managing editor, and training new staff.

Still deeply involved in music in my spare time, I eventually left the *Lancet* to study at London School of Sound while exploring the more flexible life of a freelance editor. Kindly contacts offered me some interesting opportunities, and I ended up with a contract critically appraising the latest medical evidence and working out how to apply it to an online

***You need to be decisive and responsible—although I admit it took me around a decade in the industry to feel that way***

guidance tool for doctors. Using my skills in a new context was great for my confidence and I learned a lot about clinical practice. But although I loved the flexibility of freelancing, I missed being in a lively team, the challenge of working on a weekly journal, the creative interplay with authors, and the chance to contribute directly to what was going on around me.

When I saw the advert for the job at the *BMJ* I knew the role was made for me. I still do a lot of editing, but also manage the team of technical editors, plan publication schedules, and generally get involved in all our processes. I like the fact that you have to know a little about what's going on in all the parts of the team and get them to synchronise. The



## Becoming a managing editor

- > *BMJ* publishes new content online every day as well as the weekly print journal, so I get to experience both new and traditional worlds.

Although it was a challenge to be the new girl among some very experienced people, I found that my knowledge from previous jobs was very transferable. I'm learning from senior colleagues about how to get the right content, how to implement journal policies, and how to do it all within budget. On some levels it can still be "just an office job", but I feel part of something that aims to change the world—so my degree wasn't chosen in vain after all.

I'd recommend this job for well rounded, organised individuals who enjoy working with people, solving problems, and having their fingers in lots of pies. A passion for communication and for medicine (or whatever subject you're dealing with) will get you through the day. You need to be decisive and responsible—although I admit it took me around a decade in the industry to feel that way. Adaptability and a curiosity about new media and technology will be an asset in most modern publishing environments.

You'll almost certainly need a degree to get started in medical publishing, but it needn't necessarily be in medicine or even science; studying publishing or business might well give you an advantage, but there don't seem to be any set rules. In some circles a PhD or medical degree will eventually help with career progression, in others it may render you 'overqualified' for junior editorial posts. But it's possible for a bright young person with little experience to get a publishing job that will give you the good all round training you need to become a managing editor. Mind you, you'd better not take my word for it; I'm not quite there yet.

### Lucy Banham

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## Editors might have their uses

Books are not what they used to be. According to an article in *The Guardian* about the 'lost art of editing' editors no longer advise authors on reworking a plot, character or tone and painstaking analysis of words and sentences have given way to straightforward plot recital [1]. The article opens with a report of Joanthan Franzen's discovery that the UK edition of his novel *Freedom* had a number of serious errors resulting in him urging his readers not to buy his book until the corrected edition became available. The article blames budgetary and staffing constraints, a shift towards large conglomerate publishers and a greater emphasis on sales and marketing for the lack of care in editing encountered in many books. It asks if the image of the word-obsessed editor poring over a manuscript, red pen in hand, has given way to that of the whizz-bang entrepreneur attuned to the market's latest caprice, more at home with a tweet than a metaphor. David Miller, a literary agent who still cares about standards, is quoted as suggesting that in a digital publishing world with more writers going direct to their audience publishers have failed miserably at explaining what it is that they do, most of which is intrinsically invisible. Bad editing is embarrassing but does it really matter if people are still buying books? Maybe it does. IBM has done a survey in which they found that edited versions of online marketing material received 30% more 'click-throughs' in the month than unedited versions [2].

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## Is it safe to criticise medical treatments in the media?

Last year we saw Simon Singh successfully defend a libel action brought against him in the UK for a critical article he wrote in *The Guardian* about chiropractic treatments [TWS 2010;19(2):104]. Now Astella Pharma claims articles published in the French medical journal *Prescrire* have damaged the reputation of its protopic ointment for treating eczema known as tacrolimus. Astella Pharma has brought a libel action against the journal. It seems the company also sued the FDA. Gagging medical journals that seek to further scientific discourse is the topic of discussion in <http://bit.ly/eC1eue>.



## Medical translation as a career

by Susanne Geercken

Here I was—proud translator for the German, English and Spanish language. It was the early 1990s and I had successfully completed the translation studies programme at the University of Heidelberg. In the course of my studies, I had not only refined my language skills but I had also gained in-depth knowledge in a number of subject areas including economics, international organisations and medicine. Thanks to numerous linguistics and translation theory classes, I knew how to use specific translation approaches for different types of texts and audiences. I had been taught to recognise culturally determined differences in communication patterns and had learned how to overcome them through appropriate translation strategies. And, maybe most importantly, I had acquired the ability to quickly master the terminology of different subject areas with the help of efficient research techniques. With all those valuable skills in my pocket, I felt eager to venture out and put them into practice.

***Every new drug brought new indications to learn about, new facts to assimilate, new terminology to master***

### Off to an exciting start

My first job as a translator was certainly a very exciting experience. Because one of my specialisations was in international organisations, I was accepted as a temporary translator for the terminology and German translation departments at the United Nations in New York. It was fascinating to be involved in the translation of texts like UN resolutions or UN inspection reports—instruments of political decision-making that made the daily news globally. And of course, commuting to downtown Manhattan each day, walking down 42<sup>nd</sup> Street and entering the famous UN tower to go to work felt absolutely thrilling. Little did I know that one of the office buildings on 42<sup>nd</sup> Street I walked by obviously each day would play an important role in my future professional life....

### First steps as a medical translator

Back in Germany, I learned from a friend that a pharmaceutical company named 'Pfizer' was looking for a medical translator for their German subsidiary in Karlsruhe. I have to admit that, at the time, Pfizer was not a company I had heard about much. Doing some research, I learned that Pfizer was a US-based multinational pharmaceutical company with headquarters in New York (on 42<sup>nd</sup> Street!).

I applied and was accepted as a full-time medical translator assigned to the Clinical Research Department.

It turned out to be a real stroke of luck for me to join Pfizer at this point in the company's development: in the early 1990s, the responsibilities of the Karlsruhe Clinical Research Department involved the full range of clinical trial activities—statistical planning and design, protocol generation, case report form (CRF) design, study management, monitoring, data capture, data management, coding, statistical analysis, final report, abstract, publication and manuscript writing. When I started my job with Pfizer, I was an ambitious, highly motivated, well-trained but inexperienced young translator. I was eager to learn and I was given ample opportunity to do so. The most important part of my job, at this time, was to translate locally developed (German) Pfizer study protocols, CRFs, study reports and publication manuscripts into English for headquarter review and documentation purposes. To successfully master the required translations, I had to acquire in-depth knowledge about clinical research processes including the relevant biometric methodology and terminology. In the context of

***Communication problems due to cultural differences are often identified too late in the text production process***

translating and editing abstracts and publication manuscripts, I learned how to write towards journal style guides and guidelines for authors. Even then, Pfizer was doing clinical research in many areas including infectious diseases, cardiology, pain, rheumatology, leukaemia, allergies. And with every new drug in the pipeline that moved into clinical testing, there were new indications for me to learn about, new facts to assimilate, new terminology to master.

Typically, translators, particularly if they are freelancers, work 'in isolation': they receive a text for translation, but they are unfamiliar with the 'bigger context'. I was fortunate that this was different in our setting: most of the texts I received for translation were produced in my own

**GERMAN  
ENGLISH**

## Medical translation as a career

- > company and often by my own colleagues. I was able to draw on these colleagues—clinicians, statisticians, data managers, monitors, CRF developers—to discuss any questions that came up in the translation process. As a rule, I was also familiar with the overall context of the texts I translated and could access most of the related documents and any existing similar translations. This helped me ensure that my translations used terminology consistently, were correct with regard to contents and tailored to the intended audience.

### Introducing translation memories

With the company growing and the translation volume expanding we looked for ways to economise on translation resources. In the translation industry, computer programs called ‘translation memory systems’ are commonly used to raise translation output. Translation memory systems basically work by collecting translation pairs (original text string and corresponding translation) into a large database. The database is filled as the translator types in the translation. With every new translation performed with the system, the computer searches the translation memory database upfront for identical or similar text strings in the original text and any corresponding translation. Matching translations in the system will be suggested to the translator for potential reuse. If necessary the translator then adapts the suggested solution appropriately. It should be stressed that this is not ‘automated translation’ since it is the translator who fills the database and who decides if and in what way the translations identified by the system will be used for the new text. One of the great advantages (and challenges) is that several translators can use the database, permitting shared knowledge and (ideally) consistency across translations.

It needs to be pointed out that the use of translation memories only makes sense when large volumes of reasonably similar texts are expected for translation. To ensure a high ‘recycling potential’, the texts need to be of comparable structure, contents, terminology and style. Moreover, they should preferably be available in an appropriate electronic format. Texts that are highly standardised (e.g. involving the use of templates or standard sections) are particularly suitable. Not surprisingly, when we used the translation memory system for the different text types that we translated within our setting, we found that CRFs and patient informed consent documents yielded the highest ‘translation reusability’ scores.

### Tackling the cultural aspects of medical translation

Those of you who have attended my EMWA workshops or read my TWS contributions [1, 2] will know that I am particularly intrigued by cultural issues. In my day-to-day



translation and editing routine, they take many shapes: I remember reviewing the German translation of a guidance document on physical activity for patients. The English original suggested that patients “get off the bus one bus stop earlier and walk home the rest of the way” (to get some physical exercise), adding that this should only be done “if the bus stop was in a safe area”. In a German context, the well-intended protective remark would come across as fairly odd and the reader would probably feel patronised. Another rather memorable task was the English-German translation of some diet recommendations. One of the text’s suggestions was that patients eat “half a cup of chopped carrots”. In the US, ‘cup’ is a commonly used measuring unit and measuring cups are customary household items. In Germany, we don’t use ‘cups’ as measuring units. Drinking cups, on the other hand, come in many sizes in our country and were therefore unsuitable for the required purpose of measuring. Hence, a simple translation wouldn’t do the job. In an attempt to find an appropriate German solution to the carrot measuring problem I went back to my kitchen (which was equipped with a self-imported US measuring cup and some equivalent German

measuring tools) and did a very practical comparative chopping, measuring and weighing exercise.

Another part of my job is reviewing the translation of patient questionnaires. Many

### *How should I find the most suitable set of translation providers for our specific situation?*

multicountry clinical trials, particularly in indications like pain, psychiatric and neurological diseases and also health economics, use questionnaires to collect information directly from the patient. This is commonly referred to as ‘patient reported outcomes (PRO)’. The questionnaires are typically developed in a specific language and for a specific culture (e.g. English for use in the US). Since the topics that are covered usually refer to the patients’ individual experiences in their day-to-day life, the questions are often highly culture-specific. Before the questionnaires can be used in multicountry studies, they need to be appropriately translated and culturally adapted (e.g. translated to German for Germany, German for Austria, Spanish for Spain and Portuguese for Brazil). To ensure comparability of the questions (and hence the data elicited by using them) across languages and cultures, highly controlled, multi-step translation processes are being used for PRO translations by specialised providers: typically, the process



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includes (but is not necessarily limited to) parallel translation to the target language, harmonisation of these translations, independent backtranslation to the original language and independent translation review. In addition, input on the suitability of the translation is often sought from a sample of the intended target group (e.g. German patients with diabetes) before finalisation.

Over the years, I realised that communication problems due to cultural differences are often identified too late in the text production process, and that some of the ensuing translation problems could have been avoided, had the authors of the original texts been more aware of potential cultural issues. Since medical writers frequently author texts written for a multicultural audience, I thought that it would be worthwhile to help raise awareness of cultural issues in the EMWA medical writing community. My early seminars on the subject and the more recent advanced workshop ‘Impact of language and culture on medical writing’ developed together with Alistair Reeves have offered an inspiring platform for discussion of these issues.

### Initiating internships for translators-to-be

Starting in 2001, I initiated regular summer internships for translation students in the clinical research department. With two universities running translation studies programmes located close to the Karlsruhe office we were able to recruit well-trained students who could quickly support us with all our day-to-day tasks. Working with interns inspired fresh thinking—when I tutored them on our processes, their questions often challenged me to re-think and improve our work-flows. The students, on the other hand, benefited from sound and dedicated tutoring and first-hand translation experience in a pharmaceutical company. The internship also helped the students decide about their future professional aspirations: while some successfully work as medical translators today, others have pursued different career options because they found that translating on the computer 8 hours a day was not what they wanted for their life.

### Ensuring translation quality for outsourced translations

When my job profile changed to include the additional tasks of documenting, maintaining and providing training for local working practices and processes I had to start outsourcing translations to external providers on a larger scale.

The professional translation market is basically shared by self-employed freelance translators and agencies. In the life sciences, CROs and medical writers also offer translation services. Some translation agencies employ a fixed pool of internal translators (with or without additionally outsourcing to a network of freelancers), others rely on freelance translators exclusively; some offer separate linguistic and/or expert checks, others argue that translation quality is ensured through the initial tight selection process

for their translators. Nowadays, large agencies are typically organised globally and offer translation services for many languages and subject areas.

In this diversified market, how should I find the most suitable set of translation providers for our specific situation? Just like any other business, the translation industry is driven by quality, speed and price. While it is relatively easy to compare and select providers on the basis of price and speed, ensuring acceptable quality is more complex. For the purpose of this article, I will therefore focus on some of my efforts to ensure translation quality for outsourced translations.

While it is obvious that the provider should offer the required languages and subject area expertise, I found that more subtle criteria like the flow of information can be equally important: How easy is it for the client to get requests or questions across to the translator and vice versa, and are they successfully addressed? This kind of interchange is not a problem when you work directly with freelance translators, but it can be an issue with agencies, who generally do not permit any direct contact between their clients and their translators. Here, the information flow will only run smoothly if the project manager who works at the interface has close working relationships with the translator and, beyond his or her project management skills, also understands ‘what translation is all about’.

To make sure that the translators / agencies understood our needs, I explicitly briefed them on our department’s tasks, the types of texts we typically outsource and the overall text production context: Why does this type of text need translation in our context? Who is the target audience? At what point in the overall text production cycle does translation come in?

### Helping external translators make educated translation decisions

Providing information on the overall context of a text that is submitted for translation will help translators make educated translation decisions: if a translation is geared directly at the end user (e.g. a dosing diary translated to be used by German patients) errors identified in the original in most cases should be remedied in the translation (and ideally also in the original). Therefore, the client needs to be alerted to these errors by the translator so that a solution can be found. In contrast, a ‘backtranslation’, which is needed to document the contents and wording of the original, must also document any error in the original. Here, the error will need to be translated as it stands (even though the translator might still add a comment pointing to the flawed original). As regards target audience, translating for lay people such as patients is different from translating for experts, and a translation that goes directly to the printer will need more attention to layout and formatting than a translation used in a first draft.

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- > Next, we defined a set of translation quality criteria tailored to our setting. To this end, we reviewed the translation errors that had occurred in the past and prioritised them by their 'potential to cause damage'. In our context, 'potential damage' could mean things like risk of misdosing due to a mistranslated unit, an audit finding due to inconsistent pagination or delayed release of study medication due to ambiguous translation of an ethics approval. The resulting list (which is updated regularly) is used within the overall quality review process to ensure that the most important mistakes are avoided. This has helped us render the review process more focused and objective. In addition, the list can also be made available to the translator upfront so as to make our quality criteria more transparent.

As most of you will know, reviewing and editing texts for quality assurance purposes can be quite demanding. This is also true for translations. In some ways, identifying and rectifying outright translation errors is the easy part—with sufficient language and subject area expertise on the part of the reviewer clear-cut decisions on right and wrong are not that much of a problem. Particularly in my earlier years, however, stylistic changes presented a challenge. There is a saying among translators that "only a translation you have done yourself can be a good translation". Hence, I had to discern very carefully: Did I want to correct a translation simply because I was proud to have found the perfect solution? Or was the change truly warranted because the audience would indeed find the wording inappropriate or difficult to understand? Today, with greater experience as a reviewer I find it easier to be 'gentle to the (translation) author'.

## Writing for the patient

For the past years I had been striving to increase the share of writing (as opposed to translation and process management) tasks in my day-to-day responsibilities. I was very happy to see this personal goal achieved with my recent appointment to 'subject matter expert' for German patient informed consent documents (ICDs) for clinical studies. This new role includes authoring German ICDs [2], coaching other ICD authors and serving as ICD reviewer. It also involves tailoring the ICD format to the needs of the patient, lately with a special focus on children and adolescents. To achieve this goal, we continue to involve patient representatives, a part of my role I find especially rewarding.

## Embracing future challenges

As you can imagine, medical translation and writing in a clinical research context comes with a high stress level, and juggling the different tasks outlined above can be quite demanding. But when I look back on more than 17 years of being a medical translator and writer, I am grateful for the many opportunities to learn and grow. My professional career has turned out to be very exciting and I certainly feel ready to embrace any new challenges that lie ahead.

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## Future of the pharma industry

Dr. Steve Nissen strongly advocated in an interview that drug companies which have nurtured massive sales forces for pushing their drugs need to downsize. Nissen is the chairman of cardiology at Cleveland Clinic in the US and the first clinician to link Vioxx with stroke as well as an adviser to several FDA committees. He was asked about the decline in licences for new drugs. Only 21 drug licences were granted by the FDA in the last 12 months, fewer than in any previous 12-month periods. In Nissen's opinion there are fewer opportunities for developing drugs because we already have good drugs and the drug block buster days are over for the pharma industry, which has picked all the low hanging fruit. Questioned as to whether he thought he had contributed to the decline in licences by his actions in the Vioxx case, he explained that because it is less easy to find new drugs those that are being developed have a less favourable benefit to risk ratio. Companies need to generate markets in other ways such as developing genetic markers because if "you don't invest in innovation you don't get it".

The interview can be heard at <http://wapo.st/gYi6b>



## Medical writing for the veterinary pharmaceutical industry—Specialists needed

by Susanne Goebel-Lauth

Have you ever thought about potential drug residues in edible tissues when you are writing your medical texts? No? Well, you have obviously not yet written clinical or regulatory documents for the animal health sector.

The term ‘pharmaceutical industry’ is mainly associated with the leading companies of the human pharmaceutical market. Hence, not only the medical devices industry [1] but also the animal health market are all too often forgotten. In Europe, the human pharmaceutical industry employed ~635,000 people in 2008 [2], but it should also be noted that more than 50,000 full-time jobs in Europe depend on the animal health industry [3]. Medical writing specifically for the veterinary pharmaceutical industry is, in my opinion, an underestimated niche.

Working as a veterinarian in Regulatory Affairs (RA) for one of the largest global animal health companies, I regularly have the experience that special aspects of our industry are not covered by RA conferences, congresses or seminars. Furthermore, it is very difficult to find experts familiar with the veterinary regulatory framework as well as the specialised terminology. Although the European regulatory framework for the development of veterinary and human medicinal products is quite similar in some aspects (e.g. the main EU Directives and Regulations), other areas differ markedly (e.g. the presentation and the content of registration dossiers, the guidelines for the conduct of clinical studies etc.).

**Experts in the  
veterinary field are  
difficult to find**

Veterinary registration dossiers are structured according to the so called “Notice to Applicants” format [4], not according to the CTD format. There are 4 parts of the dossier:

- Part 1: Administrative information and summary of the dossier
- Part 2: Quality documentation
- Part 3: Safety and residues documentation
- Part 4: Efficacy documentation

If the product is intended to be used for food-producing target animal species, part 3 is split into part 3A (safety documentation) and part 3B (residues documentation). Environmental safety plays a very important role in part 3A. An environmental risk assessment needs to be provided with each product application and ecotoxicity concerns can easily be a reason for the refusal of a registration.

Entirely electronic submissions (e-submissions) have recently become a new possibility in the veterinary sector. So far, registration dossiers have been submitted as paper copies. The e-submission can save a lot of money for the pharmaceutical company (costs for copying and shipment) and also a lot of space in the archive, where the full dossier was stored in the past. However, it might be worth mentioning that veterinary registration dossiers are not as large as human registration dossiers. Although for example owner consent has to be documented for each animal in the clinical field trials, not all the raw data go into the dossier.

In my field of work as a regulatory affairs manager, I have to produce a variety of texts. Similar to my colleagues in the human pharmaceutical market, the core responsibilities of a veterinarian RA manager include reviewing study protocols and final study reports prepared by other departments, preparing expert reports, compiling registration dossiers, and answering questions from regulatory bodies [5]. Part of the work is also the writing of concept texts for the product information literature (i.e. summary of product characteristics, label information and package leaflet) as they are included in the registration dossier.

The package leaflet is one of the most important pieces of work, although it is an often neglected text during the ‘hot phase’ of compiling a registration dossier near the submission date. The leaflet is the written information a veterinarian or an animal owner takes home with him

and it should give him all information about the correct administration, dosage and potential risks relevant for the product.

International companies face the problem that the product information literature included in the registration dossier needs to be prepared in English (at least for European registration procedures) and is then translated into the local language. The initial technical information needs to come from an expert on the specific product but this technical expert is not necessarily a linguistic expert, often not even an English native speaker. A lot of translation errors can therefore occur. Firstly during the preparation of the English concept texts (when the expert translates the information from his mother tongue into English) and secondly when the approved texts are translated from English into the official languages of the individual countries participating in the registration procedure.



