

EMWA

European
Medical Writers
Association

The *Write Stuff*

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Medical
Devices

EMWA Executive Committee

President:

Rita Wellens
Wellens Clinical Research Consulting
Rillaar, Belgium
president@emwa.org

Vice President:

Susan Batti
Premier Research Germany Ltd.,
Darmstadt, Germany,
vicepresident@emwa.org

Treasurer:

Gillian Pritchard
Sylexis Limited
Dundee, UK
treasurer@emwa.org

Honorary Secretary:

Sarah Choudhury
Medical writer
Letchworth Garden City, UK
secretary@emwa.org

Public Relations Officer:

Farid Khalfi
Guerbet
Roissy, France
pr@emwa.org

Website Manager:

Shanida Nataraja
Axon Communications
London, UK
webmanager@emwa.org

Education Officer:

Jo Whelan
Textpharm Ltd
Oxford, UK
education@emwa.org

Conference Director

Sunethra Wimalasundera
Medical writer
Hatfield, UK
conferencedirector@emwa.org

Journal Editor

Elise Langdon-Neuner
Baxter BioScience
Vienna, Austria
editor@emwa.org

EMWA Head Office
Durford Mill, Petersfield, GU31 5AZ, United Kingdom
Tel: +44 (0)173 071 5216, Fax: (+44) 870 442 9940
info@emwa.org
EMWA website: www.emwa.org

Journal insights

The *Write Stuff* is the official publication of the European Medical Writers Association. It is issued 4 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims, 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:

- €5 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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■ From the