## Medical writing for the veterinary pharmaceutical industry—specialists needed

- > The consequences of linguistic errors can be severe, not only in terms of target animal safety but also in terms of user safety, consumer safety or environmental safety. The funniest wording I came across was the following instruction for use on a bilingual packaging material (English/Spanish): “Use to pulverise cows”! Here, the Spanish verb *pulverizar* with the intended meaning of ‘spraying’ was translated with a false friend in English. The wording should have been: “Use as a spray on cattle”.

This example shows that the very special pharmaceutical forms and routes of administration can already pose a challenge when preparing texts for veterinary medicinal products. Spray washes, dip baths, teat dips, collars, ear tags, intraruminal medication etc. are usually unknown to writers without a veterinary background.

Also the target animal species have to be named correctly. Where it is enough in human medicine to differentiate between male and female human beings on the one hand and maybe adults and children on the other hand, the target animal species is a very important aspect for veterinary medicinal product. ‘Pigs’ can be, boars (male pig), sows (female pigs), gilts (young female pigs) or piglets and ‘cattle’ can be bulls, dairy cows (lactating cows), heifers (young cows that have not yet had a calf), or calves.

This also implies that the studies, especially the clinical field trials and the residue depletion studies, have to be performed with animals representing the breed, weight range and age of the intended target species for the product. If a

cattle product is for example intended to be used against a disease that is usually apparent in dairy cows, using calves in the residue depletion studies for edible tissues can hardly be justified. The target species, i.e. full grown dairy cattle, needs to be chosen for the study although calves would certainly be easier to handle and to accommodate during the study.

A prerequisite for naming dairy cows on the label of a product is that maximum residue levels for the active substance(s) have been set for milk, potential residues of the drug have been examined in milk and a withdrawal period has been calculated (i.e. the period between the last application of the product to the animal and the time point when the milk can be consumed). The same applies to meat and offal of cattle, horses, pigs, sheep and goats, where maximum residue levels have to be set for the individual edible tissues (usually muscle, fat, liver and kidney).

This example illustrates a very important difference between human and veterinary medicinal products: the focus on consumer safety for products intended for use in food-producing animals. As outlined above, a whole section in veterinary registration dossiers is dedicated to potential residues in food. Here, one problem for the medical writer is that there are very few dictionaries about this topic and standardised terms are sometimes not available.

I hope that I have been able to outline that even an experienced ‘broad-spectrum medical writer’ can meet a challenge when it comes to veterinary medicine. Not only the terminology has to be known but also the treatment methods have to be understood and specific consumer health legislation needs to be followed.

I personally feel the need for more communication and exchange between people writing texts for veterinary medicine. Non-native speakers of English should have more possibilities to discuss specific questions with native speakers and here not only with veterinarians but also with linguists.

I personally feel the need for more communication and exchange between people writing texts for veterinary medicine. Non-native speakers of English should have more possibilities to discuss specific questions with native speakers and here not only with veterinarians but also with linguists.

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## A tool for presenting statistics: The R project

The R project (<http://www.r-project.org/>) is a steep learning curve but worth the effort. The website explains that the project provides excellent tools for understanding and presenting well-designed publication-quality plots, including mathematical symbols and formulae where needed. R is a language and environment for statistical computing and graphics which is available as Free Software. It is a different implementation of S language, which is often the vehicle of choice for research in statistical methodology. It includes

- an effective data handling and storage facility,
- a suite of operators for calculations on arrays, in particular matrices,
- a large, coherent, integrated collection of intermediate tools for data analysis,
- graphical facilities for data analysis and display either on-screen or on hardcopy, and
- a well-developed, simple and effective programming language which includes conditionals, loops, user-defined recursive functions and input and output facilities.



## Medical writing and health outcomes

by Chris Carswell and Keith Evans



In recent times, one of the most significant events, in terms of medical communication and publication, has been the confluence of two separate, but increasingly interrelated trends. The first of these is the greater emphasis placed on measuring a greater variety of impacts upon patients and patient care rather than simply the efficacy of an intervention. The second is that as healthcare budgets have become ever more constrained, decision makers and payers have demanded increasing demonstration of the value of pharmaceutical products before they are willing to provide them and reimburse the seller. This has led to a growth in 'health outcomes', a term with no single definition that has gained widespread acceptance and is generally held to relate to those aspects of care which encompass concepts such as functionality in daily living, quality of life, compliance, adherence and cost [1,2].

This has naturally led to a corresponding increase in the levels of publications reporting topics which can be considered to be health outcomes as defined in the preceding paragraph. In the decades since 1950 the number of papers on Medline covering some aspect of health outcomes has roughly doubled every single decade, from 2,056 papers published in the period 1950-1960, to a current level of 343,695 papers published between 2000 and 2009. Whilst this is taking place against a background of steadily increasing levels of biomedical publication in general, in proportional terms the number of health outcomes papers as a percentage of all publications has risen from 2% in the 1980s to 5% in the nine years since 2000, representing an extremely high rate of growth. There would also appear to be no sign that this trend will continue to do anything other than follow an upward trajectory for the foreseeable future.

This impressive rise in output started out with the noblest of objectives, that of providing healthcare decision makers with valuable additional information upon which to base their decision-making about what healthcare intervention they should provide, and to whom they should provide it. However, the key question must be what impact this additional information is actually having upon decisions?

Perhaps surprisingly, given its relatively high profile, attempts to examine the use of this information by healthcare providers and decision makers have been few and far between. Initially it appeared that there were three main factors limiting the use of health outcomes publications and studies. Although not unique to health outcomes studies,

two concerned the presented data—reliability, i.e. the degree to which the results could be considered accurate, and free of bias, and transferability, i.e. the degree to which the results could be applied to other settings [3,4]. In attempting to overcome these two barriers, techniques were developed from other disciplines including mathematics and statistics. Yet, by adopting these increasingly complex methodologies, we have almost certainly compounded the third factor; which is that the very audiences we are trying to help do not actually understand the information that they are presented with.

The evidence for this lack of understanding is easily identified in research studies. One of the earliest published in 2002 [5] found that one of the principal complaints of the focus groups they interviewed was that authors needed to clarify and explain the use of terminology or jargon and they found that "...decision maker's knowledge of underlying health-economic concepts and methodology is often limited...consequently decision makers often feel insecure about interpreting economic results...". In 2008 another study [6] found that at a local level "Committee members demonstrated a limited capacity to access and interpret economic evaluations..." and one of their five conclusions was that there should be "more accessible forms of presentation of economic analyses".

What these two studies demonstrate is that, although published six years apart, the situation has really not changed at all, and that one of the major factors which needs to be addressed from a health outcomes perspective is how we present information to decision makers to enable them to actually incorporate it successfully into the decision-making process.

This lack of understanding brings us to the central thesis of this paper—which is that one of the solutions to this problem lies with medical writers. Initially, this might not seem the most obvious way of tackling the problem, and indeed it is not the only activity which should occur to improve understanding. However, it is one which can be tackled fairly quickly and bring benefits not only to the pharmaceutical industry and decision makers but also to medical writers, by giving them a wider range of skills and expertise and offering new career opportunities.

The vital role played by medical writers is suggested by the only study to date looking at the Outcomes Department of pharmaceutical companies. Whilst this study was

## Medical writing and health outcomes

- > conducted in 1998 and reported in 2001, there is no reason to assume that anything beyond the staffing levels and budgets reported have changed substantially since. In this study DiMasi and colleagues [7] surveyed the Outcomes Department heads of 31 pharmaceutical companies. Results showed that outsourcing of activities was extremely common, with 43% of companies outsourcing activity equivalent to >50% of their department budgets. Within this, the single most frequently outsourced activity was 'health outcomes publications/communications' with 50% of all such activities outsourced to suppliers.

This therefore emphasises the impact that medical writers can potentially have and the size of the opportunity that exists for medical writers if we can encourage them to seize it. One of the authors of this piece (CC) developed strong expertise in pharmacoeconomics and outcomes research whilst working as an in-house medical writer. Lack of company skills in the area, a high demand for such expertise, the realisation that such demand was only going to increase and a strong interest in the area were attractions to the field. Training was through distance learning and course attendance at the University of York and by attending regular meetings of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR). The author is now editor of *PharmacoEconomics*, a leading journal in the field, and is also a member of the leadership committee of the ISPOR task force on reporting guidelines for economic evaluations.

The reason we believe that medical writers have such an important role to play in advancing understanding in the health outcomes area is based upon the core ability they use in every form of communication activity. They are required to write in a manner which conveys information comprehensible to the level of understanding which the reader possesses, ranging from patients through to clinical experts, and also adapt how they present data and concepts in an appropriate manner. Perhaps the reason why clinical studies are generally better received than outcomes studies is that in many clinical studies medical writers bring their skill and perspective to bear when presenting the results, thereby improving the paper.

It is this fundamental ability of medical writers to write to the audience which we believe must now be applied to the field of health outcomes if we are to make any progress in the use of economic data by decision makers. However, this core ability must also be supplemented by an understanding of the basic techniques and methodologies that are used in the outcomes area if medical writers are to fully capitalise on this golden opportunity. It is not necessary to create medical writers who are capable of conducting research, designing studies and building models, but it is essential to have people who are willing and able to understand how and why we do what we do, and recognise what the pros and cons of each approach are. In so doing they

will be able to make such activities comprehensible to the audiences we need to reach.

To achieve this obviously requires a considerable investment, by medical writers and their employers (if they are not freelance) in order to acquire the necessary skills to allow them to specialise in the area of health outcomes. All the evidence suggests that the demand for such services is greater than ever, a recent report [8] suggests that spending by pharmaceutical companies on health outcomes activity is increasing by 21% in Europe and Canada, 8% in the US and 45% in emerging markets in this year alone. Furthermore, the UK government has recently signalled its intention to move towards value-based pricing. All this means that for medical writers there are multiple benefits to be achieved by such specialisation. First, they gain an increased skill set which would allow for tackling a greater variety of projects. Secondly this makes them more attractive to current and future employers and thirdly they are moving into an area where future growth seems highly likely in a time of economic uncertainty and perhaps adding an element of job/income security.

If this partnership can be encouraged to develop then there will be winners on all sides. For medical writers career development and opportunities are likely, for health outcomes specialists a golden opportunity is provided to reach their audiences and demonstrate the true value of their discipline in a manner in which they have conspicuously failed to do for the last 20 years. Perhaps most importantly of all, there is an opportunity to help healthcare decision makers reach difficult decisions on the allocation of scarce resources which will benefit everyone, since we are all ultimately consumers of healthcare.

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## Practical tips to help scientific researchers move out of the laboratory and into medical writing

by Phil Leventhal

Back when I was a biomedical PhD student in the early 1990s, professional scientific and medical writing hardly existed. Most professors and colleagues thought that professional scientific writing was a waste of a good scientist. So, like many scientists, I pressed on as a researcher, even though I wanted to do something else.

After some years of reflection, I realised that medical writing was the perfect career for someone like me—someone who loves learning, new challenges, and, above all, communicating science.

Now that I am a ‘real’ medical writer many people ask me how I managed to land that first medical writing job. My answer is that there are many creative ways, to get experience and present yourself as a qualified job candidate.

### Get as much practice writing and editing as you can

The first and most important thing is to practice writing as much as possible. Act as the main writer of your own research articles, and publish as much as you can. Also writing review articles and book chapters gives needed practice and confirmation of your writing skills. For example, if you are still working in an academic laboratory, help your advisor write invited reviews or book chapters. Most academic scientists are overloaded with work and will appreciate your help. Also, discuss with your advisor the possibility of writing your own review articles or book chapters. You may be able to help write grants, fellowships, patents, posters, and various applications. Whenever possible, edit and proofread for colleagues. Likewise, when possible, help your advisor or colleagues with their slides and oral presentations. This can add experience in scientific communication and can help you better understand how to present data.

One great way of obtaining writing experience and improving your writing skills is to edit someone else’s manuscripts. This can be done for colleagues in your institution. But more importantly, there are companies, especially in Asia, who hire scientists to edit manuscripts. Sometimes these editing opportunities can be found on the job sites for EMWA, the American Medical Writers Association, and the Council of Science Editors. In fact, manuscript editing is the most effective way to improve your writing skills and gain experience as a writer.

Volunteering is another great way to improve your writing and editing skills. Ideas include editing or writing articles for low-budget publications, professional societies, and charitable organisations. Also consider volunteering as a reviewer for a scientific journal.

Importantly, remember that writing is more than manuscripts and grants. Newspapers, magazines, and websites, for example, can provide opportunities to get your name in print. Many of these opportunities may not be paid, but they offer valuable experience and proof of your writing skills.

### Network with other professionals

Networking with other professionals will help you get writing opportunities. This means making sure that people know you are available to do their writing and editing or you are seeking full-time employment. Make sure you have professional-looking business cards available to give to anyone who might need your help. Also, consider placing advertisements for freelance services on Internet sites for EMWA, the American Medical Writers Association, or Council of Science Editors.

### Educate yourself about medical and scientific writing

Education is essential to becoming a better and more experienced writer. This includes not only medical writing but writing in general. Tom Lang’s recent *How to Write, Publish, and Present in the Health Sciences: A Guide for Clinicians and Laboratory Researchers* is a good example. Also, invest in copies of the American Medical Association *Manual of Style* and the Council of Biological Editors *Scientific Style and Format* and read them from cover to cover. Remember that these are guidelines and not laws, but they will teach you about standard format and style.

Professional meetings are excellent places to learn about medical writing. If you can, attend meetings such as the EMWA and Mediterranean Editors and Translators conferences. Take their writing and editing workshops. These workshops offer an opportunity to network and learn, and the courses look impressive on a c.v. Also, consider working towards the medical writing certificate offered by EMWA.

Science journalism, while not exactly the same as medical writing, is an area that can offer a chance to gain experience. Consider taking a course on journalism or science journalism. There are even some courses available online. They can improve and broaden your writing skills. For example, experience in science journalism can help you obtain work in medical education.

Finally, if you are lucky enough to have a good writer edit your work, use their feedback as a learning opportunity. Remember to keep an open mind and accept criticism. Receiving and listening to constructive criticism is an excellent way of improving your skills.

## Practical tips to help scientific researchers...

### > Reorganise your c.v.

Reorganise your c.v. to emphasise your writing experience. For example, before listing your research experience, summarise your writing experience. Highlight any organisations you belong to or volunteer for that are writing-related. Also, list your writing clients. In the publications section, be sure to include subsections for grants, patents, magazine and newspaper articles, web sites, and other writing projects you have done. Finally, most potential employers spend only a few seconds reading a c.v., so make sure that the information they need is easy to find.

### Prepare a professional 'bio'

Your dossier should also include a professional biography, also known as a 'bio'. A professional bio is a paragraph or two about yourself that is meant to quickly attract and inform potential clients or employers. It can be an add-on or even replace your c.v. on some cases. Focus your bio on your writing experience. Also include why you want to be a writer, something about your scientific background and areas of expertise, and maybe a little about your writing philosophy. But keep it concise and interesting. When applying for a job, send this professional bio along with your c.v. (Detailed instructions on constructing a good professional bio can be easily found on the Internet.)

### Prepare a portfolio of your writing

As you write, save copies of all your manuscripts, other writing and client testimonials. Insert your best samples along with a copy of your professional bio and c.v. into a binder to show to potential clients or employers. This will objectively show that you have the necessary experience. Make sure your c.v. and all writing samples are written well with perfect grammar and no spelling errors. (Do not leave your binder with the potential client or employer, although you may wish to give them copies of key articles.)

### Perfect your English language skills

Having good English skills will help enormously in getting your first medical writing job. Be sure to sharpen your grammar and writing skills by taking composition or writing courses and by reading books on writing and grammar. This is true even if you are a native English speaker or plan to principally write in a language other than English.

### Conclusion

For someone who enjoys communicating science more than working in the laboratory, medical writing is an excellent career choice. There are many practical things you can do to get the experience and knowledge you need for that first medical writing job. Hone your writing skills, get writing experience whenever and wherever you can, network, build a portfolio, and be well prepared for interviews and client meetings.

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## Are reports of randomised clinical trials suffering from a systematic failure to cite prior research?

We all know that the results of randomised, controlled clinical trials (RCTs) should be designed and interpreted according to prior research, but is this actually the case in the literature?

A recent article by Karen A. Robinson and Steven N. Goodman in the *Annals of Internal Medicine* [1] concludes that the answer is no; that reports of RCTs are suffering from a systematic failure to cite prior research. The authors set out to assess the extent to which reports of RCTs cite prior trials studying the same interventions. They made a systematic review of meta-analyses published in 2004 that combined 4 or more RCTs, and they measured the extent to which each report cited the 'eligible' RCTs that preceded it by more than 1 year. They identified 227 meta-analyses in which 1523 previous trials were cited. According to their criteria, they found that less than one quarter of the relevant reports were cited, representing less than one quarter of the participants enrolled in relevant trials. Also, in about half the cases, the articles cited none or only one previous RCT.

The authors were clearly shocked by their findings and pointed out that this could result in "ethically unjustifiable trials, wasted resources, incorrect conclusions, and unnecessary risks for trial participants." In an interview about the article in *The New York Times* [2], Dr. Goodman was quoted as saying, "As cynical as I am about such things, I didn't realise the situation was this bad."

The question is whether things are as bad as they say. The analysis depended on their subjective assessment of what they called 'eligible' RCTs, which were defined as "all RCTs in the cohort that were published more than 1 year before the citing RCT". This overlooks the possibility that the writers of the articles did not consider all of the eligible RCTs relevant. The *New York Times* article finds the same possible explanation, stating "One reason might be that investigators do not think many of the results from previous studies apply to theirs." Therefore, the interpretation of the results may suffer from interpretation bias and study design problems.

A deeper analysis is probably warranted using a more refined definition of 'eligible'. In the meantime, we medical writers should continue to invest the time to read and consider all relevant literature when writing scientific articles.

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# Clinical trial disclosure: Disclosed data under scrutiny and calls for further improvements in data transparency

by Kathy B. Thomas and Claudia Tesch de Oliveira



‘Clinical trial disclosure’ is a familiar term to those of us working on projects involving clinical trial protocols, clinical trial reports, or publications based on the results of clinical trials. It is a term that stands for recently introduced requirements with the aim of greater transparency in drug development. Regardless of sponsor type (e.g. industry, academic institutions, or government), details of trial protocols (registration of a *new* studies—other than Phase I) and results of *completed* studies (results disclosure) must be made available on a publicly accessible Internet site. This has major implications for clinical trials performed with new as well as established pharmaceutical products (drugs, biologics, and devices). In two previous articles on this topic published in *TWS* we have described the development, legislative involvement, processes affecting the stakeholders, and the potential implications of these processes on other interrelated activities encountered during the development of new interventions or clinical indications and later during the life-cycle of approved products [1, 2]. The aim of this article is to briefly summarise the important events of ‘clinical trial disclosure’, indicate the next steps, and draw attention to calls for an even greater level of transparency than what is being witnessed so far, in an effort to overcome the reporting bias of clinical trial data.

Of the many events that contributed to establishing and forcing the ‘clinical trial disclosure’, the following are worth noting:

- Action of New York State attorney general who sued a large pharmaceutical company for failing to publish the negative results of a trial drug in paediatric patients [3, 4].
- Announcement by the International Committee of Medical Journal Editors (ICMJE) who set strict and unprecedented conditions regarding registration of clinical trials in a publicly accessible database as a condition for publication [5-7].
- Enactment of a new law (Food and Drug Administration Amendments Act of 2007—FDAAA 801), which mandates the registration of *new* clinical studies (other than Phase I) as well as disclosure of results for *completed* studies with pharmaceutical products (drugs, biologics, and devices) that have been approved by the FDA [8-10]. The FDAAA contains provisions for civil monetary penalties that can be imposed for noncompliance. The law requires the posting of serious and

frequent adverse-event tables, has the possibility for a future enhancement of the results database to include lay as well as technical summaries of study results, and the posting of trial results for unapproved drugs.

- Passing of the Clinical Trials Directive and the ensuing regulations in the European Union regarding public access to information on clinical trials in the European Community. The regulations describe how and which information from trial protocols and clinical trial reports will enter the EudraCT database and be released to the public through the EudraPharm database, which is coordinated by the European Medicines Agency [11-13].
- Establishment of international and national registers for information disclosure on clinical trials [14-19], of which [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) is the most frequently used site [20].

One of the main reasons for the legislative requirement of public disclosure of clinical trial information was the loss of public trust in the clinical research community. Particularly the pharmaceutical industry came under scrutiny around 2004, after a series of allegations focusing on selective reporting of clinical trial data by the pharmaceutical industry [3, 21, 22]. Especially notable were some instances in which sponsors disclosed positive results from clinical trials while leaving out the negative results. This was seen as misleading contributions to the medical community, involving a clear reporting bias that could have serious impact on the interpretation of data, both at the individual study level and for data sets in meta-analyses on published studies [4, 23-27].

Published data from individual clinical trials have been the main source of information for systematic reviews and meta-analyses which integrate large amounts of data to inform medical practice and form an essential part for decision makers when advising on treatment. The validity of a meta-analysis depends on study design and conduct considerations, including the identification, selection, and heterogeneity of the results of individual studies as well as the availability of data and the statistical approach. Completeness of information is a hallmark of a high-quality meta-analysis. Exclusion or unavailability of relevant studies may call into question the validity of the results. Such reporting bias has long been the single biggest criticism of meta-analyses and is likely to have a major impact on the results of meta-analyses of published studies [25-29], >



## Clinical trial disclosure

- > leading to overestimation of efficacy and underestimation safety risks [30]. This was aptly illustrated in a recent review article on ‘reporting bias in medical research’, in which 40 clinical indications and their treatment modalities were identified as incomplete and affected by reporting bias. In many of these reports, study data were withheld by sponsors and regulatory agencies; in others, information was actively suppressed—either by substantially delaying publication or not publishing at all [30].

In a recent editorial in the *BMJ* (2011) on reporting bias, An-Wen Chan succinctly comments on the importance of being able to access *all* data from clinical trials to adequately decide on the value or harm of an intervention so as to stop the perpetuation of partially informed decision-making and potentially compromising patient care [31]. To illustrate his point, Chan used two thematically related publications that both describe difficulties encountered when the authors tried to obtain voluntary information from sponsors and trialists.

- **Publication by Jefferson and colleagues (2011)** [32]  
While preparing an update of the Cochrane review on neuraminidase inhibitors for influenza in 2009, the authors realised that the evidence underlying the conclusion in the previous review (in 2006) on the same topic was based on a single paper—a manufacturer-funded meta-analysis of 10 manufacturer trials, of which only two had been published in the peer-reviewed literature. Interaction with the manufacturer revealed inconsistencies between the raw data (provided by the manufacturer as sections of the clinical trial reports) and the original publications of the data. In the publication, the information on safety data was missing. As a result of their experience during the preparation of the 2009 review, the authors did not include the data from unpublished trials and concluded that the ability of the drug to reduce complications was unknown. The authors stated: “*If published studies are incomplete and do not report important outcomes, the current process for conducting systematic reviews is not sufficiently rigorous, and in some cases it risks turning into unsolicited authoritative advertising for the drug industry. In other words, we need access to all unpublished data, even of trials published in the peer-reviewed literature*” [32].
- **Publication by Smyth et al. (2011)** [33]  
The authors report on the results of comparing trial protocols with subsequent publication(s) to identify any discrepancies in the outcomes reported. This was substantiated with a summary of telephone interviews conducted with the respective trialists to investigate more extensively the reporting of the research and the issue of unreported outcomes [33]. The results identified 268 trials for inclusion (from Cochrane systematic reviews and from PubMed). Initially, 161 respective investigators responded to requests for interviews, 130 (81%) of whom agreed to be interviewed.

However, failure to achieve contact, obtain a copy of the study protocol, or both meant that final interviews were conducted with 59 (37%) of the 161 trialists. The results of the evaluation showed that investigators of 16 trials failed to report analysed outcomes at the time of the primary publication, 17 trialists collected outcome data that were subsequently not analysed, and 5 trialists did not measure a pre-specified outcome over the course of the trial. In almost all trials in which pre-specified outcomes had been analysed they were not reported (15/16, 94%), and such underreporting led to biased information being published. In nearly a quarter of trials in which pre-specified outcomes had been measured they were not analysed (4/17, 24%), the ‘direction’ of the main findings influenced the investigators’ decision not to analyse the remaining data collected. In 14 (67%) of the 21 randomly selected PubMed trials, there was at least one unreported efficacy or harm outcome. More than a quarter (6/21, 29%) of these trials displayed outcome reporting bias. The authors stated: “*The prevalence of incomplete outcome reporting is high. Trialists seemed generally unaware of the implications for the evidence base of not reporting all outcomes and protocol changes. A general lack of consensus regarding the choice of outcomes in particular clinical settings was evident and affects trial design, conduct, analysis, and reporting*” [33].

In his editorial, Chan calls upon the stakeholders involved in disseminating and using medical knowledge, including journal editors, funding agencies, research ethics committees, those involved in the preparation of treatment guidelines, and those influencing health policies, to require public access to full study protocols and their amendments as well as to anonymised raw datasets from the completed studies [31]. Such appeals for further information go well beyond what is currently required through the legislative procedures on clinical trial disclosure or through the demands of the ICMJE. Nevertheless, the message has been heard, as is evident from the recent statement by the editor of *BMJ* Fiona Godlee: “*The raw data from trials must be made freely available. Journals clearly have a role to play in making this happen. ...The International Committee of Medical Journal Editors meets during the early part of 2011. This topic will be on the agenda*” [34].

Going even a step further than Chan, are the clear recommendations for legally binding transparency rules on the availability of data from clinical studies, concerning i) extension of the FDAAA 801, to include drugs for which approval was declined, ii) provide public access to regulatory databases containing trials of older drugs, not covered by current law, iii) allow for greater data sharing between regulatory authorities, as well as re-evaluation of a drug if approval is declined elsewhere, iv) pass legal obligation for manufacturers to provide all requested data to health technology assessment bodies without commercial

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restrictions to publication [25-27, 35-37]. Several of these goals could be achieved as part of the 'rule making' of the FDAAA 801 law, [9, 10] and the current activities of the EudraPharm [35, 36], both expected to be announced during 2011. Whichever way the demands for greater data transparency of data from clinical trials is pursued, the goals are the same—to improve the quality and reliability of clinical research.

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**Affiliations/Competing interests**

Kathy B. Thomas, PhD, is an independent medical and scientific writer working on various projects from her office in Meersburg on Lake Constance, Germany.

Claudia Tesch de Oliveira is an employee of Nycomed Deutschland GmbH, located in Konstanz, Germany.

Both authors are well versed in coordinating entries for registers (new clinical trials and results of completed trials) applicable to *clinical trial disclosure*. Both have presented the topic and actively participate in professional international working groups dealing with this topic.

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**Writer's block**

Those suffering from writer's block need not despair. Their articles might still be accepted for publication. Indeed they can take comfort that a reviewer of one such paper was moved in the spirit of a remark by Mark Twain, "I am sorry I wrote such a long letter, I did not have time to write a shorter one", to salute the authors for the time they took to prepare their lovely little paper.

Source: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2078566/>



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## Fashion in medicine and language: Inferences from titles and abstracts of articles listed in PubMed

by Neville W Goodman

*It is obvious that the title words of medical articles will indicate current fashions in medical research, but the prevalence of many title words is increasing, while the prevalence of a few is decreasing. Titles are certainly getting longer, and some changes in prevalence reflect changes in general English usage, but others are more of a puzzle: why should 'likely' be eight times as common a title word in 2005-09 as in 1970-74?*

In a previous article, I showed how the titles of medical articles written in English are becoming increasingly aggressive. Writers, or editors, prefer 'novel' to 'new', and favour third person singulars that allow soundbite titles; they are choosing longer words, and the use of metaphor is increasing [1]. Presumably, for good or ill and whether mistaken or not, these tactics are intended to get articles better noticed.

Using the same methods [1], I searched PubMed on many other title words in five-year periods from 1970, and also looked in abstracts, to explore changing fashions both in medicine and in the use of English.

### Medical fashion: From vagotomy to stem cells

In 1970, the treatment of gastric and duodenal ulcers was often surgical, but is now mainly medical. In 1970-74, there were 559 article titles containing 'vagotomy', the

main surgical approach, but only 77 in 2005-09. When corrected for the overall increase in the number of articles, and then scaled to the total for 1970-74, this is a 30-fold decrease. If the search is restricted to human studies, the decrease is even greater. While vagotomy has waned, laparoscopy as a surgical technique has waxed. There were 97 articles with 'laparoscopic' in the title in 1970-74. The total number, but not the relative number, increased between then and the late 80s, after which 'laparoscopic' took off as a title word, and there was a 23-fold increase by 2005-09.

Physiology, and with it much of the thrust of medical innovation (though the thrust is still largely theoretical), has moved from the systems physiology of the 60s and 70s to the molecular physiology of today. 'Gene', 'receptor', and 'stem cell' were all there in the titles of 1970-74, but all were more prevalent in 2005-09. The absolute number of titles for all three is increasing; but the relative number containing 'gene' or 'receptor', or their plurals, peaked in 1995-99 while 'stem cell' is still rising (Fig. 1). Titles of articles also show how the science is cross-fertilising. There were a few titles in 1970-74 that contained 'gene' and 'receptor', or 'gene' and 'stem cell'. In 2005-09 there were 5755 titles containing 'gene' and 'receptor', but the relative peak, as with the individual words, had been in 1995-99. Though so far there have been fewer titles containing

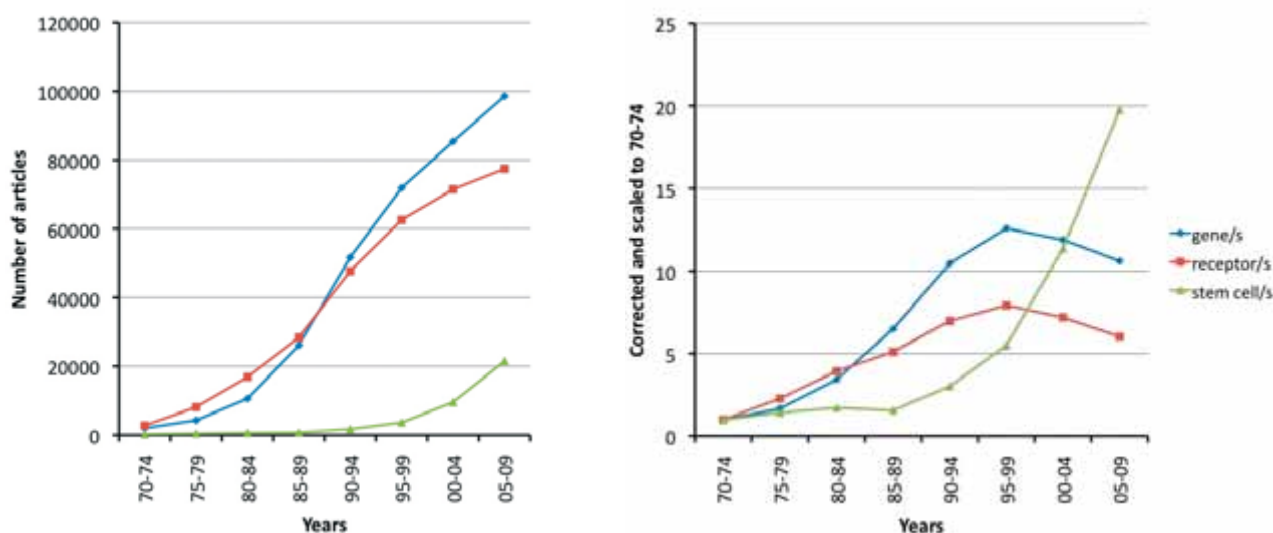


Figure 1 Left: the number of PubMed article titles containing the words shown, by five-year periods. Right: corrected for total number of articles published, and then scaled to the 1970-74 value.

## Fashion in medicine and language

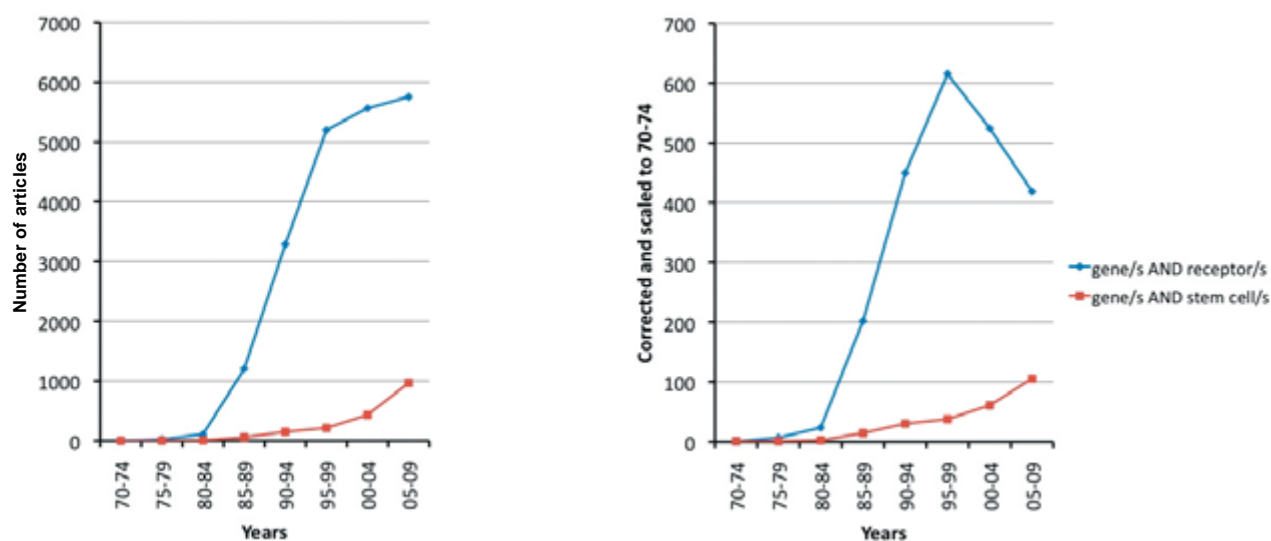


Figure 2 Left: the number of PubMed article titles containing the words shown, by five-year periods. Right: corrected for total number of articles published, and then scaled to the 1970-74 value.

> ‘gene’ and ‘stem cell’, the prevalence of the combination is increasing (Fig. 2).

I do not know which research-linked title word is increasing more than any other at the moment; it would mean trying to guess the most fashionable research. ‘Toll-like’ receptors—important in immune responses—must be a candidate. The first description in 1994 (which, probably deservedly, included ‘novel’ in the title [1]) was followed by 22 in 1995-1999, 1144 in 2000-04, and 3046 in 2005-09 (which is a twofold relative increase on 2000-04).

### Society and culture

There are also social and cultural influences. ‘Multidisciplinary’ has increased fourfold; ‘interdisciplinary’ has increased twofold, but there are many words that have increased by that amount and more without any obvious explanation (see below). ‘Multicultural’ appeared in 1959, but not again until 1974. It reached a 40-fold peak in 1995-99, and has declined somewhat since then. ‘Pathway’ gives useful insight because biochemical pathways are an old idea. If the search is limited to animal studies, ‘pathway’ has increased 3.6-fold; for human studies, ‘pathway’ has increased over 11-fold. In 1970-74 there were three times as many animal ‘pathways’ as human ones; in 2005-09, human ‘pathways’ were more common. ‘Journey’ increased twofold between 1970-74 and 1990-94, but by 2005-09 had increased nearly sevenfold. The title phrase ‘patient journey’ first appeared in 2003; although there are only 24 in total, seven were in 2009. ‘Cancer journey’ appeared in 1994; there were two in 2000-04, and seven in 2005-09.

The increasing emphasis on organisation and accountability in medicine is reflected by the sixfold increase of ‘quality’ as a title word, but oddly ‘leadership’ has increased only 1.5-fold. While ‘health’ and ‘care’ have both increased about twofold (and are common title words: ‘health’ was a title word in 2% and ‘care’ in 1.6% of all

articles in 2005-09), ‘healthcare’—coined in a description of health insurance in the United States in 1971—has burgeoned. Relatively, the total of 5710 articles in 2005-09 was 35% up on 2000-04.

### Not just evidence-based

There can be few more fashionable aspects of medicine than evidence-based medicine. The number of titles containing both ‘evidence’ and ‘based’ did not change much between 1970-74 and 1985-89. There was about a threefold increase in 1990-94, which was when the term was coined, and a nearly 90-fold increase by 2005-09. The number of titles containing ‘evidence’ but not ‘based’ has fluctuated over the years, but never to more than 1.6-fold its 1970-74 prevalence.

Then I discovered something that reflects not medicine (with a capital M), but the more general use of English. I found that ‘based’ as a title word had increased 15-fold. But whereas titles containing ‘based on’ had increased fivefold, titles containing ‘based’—but not as ‘based on’—had increased 36-fold. This turned out partly to be because of the increasing use of compound adjectives (in the way that ‘evidence-based’ is a compound adjective describing ‘medicine’).

Where might medical research be based? I thought of four *sites* (‘home’, ‘community’, ‘clinic’, and ‘hospital’), and research could also be ‘population-based’. Averaged, there has been no change in the prevalence of a *site*-word as a title word, although there are some differences between them; but there has been a 2.3-fold increase for ‘population’. Meanwhile, the prevalence of the compound adjectives (‘*site*-based’) has increased 12-fold in a nearly perfectly linear increase (see below). There has been an enormous increase in ‘population-based’: just three titles in 1970-74, to nearly 6000 in 2005-9, a 1.5-fold increase on 2000-04.

## Fashion in medicine and language

While not as popular as ‘-based’, ‘-making’ has increased fourfold, ‘decision-making’ particularly, which has increased nearly sevenfold. But then I had a surprise. It had seemed to me that the simple ‘drinks containing alcohol’ was becoming replaced by the compound ‘alcohol-containing drinks’, but ‘-containing’ was little altered by 2005-09.

### Impacted effect

Are any other changes in English usage discoverable through the titles of medical articles? Style guides have generally preferred ‘effect’ to ‘impact’ and ‘affects’ to ‘impacts on’; my impression is that the guides are ignored. The numbers bear this out.

‘Effect’ (singular) is a common title word, in 2.4% of all titles in 2005-09. But it was in 4.4% of all titles in 1970-74, when there were 53 titles containing ‘effect’ to each one containing ‘impact’. The ratio in 2005-09 was 2.6. The prevalence of ‘effect’ has decreased to 0.5-fold and ‘effects’ to 0.8-fold. ‘Impact’ has increased 11-fold, and ‘impacts’ 71-fold. These words can be both noun and verb, so I scanned the list of titles containing ‘impacts’. The plural noun ‘impacts’, replacing the preferred ‘effects’, has increased 60-fold; the verb appeared in only four titles in the twenty years from 1970-1989, but 372 in 2005-09, up from 95 in 2000-04. (‘Affects’, which can be a plural noun but is almost always the third personal singular verb, has increased 11-fold. I think that this is driven by the increasing preference of writers for active verbs [1], and that in time they will come to favour ‘impacts on’.) The past participle ‘impacted’ has increased fivefold (discounting its proper use in the titles of papers in dentistry, where it has decreased to 0.6-fold); ‘affected’ has increased twofold. The affected-to-impacted ratio has decreased from 22 to 8.

This general shift from ‘effect/affect’ to ‘impact’ has also occurred in the words used in abstracts searchable in PubMed, but strikingly the use of ‘impacted’ has increased 17-fold while the use of ‘affected’ has altered little.

### Beyond the neutral

What of ‘prior to’, generally disliked as a substitute for ‘before’? Unfortunately, ‘before’ is a *stopword*, which PubMed will not search. Both ‘prior’ (adjective) and ‘prior to’ (prepositional phrase) have increased twofold, but I cannot know what has happened to ‘before’. Here I discovered something odd. Many short, common words are stopwords, and I wondered if that were so for all prepositions: it is not, and the prevalence of prepositions in titles is increasing. Over 5% of all titles in 2005-09 contained at least one of ‘following’, ‘beneath’, ‘under’, ‘after’, ‘across’, ‘against’, ‘over’, ‘along’ and ‘beyond’. On average, there has been a 1.6-fold increase.

The average length of titles is increasing. Extrapolating from Lewison and Hartley [2] gives a 1.25-fold increase between 1970-74 and 2005-09. This is not very different from the figure of 1.6 for the prepositions, but the increase

is far from uniform. ‘Following’ has not increased at all; ‘beneath’, ‘under’, ‘after’, ‘across’ and ‘against’ have increased between one- and twofold; ‘over’ and ‘along’ have increased threefold; and ‘beyond’ has increased 12-fold.

These changes in prevalence of prepositions in titles were not so in abstracts: the average prevalence did not alter, and only ‘across’, up to 2.7-fold, and ‘beneath’, down to 0.6-fold, showed consistent change. ‘Beyond’ was still at unity in 1990-94, but has increased modestly since to 1.5-fold.

I started to look at words that I expected to be ‘neutral’, i.e., for which I expected the prevalence to be the same in 2005-09 as in 1970-74. For the words that follow, brackets indicate the change in prevalence; unity indicates there was no trend.

First of all, some general words (and their plurals) used in research papers: ‘system’, ‘material’, ‘response’, and ‘measurement’ showed no trend; ‘position’ (1.3), ‘technical’ (1.3) and ‘analysis’ (2.3) increased; ‘method’ (0.8) and ‘technique’ (0.75) decreased. Of possible subjects of research, all except ‘tissue’ (0.7) increased: ‘disease’ (1.3), ‘syndrome’ (1.5), ‘therapy’ (2), ‘patient’ (2.5), ‘symptom’ (4), and ‘people’ (4). ‘Medical’ (0.7) showed a regular decrease, but the singular ‘medicine’ (1.2) increased slightly. ‘Surgery’ (1.6) showed a regular increase but not ‘surgical’ (1).

I looked at some words of time and frequency: normal (0.4) but normally (1); abnormal and abnormally (0.7); recent and unusual (1); early and late (1.5); previously (1.9) and previous (2.2); common (1.8) but uncommon (2.5); only (3).

For some of these words, the change in prevalence over the studied 40 year-period was surprisingly linear (Fig. 3).

My final observation is four unconnected words, which also showed steadily increasing prevalence between 1970-74 and 2005-09: ‘distance’ (2), ‘otherwise’ 2.4, ‘better’ (4) >

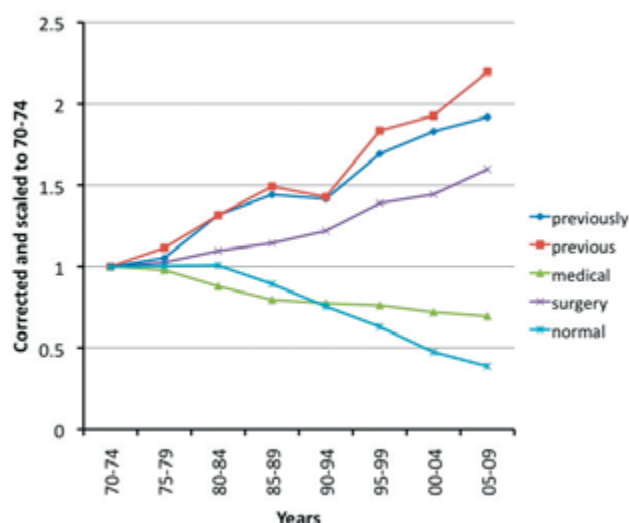


Figure 3 The prevalence in PubMed article titles of five words that showed consistent change in prevalence between 1970 and 2009 (in five-year periods). Data corrected for total number of articles published, and then scaled to the 1970-74 value.



## Fashion in medicine and language

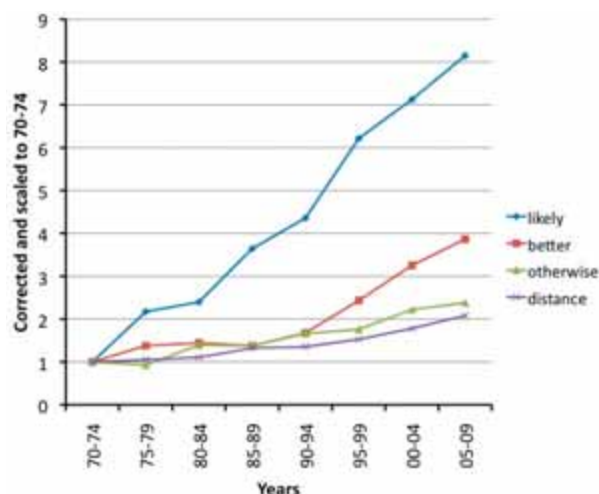


Figure 4 Answers on a postcard, please: why has the prevalence of these four title words increased more or less linearly between 1970-74 and 2004-09? (Data presented as in Figure 5.)

- > and 'likely' (8) (Fig. 4). All the lines are pretty straight, but the one for 'likely' is especially so: linear regression gives a correlation coefficient ( $r$ ) of 0.99 with a probability ( $p$ ) of 0.00003. The line for 'site-based' (see above; not illustrated) was  $r = 0.993$ ,  $p = 0.00001$ . Medical researchers would die for such a relation.

### What to make of this?

There is general advice on titles in many books about scientific style, but very little on the words used or the best structure. Hartley gives a catalogue of types [3], and has looked especially at colons in titles [2,4]. Soler [5] is concerned about the structure of medical titles and how to translate them, and gives some references to the little published work. (I note with dismay that her reference 9 is to a short editorial comment on a paper of mine, but that my paper is not cited.) Goodman [6] [no relation] is concerned that most titles lack information about study design, methods and results. Unlike in my previous article [1], which was largely a cry from the soul, I am now being more descriptive, and to some extent I am asking the question: how to explain all this?

It is no surprise that title words follow medical fashion. The prevalence of particular title words is a bibliometric measure, and such things are looked at by grant-giving and tenure-awarding bodies. I suspect that the increasing prevalence of 'stem cell' in titles is itself a measure of what those bodies are doing rather than necessarily what they should be doing. Some of the words reflecting societal and cultural influences in medicine are possibly attractive to authors as metaphor [1], e.g., 'pathway', and, particularly, 'journey', though there is danger of these (as with all metaphors) descending into cliché.

I am not aware that anyone has recorded an increasing general preference for compound adjectives (putting "compound adjectives" into Google produced a lot of stuff about hyphens, but no data), but undoubtedly medical authors are using '-based' and '-making' increasingly. This is unlikely to be contagion from evidence-based medicine because that term was coined in the 90s and the increase

has been consistent from 1970-74 to 2005-09. Perhaps this is the first observation from medical writing of a general change in English usage?

And has anyone yet documented an increasing use of impact, both as noun and verb? Burchfield [7] wrote of 'impact' for 'effect' that "the wave of hostility [in the mid-20C] has now receded, and all the more so as no permanent damage can be shown to have been done to the words that, for a time, it seemed to threaten". I reckon that an effect-to-impact ratio that has decreased 20-fold in 40 years shows that 'effect' is indeed under threat. Of the verb he is less forgiving: "It ... seems advisable to refrain from using the verb in ordinary ... non-medical contexts"—and the uses I have documented are ordinary—but he surmises that "it will pass into uncontested standard use as time goes on". That time has come, but I do not like it: 'impact' and 'impacted' mean to me a physical contact.

I then start moving into an uncharted sea of data. I can understand why, if titles are longer [2], I found so few words whose prevalence has decreased over the years, and why prepositions are becoming more common as title words; but why has 'beyond' increased so regularly, now to be twelve times more common as a title word than 40 years ago? Why is 'beyond' increasingly popular in titles, but not in abstracts? Perhaps we should take heart that 'therapy', 'patient', 'symptom', and 'people' are now more prevalent. Is it coincidence that 'early' and 'late' ('early' is four times more common as a title word than 'late') have both increased about 1.5-fold? Is it coincidence that 'previous' and 'previously' parallel one another so closely? Or does the approximate doubling of a number of words indicate that titles are, on average, now twice as long as they were in 1970-74, rather than the 1.25-fold increase extrapolated from Lewison and Hartley [2]. Why on Earth should the prevalences of the words shown in Figures 3 and 4 show such regular, linear changes?

In scientific observation, when variables show consistent, mathematically describable, change with time, there must be a reason. The reason may be trivial, or it may be profound, but some aspect of human behaviour lies behind it, and I would love to know what it is.

### Acknowledgement

I should like to thank Tim Albert for helpful discussion, and for 'pathway' and 'journey'.

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## Berlin—An open air museum of German history

by Rosie Bischoff with photos by Rainer Bischoff

This is a historical moment; we are finally back in Berlin for the Spring Conference after 15 years. EMWA (then still a chapter of AMWA) was so small that all the organising committee worked for the same local pharmaceutical company so we held the sessions in the company's conference facilities and had lunch in the work's canteen. There were only 6 workshops.

I have been living here for 35 years now. For my first 15 years, during the cold war, almost nothing changed. Over the last 20 years, everything has changed and if you know where to look, much of Berlin's history is still visible. I am going to give you some tips that will help the museums' best exhibits become visible.

### So first a potted history:

Over the last 140 years, since the first unification of Germany in 1871, Berlin has been through 5 distinct periods: first, Berlin became the capital of Germany (rather than just Prussia) for the first time, under the newly acclaimed Kaiser and Chancellor Bismarck. Next came the Weimar republic with its failed attempt at democracy after the first war and the decadent '20s of Christopher Isherwood and Cabaret fame. Then followed the 12 years of National Socialism and the second war. This was followed by the period of the cold war and the divided city. Finally the 20 years since the second unification of Germany when Berlin has again become the capital of all Germany and the country, has a stable democracy for the very first time ever. There are of course many sites that attest to Berlin's earlier Prussian history, in particular Unter den Linden (from Brandenburg gate down to the bridge over the Spree river), the Gendarmen Markt, the wonderful Baroque Charlottenburg Palace

and gardens and the UNESCO world heritage site ensemble at nearby Potsdam, but I will concentrate on sites of more recent history, pointing out any evidence of Prussia that just happens to be on the way.

I have only recommended places that are interesting for several reasons. They are spread around but the good news is that almost everywhere signs and information are given in both German and English and the public transport system is extensive and easy to use, although the Berliners complain bitterly. All sites but the last are in what was East Berlin because the organised walking tour stays in the West for reasons I will explain later.

### German lime wood sculpture and the Kaiser's aggrandizement (The Bode Museum on the museums island).

The Museums Island has 5 different museums and is vast (think Hermitage or Louvre and serious exhaustion). Most of them were built after 1871 when the Kaiser felt the need to present Berlin, the new German capital, as a city of culture ranking with the capital cities of his royal relatives ruling in Moscow and London. In particular they were to become a show case for German culture and its ancient sources. My personal favourite is the Bode museum tucked away at the north end, at the confluence of the water that flows around the building. The Bode museum is a MUST for anyone with even a remote interest in Renaissance art, both Northern and Italian. There are almost no paintings; here you find sculpture and architectural decorations. Many of the rooms are presented like the interiors of Italian basilicas and palaces. On no account miss the German lime wood sculptures on the second floor. Look for the likes of Tilman Riemenschneider and Hans

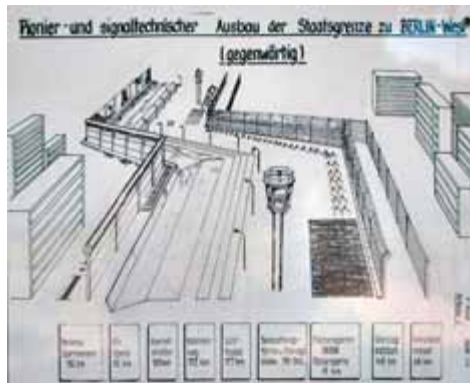


Views from the Spree River- the 33 m aluminum Molecule Man sculpture standing in the river and the Oberbaum bridge, built 1896, that crosses just behind; famous from the film Run Lola Run.

## Berlin—an open air museum of German history



The wall with the cemetery behind



The technical drawing of the wall



An old watch tower

> Leinberger (room 212 to 215). They are quite exquisite and relatively unknown outside Germany. Most of this work actually comes from southern Germany so you will be asking yourself what this has to do with Berlin. For this you must visit both the small and large domes and their stairwells, positioned at either end of the building. These were devised by Kaiser Wilhelm II himself as halls of honour for his Hohenzollern ancestors and their generals. Nowhere is the desire to legitimise himself as the monarch of a major European power expressed so clearly. In keeping with the taste of the time these spaces are truly bombastic and worth viewing.

*Late opening Thursday, otherwise till 18:00. Nearest station is Friedrich-Str. The café is quite good. The shop is uninteresting like most museum shops in Germany where commerce in temples of culture is not really approved of. Unfortunately, this means they have to make money by charging high entry fees.*

**Military heros who helped free Europe and a genuine stretch of the wall (Invaliden Friedhof, Scharnhorst Str).** This is the site of a very odd mixture of the city's history. It is one of the few places where it is possible to get a real feel for the wall, but it is also an important site of Prussian history. The veteran's cemetery is a place to reflect on the extremely varied role Teutonic militarism has played in European history. It is very quiet, well cared for and often empty. Prussian generals, particularly those who helped stop Napoleon's expansion through Europe, are buried here: the likes of Scharnhorst, Moltke, Witzleben, Winterfeld and many others. The famous World War I fighter pilot Manfred von Richthofen (aka The Red Baron) was also originally buried here. The cemetery lies on the banks of a waterway which marked the division between the East and West. The wall was built right through the middle with absolutely no regard for this place of Christian burial or Prussian history. When I first visited about 3 weeks after the wall was opened there were memorials and grave stones heaped up in piles everywhere. Although the cemetery has been fully restored, the wall, with gaps, has been left running through it as a memorial. Here there is none of the famous graffiti. Originally, of course, there was only graffiti on the west side. There are now slabs of concrete covered with graffiti on both sides all over the city. No one would be foolish enough to vouch they were

genuine and few are standing in the right place. Here a whole stretch has been preserved. Walk along the waterway and you will come to information boards up against the wall explaining technicalities. It was not one but many barriers, one behind the other, with the death strip down the middle. Keep walking a little further until you reach Kieler-Str. and one of the most surreal sites in the whole city. Here tucked in between new high-rise apartment blocks is one of the wall's watch towers just as shown in the technical drawing. Very occasionally it is open for visitors.

*The cemetery is open during daylight hours and the walk along the water is always open. It is close to the medical museum described below. Nearest stations are Schwartzkopff-Str. or Hauptbahnhof.*

**Berlin's finest Prussian architecture, National Socialism and the bonfire of books (Bebelplatz, Unter den Linden).** This is a site not to be missed by writers: The opera house flanks one side of the square and a library building the other. The Humboldt University is opposite. The Roman Catholic cathedral with its copper dome stands at an angle at the back. Many find this square, designed by that multi-talent Frederick the Great, the most successful example of baroque architecture in the city. At first glance you will not see why I have directed you here. This was the site of one of the most barbaric actions ever undertaken by students against learning and culture. Right in the centre of the square you will find glass plates let into the ground, down through which you see a library full of empty bookshelves. This is a memorial to the bonfire of the books that took place here and in 21 other cities in 1933, just months after Hitler came to power; the infamous 'action against the un-german spirit'. It was organised by the Student Association and the Hitler Youth Movement. Un-german books were anything written by socialists such as Bertolt Brecht and Karl Marx and included the likes of Ernest Hemingway, Jack London and H. G. Wells(!). First and foremost however, un-germanness was an accusation levelled against all German Jewish authors. It is particularly ironic that amongst those works burned was the play *Almansor* by the 19<sup>th</sup> C. poet Heinrich Heine, who wrote 'Dort, wo man Bücher verbrennt, verbrennt man am Ende auch Menschen' (Where they burn books, they will one day burn people).



## Berlin—an open air museum of German history

*The square is always open, but the memorial is best seen at night, (after a visit to opera, maybe?) when it is lit from below. Nearest station is Friedrich-Str.*

**Damage from allied bombing and medical history (Charité medical museum, at the intersection of Schumann-Str. and Charité-Str.).** This is of special interest as it focuses on medical history and includes a very extensive specimen collection. One could spend hours over numerous grizzly exhibits; it is not for the faint hearted. Displays also cover contemporary medicine and new developments. The building itself is a site where the history of the city is plainly visible. It is part of the medical faculty of the university, and had a lecture theater which was badly damaged by allied bombing. It has since been made weather proof and is now kept as a 'preserved ruin' and used for meetings. From the museum's entrance there is a great view of the huge new glass railway station.

*Saturday and Wednesday opening is until 19:00, all other days till 17:00. Nearest station is Hauptbahnhof. It is close to the Invaliden Friedhof described above*

**Socialist realism in homage to Joseph Stalin and a café. (Karl-Marx-Allee between Strausberger-Platz and Frankfurter-Tor).** Berlin has the distinction of being the only West European capital where you can exit a metro station and apparently find yourself in the middle of Moscow. The Stalinallee was built as a flagship residential area between 1949 and 1960 to replace a district destroyed in the war. This stretch has dual towers at each end, but the same architecture carries on for miles down the Frankfurter-Allee. The apartment blocks are 'monumental' in style and built according to Soviet plans. In the wake of de-stalinisation in 1961 it was renamed Karl-Marx-Allee. It was here that the interminable East German May Day military parades were held. Don't miss the 1959 Kosmos cinema and café Sybille, which has a permanent exhibition about the area and its worker's palaces. The café staff are members of a rehabilitation programme after recovering from psychiatric illness. If the weather is bad ask for the warm chocolate cake! Anyone familiar with the film 'The Lives of Others' about life in the sights of the East German secret police will recognise this as the site of the 'post-man' scenes at the end of the film. The bookshop is just a few doors away. Two blocks north of Strausberger-Platz

stood the Lenin statue, famous from the film 'Goodbye, Lenin'. You will pass the spot when you travel from the congress hotel into the city centre on tram M5. (If anyone badly needs to know where the 'screaming under the railway bridge' scene from Cabaret can be reenacted, send a request by e-mail. Complete discretion is assured).

*Café Sybille is at Karl-Marx Allee 72 in Block C-south and is open until 20:00, the nearest stations are Strausberger-Platz and Frankfurter-Tor.*

**Post modern architecture and the Jewish museum (Linden Str. 9-14).** The guided walking tours arranged for Thursday and Friday take you primarily to sites and memorials of the holocaust. One result is that although you will go to places where the wall stood you will not actually go into the East because it has no holocaust memorials. This isn't because the holocaust didn't happen in the East, but is a direct result of the divided city; in the East all blame was denied for 45 years. It was their opinion that the Easterners were successor to the persecuted socialists while the Westerners were successors to the Nazis.

However, in my view the tours actually miss the most evocative holocaust memorial which is Daniel Liebeskind's post-modern Jewish Museum, in particular The Voids. The holocaust is an aspect of Germany for which no adequate words will ever be found, particularly no words of explanation. I suggest standing in The Voids and trying to feel that for which there are no words.

*Open until 22.00 on Monday otherwise until 20:00. Nearest stations: Hallesches-Tor or Koch-Str.*

For those interested in the 11 months between the wall opening in Nov. 1989 and reunification of Germany 11 months later and some of the change the city has seen since, see our eyewitness account under [www.clinwrite.com/fallofwall.htm](http://www.clinwrite.com/fallofwall.htm).

This includes some background information and a brief account of why the Berlin wall was built.

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Goodbye, Lenin (removed 1992)



Soviet architecture on Karl-Marx-Allee.

## Berlin: Off the tourist trail

As regular readers of the journal will know, *TWS* has its eyes and ears on the ground everywhere and has received the following insider tips for delegates attending the EMWA's 32<sup>nd</sup> conference in Berlin conference from local spies and scouts...

### Dream topping, for the special occasion

- Ritz Carlton, Potsdamer Platz 3  
Champagne brunch for €72 (I'm not sure if the champagne is included in the price). According to a friend who used to work there, this is where Mr. and Mrs. B. Pitt hang out when in Berlin—they take an entire floor.

### High end

- Dressler, Unter den Linden 39  
Very good for breakfast (personally recommended by the Editor).
- Café Einstein, Unter den Linden 42  
Frequented by politicians.
- With the same menu, but a much nicer environment is - Café Einstein, Kurfürstenstraße 58 (nearest Underground: Nollendorfplatz) a former rich family's villa, now a café/restaurant with Viennese flair.
- Papageno, Richard-Wagner-Straße 13,  
Restaurant: not inexpensive, but fantastic quality (evening only, closed on Mondays).

### Medium high end

- Jedermann, Unter den Linden 12  
A cosy, non-swanky café that somehow strayed into a swanky area. Not even overpriced.
- Café Orange (café and restaurant), Oranienburger Straße 32  
Next door to the old Synagogue (itself worth seeing) and therefore with permanent police protection—the safest café in town!



Dressler



Jedermann

### (Real) Old Berlin

- Wilhelm Hoeck, Wilmersdorfer Straße 149  
Decorated in 1892 and hardly touched since. Hardly any tourists. (N.B. there are two parts, a restaurant and a “Kneipe”, or pub. The historic part is the Kneipe—don't bother with the restaurant. Closed on Sundays.)
- Gambrinus, Linienstraße 133  
Similar to Hoeck, though maybe a touch less authentic and plenty of tourists.

### Alternative culture

- The Schwarzes Café, Kantstraße 148  
(Not quite as alternative as it once was, but a good place. Serves breakfast 24 hours a day.)

Kreuzberg remains Berlin's most interesting and varied quarter. See e.g.

- The café ambience around the Paul-Linke-Ufer (extending eastwards from the corner of Kotbusser Straße).



Wilhelm Hoeck



## Berlin: Off the tourist trail

- Close to this, the Admiralbrücke, where street musicians congregate on summer evenings.
- The Marheinekeplatz—cafés and market.
- The Turkish market in the Maybachufer (Tuesdays and Fridays, 1100-1800 hrs).
- The Turkish quarter around the Adalbertstraße  
If you're there and need refreshment without possessing negotiating skills in Turkish, then try the Rote Harfe café (on the Heinrichplatz; Oranienstraße 13) or Max und Moritz (restaurant, Oranienstraße 162).

## Hip culture

The hip areas are Prenzlauer Berg and Friedrichshain, the latter however not especially attractive. The best-known area in Prenzlauer Berg is the much over-rated Kollwitzplatz. More attractive is the Helmholtzplatz, where the excellent Mexican restaurant Frida Kahlo (Lychener Straße 37) is located.

An insider tip in that area is the Café Lyrik (Kollwitzstraße 97, [www.cafe-lyrik.de](http://www.cafe-lyrik.de)), with free musical recitals on Thursday to Sunday evening and Sunday afternoons. (Seats about 40, so unsuitable for very large groups.)



Café Lyrik

## Jazz e.g.

- the “A-Trane” (Bleibtreustraße 1; reservation recommended via [www.a-trane.de](http://www.a-trane.de))
- the “B-flat” (Rosenthaler Straße 13; [www.b-flat-berlin.de](http://www.b-flat-berlin.de))

## Café corner

A favourite spot among Berlin's vast number of café promenades is the Weinbergstraße, which goes north from the Rosenthaler Platz. This has something for every taste, including but not limited to: Café Fleury (French flair and fantastic pastries), Gorky Park (pub with Russian beer and flair), Rose (cosy pub), Café Oberholz (on the south side of the Rosenthaler Platz; good snacks and WLAN atmosphere).

## Other things worth doing

Buses no. 200 and (especially) 100 take you along the main tourist routes between East and West. This was probably not intentional, but it could almost have been.

Big flea market on the Straße des 17. Juni—daytime Saturday and Sunday. Not a place to strike wonderful bargains, but well worth a browse just for fun.

Next to this you can have a beer or a meal at the “Tiergarten-Quelle”—a student pub where the clock stopped sometime in the 1970s and has not been wound up since.

If you are visiting the Gedächtniskirche (“Memorial Church”—originally a memorial to the first Kaiser Wilhelm, but now a war memorial), then take a close look at the imaginative fountain on the Breitscheidplatz next to the church, then go into the Europa-Center and see the water-clock—and try to puzzle out how it works!

## Tip for easy getting-around

Purchase a ‘Wochenkarte AB’ from one of the conspicuous ticket-vending machines at any U-Bahn (underground) or S-Bahn (overground) station or from a bus driver. This costs €6.30 and will give you complete freedom to use any train (of either kind), any ‘bus route or indeed any ferry, day or night, for 7 consecutive days. The ‘Wochenkarte ABC’ is valid outside of town as well, but inside the city boundary the ‘AB’ will suffice. Most of the ticket machines communicate in languages other than German if required.

**IMPORTANT: Validate your ticket before first use** by stamping it in one of the little machines at the station entrance or on the platform. A non-stamped ticket is invalid, and trying to travel on one (or on no ticket, of course) may result in your having to pay a spot fine of €40 and being severely hassled in the process; the ticket inspectors are believed to get a *per capita* bounty and are well known to give no quarter.



Note also, if relevant for you, that an ‘AB’ ticket does include Tegel Airport but does not include Schönefeld Airport, for which (being outside Berlin) you need the ‘ABC’ ticket. In that case the best bet is probably a ‘single ABC’ to get into the city and then a ‘Wochenkarte AB’ to get around.



Flea Market



## ■ Good writing practice

### Good Writing Practice

Good Writing Practice (GWP) is not a formal set of rules about how to write, like the requirements of GCP or GMP. Our aim is to highlight that the focus of all writers should always be on their readers, and that writers should make their texts as easy as possible to understand. Our aim is to go beyond the classic style guide and provide advice on practical aspects of writing that we hope will make texts easier to write and read. This means that much of what we will be saying in this column will apply to documents written in any language, although most aspects will be specific to English as the dominant language in our field.

A group of members have already collected quite a list of ideas to fill these pages in subsequent issues (see the December 2010 issue of *TWS* [1]). But we very much hope that this does not mean that these are the only people who will appear as contributors at the end of each section. This column is open to anyone who wishes to

contribute any advice on writing in our field that is not found in classic style guides and that they feel would be useful to their colleagues. The advice may also contradict classic style guides.

Our aim is to keep contributions short so that a variety of topics can be covered in each issue, but 'short' might extend up to about 1 page (about 800–900 words). Sometimes a contribution may need to be longer. So, if you have any ideas or wish to agree or disagree with any of the advice or add new aspects, please do send in a contribution to Wendy Kingdom ([info@wendykingdom.com](mailto:info@wendykingdom.com)) or Alistair Reeves ([a.reeves@ascribe.de](mailto:a.reeves@ascribe.de)), however long or short.

Ultimately, we hope to bring everything together in an EMWA Publication. Help us to make this a success!

We are starting off in this issue with a few words on abbreviations and using language dictionaries.

### Abbreviations (1)

Abbreviations should be introduced by writing the term in full on the first occasion of use and providing the abbreviation in brackets after it, e.g. systolic blood pressure (SBP). The abbreviation should be used thereafter. If a term is used only once, there is no need to include the abbreviation.

In regulatory documents, the summary should be treated separately from the body of the main document, i.e. abbreviations should be introduced in the summary and again in the body of the document.

However, there are times when following this rule is not good writing practice. As with all good writing, consider the audience, consider the purpose of the document and put the reader before the rule when deciding what and how to write.

Some abbreviated terms are more familiar than the full terms. For example, members of the public will know that HIV is a sexually transmitted disease without necessarily knowing, or needing to know, what the initials stand for. Unless there is a specific reason for including the full term in a particular document, it is not always necessary. In this example, the full term just clutters up a sentence with three words, one of which is exceptionally long, will make the text difficult for the average person to read, and does not help the reader to grasp whatever point is being made.

Context is important. It does not always matter if a reader does not know off hand what an abbreviation stands for. For example, when writing background introductory information for a scientifically educated audience, one can assume that the reader knows what common terms such as DNA, cAMP or ELISA stand for. Clearly some judgement is called for and what might be expected to be familiar to one audience might not be familiar to another. However, reading 'deoxyribonucleic acid' in the introduction

to a scientific paper gives the reader the impression that the author is very proud of knowing what DNA stands for, thereby 'dumbing down' the text.

If a misunderstanding could lead to an error in performing a task then, obviously, the rule on abbreviations should be followed. However, there are times when the full term may actually interfere with conveying the message clearly. An example of this is writing ethylenediamine tetraacetic acid in a protocol without the term in brackets after it. The rule was followed correctly because the term was used only once. However, if the intention was to communicate with site staff what we want them to do with a blood sample, this is an extraordinary way to go about it. Most phlebotomists recognise the correct tube or tubes by the colour of the cap, the shape of the tube, and what is printed on the tiny label. Site staff will know what an EDTA tube is and where to send the blood sample for analysis; it is irrelevant whether or not they know what EDTA stands for. Therefore, in this case, if the writer really had to write the term in full, and we all know that we do a lot of daft things because it is easier than arguing about it, they should have included (EDTA) after the full term because the abbreviated term is more important than the full term.

(contributed by **Wendy Kingdom**, [info@wendykingdom.com](mailto:info@wendykingdom.com))

### The benefits of using a language dictionary

**Use language dictionaries more!** Most of us make regular use of medical and other specialist dictionaries. It certainly doesn't harm to refer to a language dictionary more often than 'now and then', and not only when you come across a word you don't understand. There can be a few surprises in store, even if you think you know what a word

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means, as I recently discovered with the word ‘onset’ [2]. It is important to read the explanation at the beginning of the dictionary that describes how entries are structured and what abbreviations in the entries mean. It really is worth spending some time doing this.

**‘Devaluing’ the meaning of words.** Findings are often ‘presented’ in tables. In most dictionaries, you will find upwards of 10 definitions of the verb ‘to present’, and all of them mean more than just plain old ‘show’ or ‘give’, which is all you want to say. ‘Cows that exhibit pain in the hoof region ...’: ‘exhibit’ also has different meanings, and the principle meaning is ‘to put on public view for interest or admiration’. These cows are doing nothing more than lifting their foot off the ground because it hurts, not holding out their foot deliberately in case a vet passes by, notices, and relieves them of the pain. ‘Cows that have pain in the hoof region’ or ‘Cows with pain in the hoof region ...’ would suffice. Do patients really ‘experience headache’ as an adverse event? Can’t they just ‘have’ it? Does statistical testing really have to ‘reveal’ something? Can’t it just ‘show’ it? Almost every finding we make is unknown until we make it, so doesn’t have to be ‘revealed’, unless it really was originally withheld for some reason.

It is obviously not *wrong* to use exhibit, present, experience and reveal as in the examples given above. But what you are actually doing by using them in this way, even if you are just copying what you see in the literature or hear people say, is devaluing these words, robbing them of shades of meaning. Of course, widespread misuse of a word with a new meaning can mean that it comes into such frequent use that it becomes silly to insist that it be avoided. A good example of this is the verb ‘to address’ when used to mean ‘to deal with’ or ‘to discuss’: a new meaning we really did not need, but everybody understands what is meant and it has come into normal usage. This and other ‘lost causes’ will be addressed (i.e. dealt with or discussed, as we used to say) in a future GWP column. It is very difficult to say when something becomes a lost cause, and this is also often governed by personal taste. Some people are very resistant to the evolution of language and insist on observing rules and conventions that are regarded as outdated by most. How you deal with this in your work is also very personal. With ‘address’, for example, I have decided never to use it with this new meaning when I write something, but not to correct it in texts that I edit for other authors.

**Check the meaning of terms.** Have you ever looked up ‘in the vicinity of’? Probably not. I hadn’t either. And I didn’t do so until I had a text to edit with the terms ‘in the region of the plaque’ and ‘in the vicinity of the plaque’. The author was not using them synonymously. I felt fairly certain that they meant the same, but I had never looked up either term. That there is a difference was confirmed by the dictionary: ‘in the vicinity of’ means ‘near’ in the sense of ‘anywhere nearby’ and only this, while ‘in the

region of’ has this meaning but could also mean anywhere in the area covered by the plaque. Such a distinction can be very important: in this instance, the study was ascertaining whether certain dental biofilm bacteria were present in vascular plaque material or not, so here it was important.

If you see similar-looking words being used the same way, one of them is often being used incorrectly. ‘Regime’ and ‘regimen’ are still often confused, but mean completely different things.

**Dictionary words.** Every dictionary also gives home to many ‘dictionary words’. These are words that are retained in dictionaries after they have gone out of common usage so that readers of old texts can still look them up to see what they mean. Good dictionaries tell you that such words are obsolete. Of course, quite when a word becomes obsolete is questionable, so there is a grey area. And words may also remain in common usage in one area (geographic or specialist), but become obsolete in another.

**Spelling and word division.** Before the advent of the Internet, dictionaries were the prime resources for checking spelling and word division. This activity has largely—and very efficiently—been replaced by wordprocessing. Nowadays, you seldom need to check the spelling of a term (always use the spellchecker, even for e-mails, and make sure you have selected the appropriate language) or the way it is best divided. The latter is certainly not decisive to the readability of our types of text, and little or no time should be wasted on it. In my experience, the way Microsoft Word divides words causes no problems and there is no reason to suspect that the algorithm will get worse. Having said that, word division is not actually very kind to the reader, and unless absolutely essential for reasons of space, should be turned off in your word-processing program, at least in English-language texts.

There are, however, some spelling errors that are not picked up by the spellchecker, and you must search for these specifically using ‘search and replace’. ‘Read’ is the correct spelling of the present and past forms of the verb ‘to read’, but this is not the case with the verb ‘to lead’, where ‘led’ is the past tense. Also, do bear in mind that the Microsoft Word spellchecker is part of a word-processing package and is not a lexicographic authority. If in doubt, look it up in a good dictionary.

**Words not in dictionaries and new words.** Dictionaries do not always supply the ‘last word’. You will look in vain for the word ‘evaluable’ in most dictionaries, but it is indispensable in our area of language and everyone understands what it means. Neither will you find the verb ‘to present’ meaning the first time a patient sought medical help for a certain condition (it is not correct to use it for medical visits after that). This is because within the field of medical documents, this use of ‘present’ started off as jargon, but is now accepted as a proper meaning. It is the same with ‘indication’: remember how surprised you were

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- > when you started in this business to find that it means ‘condition’, ‘illness’ or similar?

You will also look in vain for ‘deliverable’ defined as a noun and ‘leverage’ defined as a verb. Deliverable as a noun is a respectable new word and will no doubt make it into the dictionary some time. Leverage as a verb is totally unnecessary as there are other verbs which are good enough and are better understood (gain, solicit, secure). Time will tell whether it makes it to the dictionary.

New words can take quite some time to get into dictionaries. Jean-Baptiste Michel and colleagues at Harvard University recently analysed everything so far scanned into Google Books (about 10% of the approximately 130 m documents printed since Gutenberg invented moveable type). They found that after hardly changing in the first half of the 20<sup>th</sup> Century, the English vocabulary expanded at a rate of about 8,500 words per year in the second half, and that of the approximately 1 m words in the English language, only about half are in the *Oxford English Dictionary*, the prime lexical repository [3]. The team also found that some words added to the *American Heritage Dictionary* (e.g. ‘gypseous’ and ‘amplidyne’) in 2000 had been in widespread usage a century earlier, but by the time they made it to the dictionary, they were already becoming obsolete (let’s hope this is the case with ‘leverage’ as a verb!).

You have to use some common sense with new—and ‘old’—words. A good approach is to ask a few colleagues whether they think a word has come into common currency or sounds out-of-date.

**Addendums.** New words and new meanings are often included in an addendum in paper dictionaries, until it is decided to produce an edition where this new information is incorporated in the main body. Addendums will probably now disappear from dictionaries, because electronic publishing is much less labour-intensive than traditional typesetting, where even a small addition could mean major repagination. So, when looking for a word in a paper dictionary, remember to look for an addendum as well.

**Keeping up to date.** We are editors and writers. Dictionaries are basic working materials for us. Have two or more language dictionaries, because there are differences. Renew your language dictionaries every 10 years or so, or when a new edition is published incorporating a previous addendum; it is a small investment. New editions of dictionaries do not have just a few changes. They are labour-intensive and therefore include a lot of new material.

(contributed by **Alistair Reeves**, [a.reeves@ascribe.de](mailto:a.reeves@ascribe.de))

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## Mens, ladies, area’s and family’s—in beautiful Australia

Once again on holiday down under (Western Australia), we searched in vain for evidence that written English has been better preserved than in the UK and conclude that there is no real difference.

As antihyphenists, we were refreshed to see that ‘turnoff’ (exit from a motorway) is written everywhere as one word and that ‘takeaway’ (as in ‘a carry[–]oot’ in Scotland) seems to have ousted ‘take-away’.

However:



Fig. 1 shows clearly that despite being printed or embroidered, men’s, ladies’ and children’s T-shirts are no longer worthy of the apostrophe and underlines that this is rapidly reaching lost-cause status, as in the UK.



Fig. 2 is an excellent example of the Lynn Truss Grocer’s Apostrophe and extends it to the Stationer’s Apostrophe. This may have taken hold in the UK too, but is not yet a lost cause.

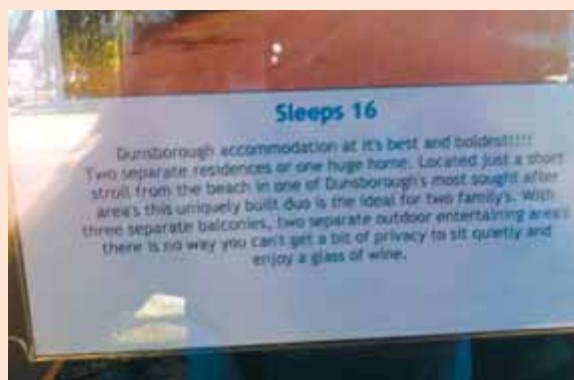


Fig. 3 shows that distinguishing between it’s and its holds the same difficulties in Oz as in the UK (see line 1), and that areas (twice—at least it is consistent!) and families now have alternative plurals in the grocer’s apostrophe league. These are both definitely not lost causes and we should still be fighting against them—in the UK and Australia.

On a different note, if the place in Fig. 3 sleeps 16, can you really be expected to find a quiet place to enjoy a glass of wine (which is very good in Western Australia, we can assure you) with at least 3 people on any of the separate balconies or outdoor entertaining areas?

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In the bookstores ... ■

## A useful guide to learn how to present with confidence



Adrian Wallwork. *English for presentations at international conferences*. Springer, 2010. ISBN: 978-1-4419-6590-5. 22.99 GBP. 179 pages.

Long before I became a medical writer, I spent my PhD period doing immunological research. Although more than 20 years ago, I still remember my first international conference. Not only

did I succeed in getting my abstract accepted, but I even got an oral presentation slot during one of the parallel sessions. If that wasn't nerve wracking enough, I discovered that my session was in an auditorium for a couple of hundred people. During my talk, my slides were magnified so much that my most important slide, containing a busy table with all my results in the default Times Roman font, was truly illegible. I still shudder when I think back. But I made it through the presentation without lasting damage and went on to become a professional medical writer, who also creates and delivers presentations for a wide variety of audiences.

Luckily, with Adrian Wallwork's book 'English for presentations at international conferences' you can skip the laborious path I followed. Wallwork has written a helpful guide for those who struggle with presenting scientific results in person. The book is mainly intended for scientific speakers for whom English is not their primary language, but is also useful for native English speakers who have never presented before or who want to improve their presentation skills. In addition, I'd like to add that the book is also useful for experienced presenters.

Scientific presentations often suffer from the 'Death-by-Powerpoint' syndrome, characterised by slide after slide filled with formal and long texts, bulleted lists, graphics and tables that are lifted directly from a manuscript, delivered in a monotonous drone by the presenter, who, more often than not, reads the slides with his or her back to the audience and has more to say, especially about all the details of his or her work, than fits in the allotted time. The result is a boring presentation that leaves you feeling sleepy, especially around lunch time, instead of excited and entertained. Wallwork's book offers an effective treatment for this syndrome.

The book is written as a resource guide and contains short chapters divided into three parts. The first part covers the preparation for a presentation, the second the development of the slides themselves and the third the delivery of the presentation. The chapter titles are to the point and it's quite easy to find a relevant chapter with the table of contents as a guide. Throughout the book, Wallwork offers useful and practical advice. His chapters are filled with examples of original and revised texts. Importantly, he stresses the need to think, prepare and practice thoroughly

what you want to say in your presentation, *before* you even open your presentation software.

Wallwork is a proponent of clear and succinct messaging. Every chapter starts with an explanation as to why the point he makes is important. About what to put on a slide, he says: "Your aim should be for the audience to quickly assimilate the information on your slides and then focus on you." and about the title: "The title of your presentation is like an advertisement—you want as many people as possible to [be] interested in it, so it should not be too technical or too generic."

In the book you'll find advice on how to effectively use English without getting stuck on difficult words or tortuous constructions, how to create effective and complementary slides, and how you and your slides can combine effectively during your presentation, so that the impact is as memorable as possible. In addition, Wallwork writes about changes in the attention span during a typical presentation, about what works and doesn't work in a presentation and why, and about alternative methods to capture, retain and regain the attention of your audience.

Some of his tips, however, may not always be as useful as stated in the book. One of the tips for the preparation stage is that you try to find out who your audience is, e.g. in the bar and at social dinners. I don't think that this is very practical for large international conferences with hundreds, maybe thousands of participants and many parallel sessions, when your contribution is an oral poster presentation of 7 minutes. But if you're going to present at a smaller more focused meeting, this would indeed be useful information to have. Also, not everyone may have the confidence or courage to use his more unorthodox tips about how to begin a presentation, something that he also acknowledges himself. While it surely could be attention-grabbing, starting off with a personal story or by asking the audience to do something, this may not always have the intended effect.

I found that the book doesn't read very easily, since it seemed to be printed by a local copy shop, rather than by Springer, a major publisher. There are numerous text examples of what one could say during a presentation, but I feel that these examples would have more impact if accompanied by an example of the actual accompanying slide, instead of just a description of it. For a book that is meant to be thoroughly used, these things are quite unfortunate.

Nevertheless, I do recommend this book for anyone who is seeking to gain confidence as a scientific speaker or who wants to improve his or her presentation skills. Although the 'Death-by-Powerpoint' syndrome still is ever-present around us, this book could be the right antidote for those who are willing to battle the syndrome. The book is one part of a series of books designed to help non-native English speakers to communicate in English.

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## Webscout



## Pharmacoeconomics— An opportunity for medical writers

by Karin Eichele

The economic crisis has led to restrictions in the public health sector worldwide. The field of pharmacoeconomics thus becomes more and more important. This sub-discipline of health economics evaluates the costs and effects of a medicinal product. There are three forms of economic evaluation, cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA). The analyses differ in the way the consequences of a treatment are measured. This could be either as the most obvious effect (CEA) like for example ‘symptom-free days’, a single generic measure (CUA) like quality-adjusted life years (QALY) or a relative monetary measure (CBA).

Public health service providers in many countries, e.g. UK, France, Sweden and Germany, request new information on the economic aspects of a new product. The information is usually required in form of a country-specific value dossier. The requesting authorities publish guidelines on the submission of data, in general these are very similar but there are slight details that differ. Usually a value dossier defines the clinical added value in the approved indication in comparison to the standard of care, the patients and patient groups who probably benefit from the new treatment and the extent to what these patients might benefit. Finally, based on the assumptions on the added value, the yearly costs of the medical product are displayed. Decisions on reimbursement and pricing will be finally based on these dossiers. It is clear that well written and substantial dossiers are crucial for pharmaceutical companies—and thus writing in the pharmacoeconomic area can be a great opportunity for medical writers. Time to get oneself familiar with this discipline. In the following you will find some helpful links on the topic.

<http://bit.ly/eMx1nU>

The pharmacoeconomic analysis will be the heart of a value dossier. This article gives you a brief introduction on the purpose of pharmacoeconomics and some basic concepts. It does not go too much into detail, yet it is a good starting point to enter this world.

<http://bit.ly/h2EB02> and <http://bit.ly/e60J36>

These links come from a preview of a book entitled *Introduction to Pharmacoeconomics*. Chapter 1 and 11 are available online. In chapter 1 you can again find some introduction and explanation of basic concepts of pharmacoeconomics. Data on the economic value of a drug will have to be generated in addition to clinical efficacy and safety data in order to support the process of pricing. The objectives of clinical trials should therefore include economic issues. These issues might be outlined in a value development plan which parallels the clinical development plan mentioned in the article above. Chapter 11 of *Introduction to Pharmacoeconomics* deals with the question of how to include these pharmacoeconomic issues into clinical trials during drug development.

<http://www.ispor.org/>

ISPOR is the International Society for Pharmacoeconomics and Outcomes Research with members from 90 countries, the majority of which come from the US and Europe. ‘Value in Health’ is the organisation’s peer-reviewed journal, however, it is not free of charge. Yet, the webpage contains valuable information on pharmacoeconomic guidelines, outcomes research practices and modelling for free.

<http://bit.ly/fjehTz>

This is an interesting article on the necessity to communicate the value of a drug and introduces a strategy for communication. A ‘Value Development Plan’ is proposed. The cornerstones of this plan are value determination, value demonstration, value communication and value realisation. These principles are especially interesting as this information will finally culminate in a value dossier which usually is the basis for discussion with health service providers on the price of a new product.

If you have any further questions or you have any other comments or suggestions, please e-mail me at: [karin.eichele@novartis.com](mailto:karin.eichele@novartis.com).

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### Extract from a test

Name six animals which live specifically in the Arctic.

Two polar bears  
~~Three~~ Four Seals



# Ghostwriting and public trust in medical science, positive-outcome bias in peer review, and Blackawton bees

by Nancy Milligan

## Medical writing, ghostwriting, and public trust in medical science

The ghostwriting debate received further attention in a recent short article by Górski and Letkiewicz [1]. The authors claimed that ghostwriting, when an individual makes a substantial contribution to the development of a manuscript but their role is not acknowledged in the manuscript itself, is profoundly damaging as it can promote non-disclosure of conflicts of interests, is a danger to the public perception of medical science and scientific publishing, and ultimately can mislead medical practitioners about the risks and benefits of a treatment. The main issue appears to be the fear that ghostwriters are involved in manipulating manuscripts to promote the marketing interests of a sponsor rather than providing a clear description of the full results of a study. Essentially, the scientific value of a study is undermined by marketing goals.

Górski and Letkiewicz pointed out that the practice of ghostwriting is generally condemned, among people working in the industry and in scientific journals (some journals even have their own policies on ghostwriting). However, the authors also questioned the role of professional medical writers in manuscript production, suggesting that some believe this practice should also be banned. The distinction between a fully-acknowledged professional medical writer and a hidden ghostwriter should be highlighted here.

The authors went on to discuss the benefits of using a professional medical writer and gave a number of reasons why so many companies choose to use them; for example, to save time or when a research team may lack the necessary writing or language skills. In addition, there is some evidence to suggest that professionally written manuscripts may actually be higher in quality and more likely to be accepted for publication [2]. The authors suggested that the main issue with an outright ban on the use of professional medical writers is that this may increase non-publication, already considered quite a significant problem in the biomedical industry.

## Positive-outcome bias in peer review

In a recent article, Emerson et al described a study that found evidence of a positive-outcome bias during the peer review process [3]. A positive-outcome bias is defined as the increased likelihood that studies with a positive outcome will be accepted for publication than will

similar-quality studies with negative or neutral results. In their study, Emerson et al created two versions of a fabricated but well-designed randomised controlled trial on the subject of antibiotic prophylaxis for clean orthopaedic surgery. The two manuscripts were nearly identical except that one version had a positive conclusion (i.e. it found a difference between treatment groups) and the other version was neutral (i.e. it found no difference). The introduction and methods sections of the two manuscripts were identical; only the results and main conclusions differed. Furthermore, the authors placed a number of deliberate errors in both versions to investigate whether reviewers would scrutinise the neutral no-difference version more severely.

The two versions were submitted for peer review to two journals who had agreed to cooperate in the study, *The Journal of Bone and Joint Surgery* and *Clinical Orthopaedics and Related Research*. 238 peer reviewers were randomly allocated to review either the positive or the no-difference version of the manuscript, and 210 returned reviews. The reviewers had agreed to take part in a study about peer review, but were unaware of the aims of the study, that the manuscript they received would be fabricated, or when they might receive the manuscript. Although the strength of the effect varied between the journals, overall the reviewers were more likely to recommend the positive version of the manuscript versus the no-difference version (97.3% versus 80.0%;  $p < 0.001$ ); the reviewers awarded higher methodological quality scores to the positive version of the manuscript versus the no-difference version (8.24 versus 7.53;  $p = 0.005$ ), although the methods sections were identical; and they detected more errors in the no-difference version of the manuscript versus the positive version (0.85 versus 0.41;  $p < 0.001$ ).

Positive-outcome bias is expected to compromise the integrity of the literature, including affecting treatment effect sizes when published data is subjected to meta-analysis. It is therefore important to remember that only by publishing neutral and negative results as well as positive results can we get the full picture of the effectiveness of a treatment.

## Blackawton bees

Finally, we end this issue of journal watch with a lovely article written by a group of schoolchildren which provides a lesson in understanding science in its truest form. The Blackawton bees project carried out by a group of 8- to

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## Journal watch

- > 10-year-old children from Blackawton Primary School in Devon in the UK aimed to bring together the processes of science and the 'deeply resonant, natural processes of play' [4].

The paper presented a novel study on the vision of bumble bees asking whether bees could learn to use the spatial relationships between colours to distinguish between flowers that contained sugar water and those that contained salt water. The children thought it was an interesting question to ask as it reflected the natural habitat of bees in which they need to learn which flowers to go to or avoid to obtain nectar. To test this, the children gave bees a series of challenges and tests relating to going to flowers of differing colours in order to see if bees can learn to solve puzzles. They concluded that bees can solve puzzles by learning complex rules, but that sometimes they make mistakes.

This study and the way it is described by the children in the paper highlighted the true motivation for a scientific

study, which for the children was not inspired by references to the past scientific literature but their own curiosity and observations of the world.

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## Dear TWS

I was interested to read the editorial 'Is medical writing a model for a workforce with feminine values?' in the December 2010 issue of TWS. The 45% discrepancy between men and women in starting salaries found in the EMWA 2006 salary survey sounds dramatic, but I wonder how reliable that statistic is, and whether it's really comparing like with like. For one thing, that statistic was based on a very small sample size (N = 27, I don't know how that breaks down between groups), so it may only take 1 or 2 men with an unusually high salary to skew the statistics. It may also not be comparing like with like. We don't know how many of those jobs were part time (women are more likely to work part time), nor at what level the jobs were. A starting salary for someone going into medical writing straight after a 1<sup>st</sup> degree would be much lower than someone going into medical writing as a career change after 10 years experience in a related field, such as clinical operations. I have no idea whether there's any difference between men and women in the stage of their careers at which they go into medical writing.

I don't know if EMWA are planning to do another salary survey, but if so it would be fascinating to collect sufficient data to be able to answer those questions. I'd actually be quite surprised if men and women were getting such different salaries for doing comparable jobs, and suspect that most of the discrepancy in male vs female salaries can be explained by the fact that the jobs are not comparable.

**Adam Jacobs**

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## Duplicate publication is editors' main concern

Publication ethics are not of great interest to the majority of editors of science journals who believe that misconduct is rare in their journals. Most editors are not au fait with publication guidelines. These are the conclusions drawn from a survey of journal editors conducted by Wiley-Blackwell. The survey also found that the editors considered duplicate publication the most important issue that they needed to tackle.

**Source:** *Journal of Medical Ethics* 2010 25 348–353

## Universal rejection

The best biomedical journals have high rejection rates but there is one journal that rejects all the manuscripts it receives. Details of the *Journal of Universal Rejection*, its instructions to authors, subscriptions and archives can be accessed at <http://bit.ly/fIMpFh>. Reasons given for sending your manuscript to the journal include that you need not suffer anxiety because it is 100% certainty that it will not be accepted for publication, you can claim to have submitted to the most prestigious journal (judged by acceptance rate), you retain complete rights to your work and there are no page fees.

## Out on our own

## Out on our own

Welcome to the first 'Out On Our Own' (OOOO) of 2011 and a fresh new look. We say a huge thank you and goodbye to Alistair Reeves, who has given his time generously these past 8 years in supporting EMWA freelancers. His tireless efforts have given voice to and shaped our contingent into a self-supporting body that is strengthened through shared endeavour and experience. We hope to continue Alistair's good work through team effort.

We have great pleasure in introducing the members of the new-look EMWA Freelance Support Team: Sam Hamilton, Anu Alahari and Kathryn White will help provide the interface between you and the EMWA Executive Committee. Raquel Billiones is the new 'OOOO Content Coordinator', who will ensure that each OOOO section is packed with interesting and creative material. Finally, Ingrid Edsman will continue to develop our fantastic Freelance Resource Centre (FRC) on the EMWA website. You will be able to meet most of the new team in person at the Berlin conference in May 2011, but in the meantime, we hope our contributions to this OOOO help you get to know us a little better—and who knows, inspire you to contribute too.

Look out for a fresh look for OOOO in the coming year as we introduce our very own freelancer logo. The exciting 'design a logo' competition is open to all EMWA members, so please read the information box on page 61 and join in!



Sam Hamilton Anu Alahari Kathryn White Raquel Billiones Ingrid Edsman

In addition to hearing from the team, we meet freelance medical translator and conference newcomer, Jason Willis-Lee and read his take on the Nice November 2010 conference. Diana Raffelsbauer launches a series of interviews on 'going freelance', with contributions over the coming months from freelancers involved in every arena of medical writing. Adam Jacobs and John Carpenter start the ball rolling by telling us of their freelance experiences in the areas of regulatory writing and medical communications/education, respectively.

On the lighter side, we start a new Q & A series "Out of Hours" (great idea, Kathryn) on what we write beyond the realm of medical writing.

Enjoy!

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## Going freelance: The first of a series of interviews

by Diana Raffelsbauer

There are not many lines of business that offer the possibility of freelancing like that of medical writing. About 25% of EMWA members have chosen this option: they work as freelance medical writers, editors and/or translators either full- or part-time across Europe.

What are the advantages and disadvantages of this choice? What academic background, scientific knowledge and soft skills are required? Do these requirements differ between the fields of pharmaceutical regulations, medical communications and technical translations? How many years of experience are needed? How many contacts to prospective clients should be available? When is the best time to go freelance? These are only a few questions one should consider before making the decision of starting a business. The OOOO section of *TWS* will publish a series of interviews with experienced freelance medical writers, editors and translators from the fields of both regulatory and medical communications writing to find answers to these questions.

In the first interview, Adam Jacobs and John Carpenter describe their first steps into medical writing, their reasons for going freelance and the challenges they face in daily work. This information may provide advice to young colleagues who are considering a freelance career. Adam is director of the company Dianthus, which specialises in the preparation of regulatory documents, statistical consultancy and clinical data management. John is a freelance medical writer and consultant, specialising in writing materials for medical communication and medical education.

### What services do you provide? What types of materials do you write?

**A.J.:** I almost never do any writing myself these days, as it is a full-time job running my company. Any time I have left over after that for project work is usually spent on my statistical consultancy activities. I have a team of brilliant writers who do all the writing at my company, and probably do it far better than I could. But the writing they do

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> is very varied, including regulatory documents such as protocols, study reports, clinical overviews etc., and then a whole bunch of medical communication stuff as well: mainly papers for publication in journals, but also conference abstracts, posters, monographs, etc. And apart from the medical writing, we also do statistics and clinical data management work.

**J.C.:** Medical communications and medical education writing encompasses a huge range of materials. And I have written most types at some time or another. Some examples of things I have done include: developing the content and slides for symposia at international meetings; writing guidance for patients and their families about medical conditions and treatments; product monographs; training materials for pharmaceutical company staff; systematic reviews of treatments for medical conditions; symposium proceeding supplements for publication in peer-reviewed journals; educational slide kits for healthcare professionals; papers reporting the results of clinical trials (developed from clinical study reports) for publication in peer-reviewed journals; therapeutic reviews and updates for healthcare professionals; reports of advisory board meetings for internal circulation. These are just a few.

### How did you become a medical writer?

**A.J.:** Like many medical writers, I didn't really plan to be a medical writer from the start. It just sort of happened. I started out as an organic chemist, but after a little incident involving a rather cavalier Australian post-doc, some phosgene gas, and a night in the hospital for me and five of my colleagues, I figured there were probably easier ways of making a living. I applied for some medical writing jobs then, but no-one wanted me. Instead, I became a medical translator, mainly translating things from German to English. After a couple of years I started to get bored of that and decided to have another try at getting a job in medical writing, this time successfully. I had a couple of medical writing jobs, one at a CRO, and one at a medical communication agency, before starting my own company in 1999. It was just me to start with, working as a freelance medical writer. Shortly after that, I did a part-time MSc in medical statistics, which allowed me to add statistics to our range of services, and also started slowly growing the company. I am still running the company today.

**J.C.:** I have always enjoyed reading and writing. As a graduate student I had to do some teaching and realised that I had a knack for explaining difficult concepts to others. The best part of doing my PhD was writing my thesis—I had a ball! When I was appointed Lecturer in Pharmacology at a large medical school, I helped develop lectures and lecture notes for medical, dental, pharmacy and BSc pharmacology students. This led to me being asked to contribute sections to several textbooks on pharmacology. I also wrote a small textbook on pharmacology and helped compile a dictionary of pharmacology. I also started writing pieces for a small medical writing agency.

All these activities gave me much more satisfaction than writing grant applications and laboratory work. I therefore started looking for jobs in medical communications and left the university to join a fast-growing medical communications agency where I worked for seven years. This is where I learned my trade. After brief spells in other agencies, 10 years ago I decided to pursue a freelance career.

### Why did you choose to work as a freelancer/set up your own company?

**A.J.:** I initially chose to work as a freelancer for two reasons: First, I had left one job with a hideous boss to get another job, which seemed to have a wonderful boss. That wonderful boss left the company three months later, and I found myself working for a hideous boss again. I figured that maybe I just wasn't really cut out to work with bosses, so that was a motivation for working freelance. But also, I saw it as a positive career development move, in that working freelance would be just the first step towards building up a company, which I thought would be a fascinating and challenging way to develop my career. And 12 years later, I can confirm that it has been.

**J.C.:** First, it made financial sense to work freelance rather than be employed full-time by someone else. I calculated that I could have the same income by working approximately half as many hours. Second, working freelance meant that I would be free of the burdens of management and corporate politics. It also meant that I could control how I worked: if the weather was nice, I could go out and play and do the work in the evening, for example. The decision to go freelance was relatively easy as I was receiving a pension from the university, so I could afford to have a lean spell while getting established. However, my phone started ringing almost immediately as people I had worked with in the past learned that I was working freelance and wanted to use my services.

### In your opinion, what are the main skills and abilities needed to be a good professional in your area of expertise?

**A.J.:** In my current role as director of the company, the main skills are to have an all-round appreciation of every area of the business. I don't need to be an expert in every area: for example, I can (and do) use external consultants to help with specialist areas such as finance and marketing. But I do need to know enough about every area to know when things are going well and when specific things need attention, and to make sure that nothing gets overlooked. Probably the most important thing I do is leading and motivating my team, which is something I try particularly hard to do well. My business would fail pretty quickly if the people who work for me weren't interested in and motivated to do their jobs. I am lucky that I have a fantastic team, which makes that a lot easier than it could be, but it is an area of my job I take very seriously and have been on courses in. My military background (I was briefly an



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officer in the Royal Naval Reserves) is more helpful here than you might think. Naval officers are given excellent training in leadership skills, which have proved surprisingly transferable to a civilian environment. But don't worry, that doesn't mean I expect my medical writers to scrub the decks and do 50 press-ups before work in the mornings.

**J.C.:** There are two key skills for medical writers. The first is an ability to write clear and effective English and the second is the ability to master new therapeutic areas rapidly. I have written about most therapeutic areas, and in many of these, I had only outline knowledge when I started. But within a few weeks, I am able to master the key essentials and literature to a level sufficient to allow me to communicate effectively with top researchers and opinions leaders. When I started as a medical writer, this involved spending days in medical libraries. Now I can do this on my laptop sitting in the garden with a cup of coffee. The most important skill for consultants in medical communications is experience. You need to have been involved in all aspects of medical communications and you need to know how pharmaceutical companies think, what drives them and what their goals are. You also need excellent interpersonal skills in order to both discover what clients actually need (rather than what they think they need) and also to be able to explain this to them. Similar criteria apply to facilitating or chairing expert panel meetings and advisory boards. In these roles, you have to be able to act as an intermediary between the pharmaceutical company and the external advisors. For a trainer, I think the key is being able to put yourself in the position of the trainee: what are their difficulties; why do they do things this or that way; what constraints are imposed on them in their working environment? You also have to be a bit of an actor in order to grab and keep trainees' attention, and you need to learn tricks of the trade that help people acquire new skills.

**What are the biggest challenges you face in your daily work?**

**A.J.:** It varies from day to day, often in unexpected ways. Today, my biggest challenge is that someone has stolen the wheelie bin in our car park where our rubbish should go. Bizarrely, this is the second time this has happened to us, and the latest bin has gone missing despite the fact that it was securely locked up. I have no idea why our bins should be such a highly prized commodity, especially when many of the other businesses in our road don't lock up their bins. Over the last couple of years, while the world has been in the grips of a nasty economic recession, the biggest challenge has been to ensure we have enough work to keep us all busy, although thankfully things are starting to look more positive now. Another challenge I faced recently was someone writing some very unpleasant and untrue things about my company in a public forum. I don't want to say any more about that for now, but once certain bits of due

process are complete, I'll certainly be writing about that experience for a future issue of *TWS*. But there are always challenges: stolen wheelie bins, clients who don't pay their bills on time, arranging cover for staff on maternity leave, dealing with the local council's Department of Torturing Local Businesses with Petty Bureaucracy, malfunctioning heating systems, incessant sales calls from morons who don't understand how the Telephone Preference Service works, phone companies behaving like idiots, new government regulations requiring extra form-filling from us, and so on. But that's just part of the job.

**J.C.:** Learning new therapeutic areas and establishing good working relationships with the client, leading researchers and opinion leaders.

**What aspects of your job do you like most/least?**

**A.J.:** Like the most: seeing e-mails from grateful clients thanking my medical writers for doing a brilliant job. Like the least: updating SOPs.

**J.C.:** The most enjoyable part of my job is that I have control over what I accept and how I choose to work. I also get enormous pleasure from building up sound working relationships with clients and from solving or contributing to the solution of their problems. This is particularly the case with training courses. Seeing participants develop new skills and knowledge is always immensely satisfying. The most frustrating aspect of my job is giving advice to clients who think they don't need advice. The positive side of this is that they still pay me, so I don't really mind. I am also liable to throw things about when authors or clients make changes to their own changes (i.e. things that they have already changed)!

**How would you advise young medical writers who want to work in the same field?**

**A.J.:** Never take anything for granted. If something you are writing about looks odd, do not assume it is correct. Find out why it looks odd. First, it is possible that it looks odd because there is an error somewhere; and second, even if it really is odd, your reader will also think it looks odd and will want an explanation.

**J.C.:** Do not start out as a freelance writer. Get a job with a full-service agency and do a bit of everything. Pick as many peoples' brains as you can. Take all the training courses that your employer offers or do everything you can to persuade your employer to pay for training.

The editorial board of *TWS* thanks Adam and John for their willingness to answer these questions and share their experience with EMWA members.

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## Living and working in the northwest of France

by Anuradha Alahari

The Nice meeting is behind us (*sigh*)—and will be way behind us by the time you read this. This was my first EMWA autumn meeting and I felt disappointed that it was so short, especially as it was held at such a lovely place. I hope you were all there and that none of you missed the lively opening session starring Helen Baldwin and Alistair Reeves. Alistair was hilarious as he vented his frustration with daft writing. Helen gave an infotaining (*adj., n., infotainment*) presentation entitled “Living and working in the South of France”. The title was precise; it was not about working in France, but about working in the South of France! Her presentation made me reflect on my own experiences in France, as a scientist and a scientific writer. Currently, I am living and working in Caen, Normandy, Northwest of France. About a decade ago, I spent two years in Nice as a post-doc at the University of Nice and Sophia-Antipolis, in the South of France. In the accompanying table (Table 1) I’ve compared living and working in Nice versus Caen—you’ll get a general picture of the contrasting conditions.

Table 1: Nice versus Caen

Characteristic	Nice, South of France	Caen, Northwest of France
Population	343,000	114,000
Climate (annual figures)	2668 h of sunshine, 668 mm of rain	1873 h of sunshine, 723 mm of rain
Beaches	French Riviera	D-Day beaches
	Fun and frolic	Serious, awe-inspiring history
	Marked tendency to cast-off clothes	Coats, windcheaters, mufflers, gloves, etc. are recommended
People	French with a touch of Italian	French with a touch of English
Food	Rosé, socca, pissaladière, beignets	Calvados, cider, camembert, tripe
Industry	Fair amount of pharma, mw	Cows, apples, 1 mw*

\* Anuradha Alahari is the only known medical writer in Normandy.

Caen is a charming little town, stuffed to the gills with history. For example, I didn’t know it at the time I rented it, but my previous apartment used to be part of a printer’s workshop, at a time when the printing press was as sensational as the iPad is today. Most of the ancient structures were reduced to rubble during the famous D-Day bombings of World War II, but a few churches and parts of the castle built by William the Conqueror survived. The castle, along with other heritage remnants of that era are the main tourist attractions in Caen. The glorious D-Day beaches are about a 20-minute drive from here. In downtown Caen, a majority of the buildings were hurriedly built post-war

and it is evident that quality was passed over in the need for speed. Nevertheless, the city has not lost its old charm and is in the continuous process of development and modernisation, albeit at a slow pace. And the sky is not grey all day, everyday—indeed, it is blue and sunny for some time every day all through the year. Then, the people are generally nice, very French. Yes, you do see the quintessential baguette under the armpit sometimes. I was struck by the homogeneity of the population, which is so rare in larger cities. For instance, at the local neuroimaging and research centre where I worked for a while, I was one of the few non-French researchers and the only non-European they had ever hired!

How I landed in Caen is another story that I’ll save for a rainy day. Let’s just say I found myself in Caen. Up until then, I had led an exciting life playing ‘scientist’ in various labs in different parts of the world. However, at the University of Caen or at the few local research institutes, it seemed impossible to find a placement. Eventually, I wrote a grant proposal and obtained my own funds that allowed me to work collaboratively in a well-equipped, neurobiology lab. It soon became clear though, that any long-term plans of staying in research and in Caen would necessitate too many compromises that I was not prepared to make. Finally, sometime in the middle of 2009, after a long and serious SWOT (strengths, weaknesses, opportunities and threats) analysis, I surrendered the pipette and took up the pen. The legal declaration as a freelance medical writer in France was not exactly a walk in the park, but was not as tough as I had anticipated either. Several of my friends congratulated me saying I was brave to take this step, and every time I heard that, a little voice whispered, “fools rush in where angels fear to tread”. So I smiled at them weakly and continued with hope in my heart. I work out of my home, like most freelancers. The guest-cum-junk room was transformed into my office, which keeps out the guests but not so much the junk.

My first attempts to forge client contacts in Caen were a mixed bag. Most people were unaware of what medical or scientific writing is. When I offered to rewrite their manuscripts for them, they were like, “can you do that?” and I was like, “try me”. Those who knew me from my earlier life as a scientist, felt confident enough in my abilities, while others whom I contacted by e-mail, were a bit flummoxed. First of all, they had never heard of a name like mine—it didn’t convey anything to them. On learning that I hail from India, they wondered about my capabilities in English. And then there were those who considered that

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scientific writing is part of a scientist's job and it is unethical to outsource it. Of course, I understood their apprehensions—I would have been suspicious myself if I was in their place. My only recourse was to try and convince them and ask them to wake up and smell the coffee. Well, you win some, you lose some, right? I now have a fair bit of following at Caen University-Hospital and a cancer research centre and the word is getting around. Also, they are oh! so relieved that they don't have to deal with me in English and fortunately they seem to understand my French. My major sources of irritation are the bureaucratic delays and the taxes (alluded to by Helen too, in her presentation). Hey, I'm getting used to it. Having said all this, I should add that it's possible that as a freelance medical writer just starting out, I might have had similar experiences in some other small town elsewhere in France.

So, the view from here is: sure, I am not working in the French Riviera nor in a happening place like Paris—I go there for vacations! All said and done, our kind of work is predominantly conducted via the Internet. In fact, the bulk of my business comes from outside Normandy, from outside France even. Personally, I am glad to be tucked away in this quaint little corner of France, quietly minding my own business. It works for me. An ambition to grow and succeed, and a fire in the belly (I don't mean the one after eating Indian food), are not likely to be dampened by the Normandy weather—it's all in the mind.

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## Professional Indemnity Insurance

Professional Indemnity Insurance is an often-raised subject at the EMWA Freelance Business Forum (FBF). A small number of insurance companies now offer policies. The majority of freelancers remain uninsured, taking the view that as clients sign off on all authored documents, this effectively indemnifies them. From freelance discussions at the Nice FBF (12 November 2010), which focussed on insurance being taken out in the UK, we conclude:

- It is difficult to find an appropriate provision.
  - PIA commercial may be able to offer a suitable policy. Their insuring clause is relatively loose and they can provide different levels of limited liability. The premium should be in £100's/year but will be dependent on the personal circumstances of the individual
  - Hiscox offers similar insurance. An individual can stipulate the limit of liability to be the value of the contract being undertaken for a given client, or can stipulate the amount taken out in insurance
- Being a limited company will also limit your liability.

## Freelance Resource Centre

Where can you find information of specific interest to the freelance medical writer? The answer is the Freelance Resource Centre (FRC) on the EMWA website. The FRC is a collection of good freelance advice from various sources: articles from *TWS*, minutes from the biannual Freelance Business Forum (FBF), and discussions from the now retired Freelance Email Discussion Forum. The FRC has recently been updated and now contains over 120 items categorised according to topic:

- Advice on starting-up and running a freelance business
- Legal aspects of running a freelance business
- Technical advice
- The personal experience of freelancers
- Journalism and translation, careers typically dominated by freelancers
- Conference forums, including FBF minutes, and e-mail discussions
- A general category, covering miscellaneous articles not fitting into the above categories

As you can see, you can find lots of useful information on different aspects of freelancing, and there is more to come. The FRC is a growing resource for new and experienced freelancers, where relevant materials from the FBF and the Out On Our Own section in *TWS* are (ir)regularly added as they become available. Behind the scenes, it is a collaboration as I manage the FRC updates with input from the EMWA Freelance Support Group, and the EMWA web team provide technical support.

Since the launch of the FRC in January 2010, there has been some maintenance work, but with changing requirements, we may need to do a thorough makeover of the FRC structure. What a new version would look like depends on what you, the EMWA freelancers, want. So, have a look at the FRC, and let us know of any ideas you have on how to develop this great resource to increase its usefulness and reflect your needs.

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## My first EMWA conference: Reflections of a newbie

by Jason Willis-Lee

Although I took out EMWA membership approximately 18 months ago, it has taken me a while before deciding to commit to attendance at my first actual conference which was the 31<sup>st</sup> of the Association—held at the comfortable Radisson Blu hotel in Nice in the South of France.

I live and work in Madrid as a freelance medical translator, hired mainly by universities, medical communication agencies and clinicians who wish to publish research articles in academic journals. Medical writing was on my radar but not a top priority at the time of joining EMWA. As my work has evolved more specifically towards medical research articles I began to realise that some of the training workshops would be directly relevant to what I do, so I finally decided to take the plunge. I was also encouraged by the fact that EMWA assigns first conference attendees a buddy to help them network and explain the ropes. My buddy was Alison McIntosh. I considered myself fortunate that I had already met Alison a couple of years earlier in London during an introductory session to medical writing and she very ably took me under her wing in Nice.

I was not to be disappointed by the conference itself. After two very informative and entertaining introductory sessions by Helen Baldwin (Living and Working in the South of France) and Alistair Reeves (Why Sensible People Write Daft Things) on the Thursday evening followed by an informal networking reception, the conference workshops kicked off the next day.

I had signed up for the workshops Writing Successful Manuscripts (Julia Forjanic and Phil Levanthal), From CSR to Manuscript (Helen Baldwin) and Basic Concepts of Study Design (Rosemary Binchoff and Adam Jacobs).

My first workshop, Writing Successful Manuscripts, was extremely helpful to me, as I frequently translate or edit research papers for Spanish hospital clinicians and there were lots of tips to be picked up. I was particularly interested to learn of the existence of an online tool, <http://bit.ly/TGDpG>, to help identify the most appropriate journal to send the paper. Often, authors do not have this clear in their mind, and it is of paramount importance to clarify this before commencing the writing process, not least because the writing must always comply with the Instructions to Authors which differ from journal to journal.

My next workshop, From CSR to Manuscript, taught attendees how to convert Clinical Study Report text based on ICH E3 guidelines into manuscript format and an appreciation of the major differences between these two documents. As I listened, I found myself starting to ponder whether I could actually offer my clients the additional service of writing their manuscript if they gave me their raw data and other necessary documentation. What I was most struck with

from this session was the importance of having a clear, central message before writing (or translating!) the manuscript at hand. My experience working with clients shows me that this is frequently not the case. There is often vague discussion about a topic with 2-3 conclusions drawn but no central take-home message. Since the medical translator is frequently the first filter of a manuscript before it is submitted for peer review or journal reviewers, they are a very important part of the feedback loop.

My third and final workshop at the conference, Basic Concepts of Study Design, provided an extremely thorough overview of how clinical studies are designed and what the implications of these decisions are for clinical trials. Many issues were dealt with including sample size, administration of active vs. control drug, blinding, bias, and the ethical aspects of current clinical trials. This workshop was of particular interest to me as my curriculum vitae includes a stint of work experience as a clinical research associate where I was responsible for collating clinical trial data for a British company specialising in cognitive function assessment. It will definitely help to enhance the overall picture when working on biomedical articles aimed for publication.

I also regularly attend biomedical meetings of other groups such as Mediterranean Translators and Editors (MET) and, for the first time, Biospain 2010, held this year in Pamplona. For those of us living in Spain and affiliated to Spanish-based groups, EMWA workshops and social events are certainly more expensive. As EMWA was my third and final conference for 2010, I was on a tighter conference budget and opted not to sign up for the social events this time.

I also attended the freelance business forum in Nice as I felt this would be a good idea to pick up networking ideas. Attendance was good and there was a lively discussion on freelance issues. I will certainly keep a close eye on the EMWA website for freelance opportunities and consider signing myself up for the freelancer mailing list.

All in all, I am pleased to report that my first EMWA conference was an extremely positive experience and I would urge my medical translator colleagues who have not yet joined EMWA to consider attending one. I believe the principal benefit for me will be training directly related to my work and I am already giving serious consideration to attending the next conference to be held in Berlin in May 2011.

### Acknowledgements

I am most grateful to Thomas O'Boyle and Raquel Bilonio for making some useful comments on an earlier version of this article.

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## Out of Hours

Sam kicks off the first in a series of articles on alternative forms of writing that medical writers get up to ‘out of hours’.

### **Describe the type of writing you do ‘out of hours’.**

I have dabbled in various other doodlings, which in the past have included creative writing, writing for charities and researching and writing up my family history.

### **Do you have a favourite topic or a preferred style of writing?**

Yes, I really enjoyed the challenge of creative writing after such a long break as I hadn’t done any since I was at school. I was afraid that with all my scientific training, I would have forgotten how to be creative, but I’m happy to say, it was like riding a bike, and just as much fun! My favourite ‘out of hours’ job so far has to be writing up my own family’s interesting history.

### **Describe a recent assignment.**

In 2007, I completed the two-year long labour of love of writing up my family history. My parents’ and grandparents’ stories were so interesting that I felt committed to getting them down on paper before the chance slipped away. I worked with my dad to a large extent to capture his memories, and I discovered in the process where I got my ability to write from. His contributions were well thought out and very moving. The process was cathartic for my dad who hadn’t given voice to some difficult issues for a long time, and it brought the two of us closer together. Other family members were very generous in what they shared too.

### **How did you choose the topic?**

This was always something that I had wanted to do, and as the last generation aged, I realised I couldn’t delay it any longer. I wanted to make a living document that my children’s generation could read and add to if they so wished. I was so well-supported by the rest of the family that I feel the topic really chose me, not the other way around.

### **What did the assignment involve?**

I wrote a plan for the project as a whole and circulated it to interested members of the family by e-mail. I then discussed each person’s intended contribution with them, to help them develop their ideas. As they provided their contributions, where I saw a really interesting story that I thought needed more focus, I solicited a more in-depth piece about it from the family member in question. Some were able to write with relatively little support, but others needed a little more guidance. An aspect that I couldn’t help so much with initially was the creation of both my maternal and paternal sides of the family tree. This was mainly done on paper by the older generations and was posted between the UK, USA and Pakistan to add detail. I then reproduced the resulting tree electronically. As we discovered more and more information, I would receive emails from family members and update the tree accordingly. The family history now consists of the tree documents, plus a collection of memories and anecdotes written by three generations of my family. I had copies of the document hard bound for all the children in the generation subsequent to mine, and distributed these at Christmas 2007.

### **Describe how this type of writing helps you with your technical work.**

Creation of the tree was a challenge and I am now an expert in creating large flow diagrams in Microsoft Word!

### **How do aspects of your technical work help with your writing “out of hours”?**

The project required extensive project management—a skill I use daily in my medical writing work. The editing and proof-reading skills I have acquired over the years were also put to good use in this project of contributions from non-professional writers.

If you have an ‘out of hours’ story to share, please contact Raquel at [medical.writing@billiones.biz](mailto:medical.writing@billiones.biz)

## EMWA freelance logo design competition

The freelance section of *The Write Stuff* (TWS), ‘Out On Our Own’ (OOOO) is getting a new logo. We are lucky to have the help of a graphic designer but also want to give you the chance to be involved. EMWA members are therefore invited to use their creativity and submit their logo ideas and designs for consideration.

The logo should contain the words ‘Out On Our Own’ or ‘EMWA Freelancers’, if possible. Ideas can be provided descriptively; designs should be submitted in any of the following file formats: .eps, .wmf, .pdf, .tif, .jpg, or .bmp and be e-mailed to [sam@samhamiltonmwservices.co.uk](mailto:sam@samhamiltonmwservices.co.uk) and [medical.writing@billiones.biz](mailto:medical.writing@billiones.biz) by 20 April 2011.

The winning entry will get a graphic design makeover prior to launch; will appear in each subsequent issue of TWS and will become synonymous with the EMWA freelance contingent. The winner will receive a prize and be interviewed for OOOO—and, of course, be elevated to cult freelance hero status! The final logo will be unveiled at the Berlin May 2011 Freelance Business Forum.

Please show your support: Get involved, share your hidden talents and make an enduring contribution to *your* organisation, EMWA. Happy designing!

## ■ Biomedical publishing shorts

### Social effects of misrepresentations in reports of studies in ADHD

Francois Gonon and colleagues have recently published findings on data misrepresentation in attention deficit hyperactivity disorder (ADHD). They identified three types of misrepresentation in the scientific literature: 1) inconsistencies between results and conclusions claimed in the title and summary, 2) firm conclusions in the summary with raw data that strongly limit the claim only given in the results section, 3) extrapolation of basic and pre-clinical findings to new therapeutic prospects in inappropriate ways.

Whereas the first two types of misrepresentation obviously corrupt the message received by the public and physicians, extrapolation from studies in animal models, which are not suitable to develop psycho-social interventions, are also dangerous because they support drug treatments as the only solution to mental disorders.

The distortions were carried over into the media where they found few discrepancies with conclusions in scientific articles. Scientific articles that overstate the therapeutic prospects are more likely to be accepted for publication by leading journals and articles reported in the media are more likely to be cited, thus carrying advantages for both authors and editors.

The data misrepresentation biased the evidence towards the stand that ADHD is caused by biological factors as opposed to social or environmental factors and thus should be treated with drugs rather than by psychotherapy. The authors illustrated the social effects of the misrepresentation in relation to the dopamine deficit theory of ADHD. This theory is often supported by the finding that psychostimulants alleviate symptoms and enhance extracellular dopamine levels but without mention that psychostimulants have the same effect in healthy children. Studies to search for biomarkers are thereby encouraged (although no biomarkers have been validated in psychiatry to date), subjecting children to intrusive interventions.

The authors suggest that the misrepresentations can lead to the public becoming suspicious of neuroscience, which could affect allocation of future funding to the science. The neuroscience community is urged to lobby for grants for research which is not linked to drugs, editors are urged to reject sensationalism and condemn data misrepresentation.

**Source:** Gonon F, Bezard E, Boraud T. Misrepresentation of neuroscience data might give rise to misleading conclusions in the media: The case of attention deficit hyperactivity disorder. *PLoS ONE* 2011 available at: <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0014618>

### Ghostwriting

An attack on medical writers can be read in an article titled 'Playing Doctor' written by Carl Elliott from the University of Minnesota and published in *The Atlantic Magazine*. It has prompted quite a bit of discussion with mentions of EMWA's guidelines and a contribution from Adam Jacobs, EMWA's press officer. The article is available at: <http://bit.ly/9x9NLb>.

### The average adult cannot understand Parkinson's disease webpages

Patients increasingly use the Internet as a source of healthcare information. Fitzsimmons and colleagues have published an interesting study in which they determined the readability of the 100 highest ranked consumer-orientated Parkinson's disease webpages. They used the Flesch-Kincaid and Simple Measure Of Gobbledygook (SMOG) readability tests and found that only 1% of the webpages were fully comprehensible to the average adult when the SMOG formula was applied. The authors favoured the SMOG test as the Flesch-Kincaid formula significantly underestimated reading difficulty.

The article discusses health literacy which it defines as "the ability to perform basic reading and numerical tasks required to function in the healthcare environment". Poor health literacy leads to poor treatment compliance. Some alarming statistics are presented, e.g. 16% of the UK population has low general literacy skills. As the UK has no quantitative guidelines on the readability level at which patient-orientated literature should be pitched Fitzsimmons and colleagues referred to the US guidelines which recommend that text should be written at or below the sixth-grade level (ages 11–12). Most pages (60–89%) were, however, written at above the 12th grade level.

**Source:** Fitzsimmons PR, Michael BD, Hulley JL, Scott GO. A readability assessment of online Parkinson's disease information. *J R Coll Physicians Edinb* 2010;40:292–296. Available at: <http://bit.ly/glhcmY>

### Manuscript abstract word limits

Most journals restrict the number of words authors can use in the abstract of their manuscript. This restriction was based on the length of abstracts allowed in MedLine. However for records created after the year 2000 the maximum length for abstracts in MedLine/PubMed has been increased to 10,000 characters, which would allow for up to 600 words and accommodates a CONSORT or PRISMA style abstract. The question is how many journals are aware of this change?

**Source:** <http://www.nlm.nih.gov/bsd/mms/medlineelements.html#ab>



## Looking more closely at our attitude towards mistakes

*Most people die of a sort of creeping common sense, and discover when it is too late that the only things one never regrets are one's mistakes.*

Oscar Wilde

Even the most casual reader of *The Write Stuff* will have noticed a substantial typographical error on the front cover of the last issue; those who did not, and those who did but graciously put it out of their mind at once, may wish to refer to the Errata sidebar. Another chunky copy-and-paste blunder appeared inside the same issue. After noticing these errors myself (far too late to correct them, of course) and after several days of wishing that the buck stopped somewhere else, I remembered that we are supposed to learn from our mistakes and set about tracing the sources of mistakes and our attitude towards them.

I sought out research on why, rather than welcoming the opportunity to learn, we react to our mistakes by chiding ourselves, looking for someone else to blame, trying to cover up the mistake or comforting ourselves with the thought that others make mistakes too. Soon I found an article that Rick Brenner, a fellow editor, wrote on the topic after he had made a mistake in the configuration file of the newsletter he edits [1]. He argued that we have such a hard time accepting our mistakes because there is a survival rule that forbids the making of a mistake. Survival rules he defines as over-generalised imperatives that we usually learn when very young, like “I must eat everything on my plate.” As we all make mistakes, rather than prohibiting them Brenner commends a more forgiving approach such as “I do my best not to make mistakes, and I’m human.” (Sesame Street character, Big Bird, went a step further with his motto “Everybody makes mistakes, so why can’t I?”) Brenner believes that reframing mistakes can turn them into gifts in disguise, such as the realisation that mistakes are not fatal (you’re still alive), or opportunities to practice owning up to mistakes, or providing a service to the community by making everyone around you feel better about their own fallibility. Another gift I would suggest is the delightful *Schadenfreude* that the tidings of your mistake can spread among your fellows and the comfort that everyone loves a failure.

From childhood on we are praised for getting things right—not for our mistakes. However, Carol Dweck, a professor of psychology at Stanford University, believes that—while we should not exactly be lauded for erring—praise is more constructive if it is given for making effort and for learning from mistakes, rather than (as is usual in our society) for being clever (as cited in [2]). She studied 400 fifth-graders in the USA, half of whom were praised for being clever and the other half for their effort. She then confronted the students with the choice between an easy task in which they knew they would do well and a more interesting and challenging one where making mistakes was more likely. Most members of the group who had received praise for being clever chose the easy option. By

contrast, 90% of the group who had been praised for effort chose the challenging task. The students were subsequently given a difficult test in which they were bound to do badly and asked to report their scores anonymously to another school. 37% of the ‘clever’ group lied about their score against only 13% in the ‘effort’ group, pointing to the social consequences of demonising mistakes.

Within the business world an internationally renowned thought leader in the fields of strategy and decision making, Paul Schoemaker, points out the incongruity between our fixation on achievement and our demand for innovation, stating that if you avoid error you avoid the learning process (as cited in [2]). Risk-adversity, he claims, arises because personal and professional pride are tied to being right. As a result we expend too much time and energy on avoiding mistakes. Employees who do not make mistakes “may become so good at the game that they’re used to playing that they no longer see ways to improve significantly”. But, equally, perpetrators of error who fail to learn from their mistakes will not be innovative and are a burden to their employers and to themselves. Naturally though, there has to be a balance between taking chances that can be afforded and ones that endanger your own or other people’s well-being.

Mistakes, then, are an interesting topic that is fraught with ambiguity. However if fate decreed that I had to make a mistake on the cover of *TWS*, then the only thing I regret is that it was not a funny mistake. One like the “massage from the president”, or my wonderful discovery in a previous job that the publisher had placed the caption for the editor-in-chief’s portrait photo under a picture of a mouse [3]. Another enviable mistake was reported to me by Neville Goodman. A book he contributed to was printed with “Forward by Prof V. Important”, emblazoned on the cover. The professor was less than amused and insisted that the entire print run be pulped and reprinted.

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### References:

1. Brenner R. When You Make a Mistake. *Point Lookout* 27 March 2002 Available at: <https://www.chacocanyon.com/pointlookout/020327.shtml>
2. Tugend A. The Many Errors in Thinking About Mistakes. *The New York Times* 24 November 2007. Available at: <http://nyti.ms/hvVnoN>
3. Langdon-Neuner E. From the Editor’s desk: Editing and Writing. *TWS* 2004;13(3):64-65.

### Errata

**Erratum** on the cover of *The Write Stuff* 2010;19(4). The words depicting the theme of the issue “A femine workforce” should have been written “A feminine workforce”

**Erratum in** De Faoite D. Doctor, manager and mother: An interview with Beate Hanson. *The Write Stuff* 2010;19(4):257-258. The text on page 258 is a repetition of the text on page 257. The correct texts for pages 257 and 258 are included as an insert in this issue of *The Write Stuff*.

These errors were the fault of the editor and the publisher. We sincerely apologise to the members of EMWA and subscribers to *The Write Stuff* as well as to Diarmuid De Faoite and Dr Hanson.

## Words, Grammar & Co

### Bloods and urines

*The pH of 2-hour fasting urines (2<sup>nd</sup> morning urines) was determined.*

*All bloods must be analyzed within 2 hours of collection.*

Although ‘urine’ and ‘blood’ look like countable (concrete) nouns, they are actually uncountable (abstract) nouns and are never used in the plural in formal writing, or even informally outside the healthcare sector. Talking about ‘urines’ or ‘bloods’ is jargon and should be reserved for lab notes, informal e-mails, or when speaking informally. To make them countable and acceptable for formal writing, the easiest thing is to add the word ‘samples’.

### Semicolons and e.g.

Karl Kleine of Simply Quality in Weilheim, Germany writes:

*I am writing up my notes from a qualifying visit to a laboratory and in the study protocol related to this visit, the abbreviation e.g. was frequently (not consistently) followed by semicolon, i.e. ‘e.g.;’. This is not the first time I have seen this and I am curious if this is a rule or whether there are different possibilities and you should just be consistent.*

I have also recently seen e.g. followed by a semicolon, which is nonsense. A semicolon means ‘What I have just said is completed; something closely related will follow’, or is used by some people (not me) as a separator in lists or at the end of bullet points. I often hesitate to say that something is wrong in English, but to me it definitely is wrong to use a semicolon after ‘e.g.’. It would at least be understandable if it were a colon. The main meaning of the colon is ‘I am now going to explain what I introduced before the colon’, so there would be some logic in its use, explaining what the examples are. However, it is so obvious when you write ‘e.g.’ that you are going to give at least one example that inserting a colon is totally unnecessary.

Some people feel the need to use a comma after i.e. and e.g., and indeed, this is preferred by some style guides and is sold as a ‘rule’ by some people. As far as I am concerned, this is also unnecessary and a waste of time, and it is certainly not a rule. It is not only a waste of time doing it—you also have to waste considerable time checking that you have been consistent.

I also always use both with the full stops. Some people prefer ‘eg.’ > and ‘ie.’, or just ‘eg’ and ‘ie’. All are used in many different publications, so it is difficult to say that the latter two are wrong. I just prefer the full stops.

We always have to remember with English that even someone as eminent as George Bernard Shaw refused to use the apostrophe (calling them ‘uncouth bacilli’) and insisted that his plays be printed without them. So there is always a lot of room for personal preference in English. I actually agree with Shaw about the apostrophe, but still use it, and I like to think that he would have agreed with me with regard to the use of the semicolon after ‘e.g.’.

### More overwriting

*After providing patients with a complete description of the study, informed consent was obtained before conducting any study procedures.*

Informed consent means ‘providing patients with a complete description of the study’ (and more actually!), so it suffices to say in your publication or report:

*Informed consent was obtained before conducting any study procedures.*

**Alistair Reeves**

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### A fun dictionary of rare words

*The Grandiloquent Dictionary* is a collection of the most obscure and rare words in the English language put together by Christopher Bird, who is a theoretical physicist. The dictionary is an ongoing project and currently contains about 3000 words. It can be accessed online, downloaded as a pdf or purchased as a book.

It’s fascinating but you need a *feriation* (taking time off of one’s work to relax or to travel) to really enjoy it. I started to explore the dictionary at the letter ‘T’ because I had just read the word *toponymics* and was keen to discover its meaning (the study of place names). It was comforting to see *temerity* (a form of extreme boldness) in the section as I knew what that meant, but otherwise the words were mostly new to me. Many of them were the names of phobia, e.g. *torschlusspanik* (fear of young women that they will not be married until they are too old to have children), *triskaidekaphobia* (fear of the number thirteen) and *frienderphobia*, which contrary to expectation is not a fear of friends but a fear of forgetting a password.

While female medical writers might fear a *tibialoconcupiscent* (having a lascivious interest in watching a woman put on stockings), male medical writers are more likely to suffer from *lysistrataphobia* (fear that women will subvert men and take over the world). *Wegotism* is something that scientists seem to fear (the excessive use of ‘we’ in writing). Perhaps some medical writers are *logastellus* (a person whose love of words is greater than their knowledge of words). But shame on any of us who do not know what a *lohock* is (medicine which is administered by licking it).

After a session reading the dictionary you will need a *lopadotemachoselachogaleokranioleipsanodrimhypotrimmatosilphioparaomelitokatakechymenokichlepiakosyphophattoperisterektryonoptekaphalliokigklopeiolagoiosiraiobaphetraganopterygon* (a goulash composed of all the leftovers from the meals of the leftovers from the meals of the last two weeks) and to retire to *lubberland* (a mythical paradise reserved for those who are lazy), where hopefully you will not feel like a *wuntee* (a lonely old buffalo bull).

With many thanks to Alistair Reeves for passing on this website: <http://bit.ly/BB0e>.

## An unlikely source

I landed on a useful grammar resource site (<http://bit.ly/xHtoi>) when searching Google to find out if ‘correlates with’ or ‘correlates to’ is correct. The site is designed to advise hopeful students on preparing MBA applications and beating the GMAT (not Greenwich Mean Astronomical Time but Graduate Management Admission Test), but has other useful information such as ‘correlates to’ is correct (although Google comes up with about as many ‘to’s as ‘with’s). The site has a sentence correction area and grammar articles, e.g. one entitled ‘Count Nouns and Mass Nouns—Choosing the Right Modifier’.

## The evolution of the acronym

Are the kids starting to ruin our language with their text acronyms? Not according to Lane Green writing in the *Intelligent Life* magazine. Acronyms took off in the First World War when soldiers invented subversive acronyms as a way of coming to terms with the shadow of death and a life dominated by a massive military bureaucracy. But acronyms soon caught on in other fields, starting with the new economic programmes brought out by governments in the Great Depression. These had long names that naturally condensed into acronyms.

In science, he suggests, the acronym had the attraction of making something feel scientific and controllable. Hence the progression from Latin- and Greek-derived names for illnesses (e.g. cholera, mania) to a series of polysyllables in the late 20<sup>th</sup> century (acquired immunodeficiency syndrome), which became known as AIDS and co. Then the marketing folk came along. Green illustrates their influence as “Having a hard time getting men to their doctor about certain boudoir-related issues? A clever two-stop solves the problem. Dub it “erectile dysfunction”, and then since nobody wants to talk about that either, “Ed”. Before you know it, celebrities are advertising your medication”.

In the business world what started as the boss’s or managing director’s recreation as the CEO has become a viral infection with the CIO, CTO, CFO, COO etc. Green mentions that the VPs and SVPs members of LinkedIn are growing three to four times faster than the membership overall and asks “Who, then, is managed anymore?” Acronyms certainly have their uses though: some express notions which cannot be expressed otherwise, e.g. SNAFU (situation normal: all fucked up). This is not just screwed up but a “screw up caused by some title-inflated CTO or SVP trying to impose TQM (total quality management) on his remaining subordinates.”

**Source:** Green L. When did we start speaking in sets of capital letters? *Intelligent Life* Autumn 2010:62-66

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## How to start e-mails: As many views as salutations

The BBC reports that Giselle Barry, who is US congressman Ed Markey’s spokeswoman, wrote an e-mail to some reporters with the salutation “Hey, folks”. *The Wall Street Journal* was less than impressed noting that e-mail communications are sending ‘Dear’ the way of sealing wax. Jean Broke-Smith, described as an etiquette guru, maintains that if you send a business e-mail politeness still requires that it starts with ‘Dear’. Barry’s point, however, is that this is too intimate if you do not know the person. While social behaviour expert Liz Brewer thinks you should not presume the familiarity that ‘Hi’ conveys. Rather you should treat introducing an e-mail like arriving at a party “Better to be overdressed. You can always take off the pearls”.

The article together with its readers’ comments covers every view imaginable. Here are a selection:

- ‘Dear’ gives your age away “It’s old-dearish”.
- Starting with just the person’s name is the solution. No it’s not. It’s rude.
- Greeting with the time of day, e.g. “Good morning”, followed by the person’s first name is polite and not too personal, but ok for friends too.

One reader advocated starting with ‘Hi’ and ending with ‘Kind regards’, which seems incongruous as ‘Hi’ is informal and ‘Kind regards’ formal. Brewer believes you can never go wrong with ending ‘Best wishes’. The sign-off ‘Cheers’ also came under fire from one reader but was valiantly defended by another who pointed out “Cheers is not too shallow. It’s a happier and less drab way of saying thank you”.

The crux of the matter as expressed by the final comment on the article is that “As English lacks any sort of address form other than ‘Dear...’ for the beginning of letters, I would suggest that using ‘Hi’, ‘Hello’, and the like is simply an attempt to create one. However, these attempts are not successful (not polite!). Until someone comes up with a polite form of address other than ‘Dear’, you had better stick to it.”

**Source:** <http://www.bbc.co.uk/news/magazine-12247262>

## Positive negation

After cultivation of T cells and antigen-pulsed B cells, TNF- $\alpha$  was immeasurable (3 pg/mL) in the supernatant.

Strictly speaking, this sentence should be OK, but *immeasurable* doesn’t work here. Why, you might ask – *measurable* means that something can be measured and *im* is a prefix that negates in English, and the dictionary says it means *not measurable*. But the dictionary also says that it means *immense*. And this is why *immeasurable* doesn’t work here. It is used when something is too *big* to measure (like wealth or harm) and not when it is too *small* to measure. This author should have chosen *not measurable* or *was below the limit of detection in the supernatant (3 pg/mL)*.



## ■ For regulatory writers

## Trials and tribulations

The Clinical Trials Directive 2001/20/EC [1] will be 10 years old this April. At the time when the directive was drafted, the procedures for conducting clinical trials in Europe varied greatly from country to country. The resulting administrative and logistic burdens, particularly in the case of large European-level multicentre trials, were considered a hindrance to drug development while the quality of trials and level of patient protection were uneven. The Directive represented an opportunity to homogenise the conduct of clinical trials and to ensure that good clinical practice was always implemented, ultimately ensuring greater patient protection, or so the reasoning went.

As we approach the 10-year milestone of the Clinical Trial Directive, and as part of the preparation for an imminent overall, a public consultation paper was issued by the European Commission to obtain feedback and opinions from some of the stakeholders [2]. The responses were not always flattering (for a summary, see [3]).

## Has harmonisation really occurred?

One of the major problems of the Directive is that it is, just that, a Directive. In European law, this means that the member states have a certain amount of leeway in how its content is implemented. Many member states seem to have interpreted the Directive in the context of their pre-existing practices, with the result that procedures and documentation requirements for setting-up and conducting a clinical trial can still vary from country to country. Another potential headache is that a trial can be approved by the health authorities of one country but rejected by those of another. The Directive would therefore seem to have failed in one of its major objectives—that of unifying clinical trial conduct across Europe.

## Has the Directive stimulated quality research?

While the more formalised procedures introduced by the Directive, with the requirement for full insurance and a generally greater burden of liability on the sponsor, may have helped protect patients (though respondents in general weren't fully convinced), some have openly criticised the Directive for hindering independent research. In oncology in particular, so-called 'investigator-initiated trials' have a long tradition of advancing knowledge and improving treatments [4]. Often these trials are aimed at optimising aspects of already licensed therapies, and so some argue that the trials can be considered 'low risk' (in the sense that the active treatment shouldn't hold any nasty surprises) and so could be treated differently. It has been noted that after the introduction of the Directive, the cost of conducting clinical trials in oncology increased 85% and there is the worry that important independent research is being compromised. A direct cause-and-effect relationship cannot be assumed, but it seems fair to say that the Directive has not delivered with regards one of its major objectives—that of encouraging competitive research by European countries.

## Some good news

Although the Directive may have failed to provide a more harmonised environment and has probably increased the

cost of clinical trials, the conduct and reporting of clinical trials has improved since the Directive came into force. Again, a direct cause-and-effect relationship cannot be assumed as awareness of ICH and GCP principles may have improved without the Directive, but most respondents to the public consultation gave it some credit.

## The way forward

In conclusion, although the Directive was introduced with the best intentions in the world, it seems to have failed in important areas. It is hoped that the coming changes will go some way towards rectifying these shortcomings. Possibilities include streamlined authorisation (via a reference health authority), central authorisation (partly analogous to the centralised approval procedures for drug products) and voluntary harmonised procedures. These options all have their drawbacks, and their implementation in the much awaited overhaul would need to be done carefully given the experience with the Clinical Trials Directive itself, which has not been all that positive.

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## References:

1. See <http://bit.ly/eMUdZ2>, accessed 3 January 2011
2. See <http://bit.ly/f44OKR>, accessed 3 January 2011
3. See <http://bit.ly/hRzxUC>, accessed 3 January 2011
4. Hemminki A, Kellokumpu-Lehtinen P. Harmful impact of EU clinical trials directive. *BMJ* 2006 Mar 4;332(7540):501-502.

## Inclusive or overly insensitive?

According to the AMA Style Manual, we should try to avoid labelling people with their disabilities or diseases (see page 416 of the 10<sup>th</sup> edition). Thus the phrase 'patients with diabetes' (putting the patient first) is preferable to saying 'diabetics' (a label, us vs them). In a further attempt to ensure inclusive language, the same section then suggests that we avoid using emotional terms such as 'suffering from' that suggest helplessness. While this may seem like good advice in some contexts (we generally wouldn't write "X patients suffered Y adverse events"), in others it might seem slightly absurd; someone with advanced emphysema is surely suffering (and not just 'experiencing' problems with their breathing). In going out of our way to avoid turning the patient into a victim, we might sound like we (or the physicians we write for) lack empathy with the patient. The risk is that the practice of medicine sounds dehumanised, even though the human relationship between physicians and their patients is central to clinical practice. Sometimes, we can perhaps be overly sensitive.

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## Current medical discourse research

### Important aspects of teaching English for medical academic purposes



Sofija Micic is an Associate Professor of English, Belgrade University Faculty of Medicine, Belgrade, Serbia. She has extensive Medical English language teaching experience and is also involved in medical translation. She has published articles in specialised journals, three books (one on medical collocations), a textbook and a bilingual, English-Serbian

Serbian-English, medical dictionary. Sofija has been an active participant at national and international conferences on teaching and translating English for Specific (Medical) purposes. Sofija was a Fulbright Scholar (2004/05), a Salzburg Seminar Fellow (2005) and a Morley Scholar (2007). She is an editor of the column 'Language of Medicine' in the oldest medical journal 'Serbian Archives of Medicine' (in 2009 she was appointed the first non-medical Member of the Editorial Board of the journal). She is also a proofreader for the English language in the above journal. Sofija was an European Professional Development Committee member of the European Medical Writers Association (EMWA) (2007-2009). She was awarded the City of Belgrade prize for Education for her Medical Dictionary (2007). Dr Micic is involved in the development of the international project on standardization of the English for Medical Purposes test (since 2009). The 2<sup>nd</sup>, revised, edition of Dr Micic's Medical Dictionary is in press.

#### Abstract 8

Micic, Sofija. *Collocations in Teaching English for Specific Academic Purposes*, Philological Review, XXXIII, 2, 2006, 131-149.

The aim of the paper is to show that technical vocabulary may be successfully mastered via teaching collocations.

The study introduces a polysystemic view on lexis according to which lexical fields represent subsystems of lexicon as a system. It is suggested that a 'word' is no longer a basic unit of meaning. The term 'lexical unit' should be used instead. Lexical field includes nouns, adjectives and verbs as its main constituents.

The importance of dependency grammar is stressed with its hierarchical, semantic and structural, relationships among the above three word classes. The 'collocation' is defined because a term and its lexical rules can be most accurately defined by using it. A specific 'collocational method' is described. Examples of collocations (adjective-noun, verb-noun, verb-adjective-noun) are given from medical lexical field within groups of terms for illnesses classified according to the nature of the illness.

In conclusion, it is postulated that teaching technical vocabulary may be more successful by using collocational method. Also, there is a need for more pragmatically text-oriented dictionaries.

The principles of specific collocational method are: language items are compatible when they share elements of meaning, and thus they can collocate; words are grouped in lexical fields; according to their definitions and important lexical features, words may be combined with other words that are not given here. Each language maps the perception of the same world in a different way. Based on the above method, we have come up with 23 groups of terms for illnesses in English, having in mind semantic components of the nouns in question. Those groups are made according to the nature of disease (e.g. 'congenital' – 'acquired'), place (e.g. 'organic'), manner of manifestation (e.g. 'acute' – 'chronic'), severity (e.g. 'slight' – 'serious'). By combining them with adjectives and verbs we can draw out important conclusions about terms for illnesses in English: e.g. the noun **cough** with the adjective **whooping** and the verb **pass on** suggests the meaning 'contagious illness'.

#### Abstract 9

Micic, Sofija. *The English Language Curriculum for Doctoral Students of Medical Sciences*, Primenjena lingvistika, Linguistique appliquée, 10, Društvo za primenjenu lingvistiku Srbije, Filološki fakultet u Beogradu, Filozofski fakultet u Novom Sadu, Beograd-Novu Sad, 2009

English for Medical Academic Purposes (EMAP) is being introduced into doctoral studies at the Belgrade University within the Bologna reform process (one such course for Dentistry doctoral candidates was directed in 2007/08 by the author of this article; the other, for the Medicine ones, is under way). There has been a need to develop an appropriate curriculum of English for Doctoral Students of Medical Sciences (EDSMS) (including pharmacy and veterinary medicine). English as an International Language (EIL) scholars (formerly non-native speakers) increasingly need to publish in English, the *lingua franca* of science. Their English language level is low (reading, primarily writing for scholarly publication, speaking). They lack basic understanding of discourse patterns of research articles (RAs). Extralinguistically, their location, level of expertise and network access influence their success. This paper offers an outline of a prospective EDSMS curriculum whose standardized format would enable EIL authors to produce internationally recognized RAs.

Here is the outline of a prospective EDSMS curriculum:

1. features of English for Specific/Special Purposes (ESP)/ EAP/EMAP; the English language of biomedicine, as the leading language of medical science and its specificities;
2. reading techniques, data collection; writing RAs; giving oral presentations;
3. the use of specialized/medical and related dictionaries;
4. the use of citation indexes (Current Contents);
5. formal medical correspondence in English (forms, letters, CV).

The EDSMS curriculum implementation seems to be mostly dependent on the nation state having a potential role to play in terms of its policy regarding English language education for science researchers. In several developing countries, there exist scientific writing courses in English (India, China, Iran, Croatia, Brazil and Venezuela) (noted by Salager-Meyer in 2008).

EIL doctoral candidates in medical sciences would be able to produce internationally recognized RAs in the English language published in prestigious professional publications.

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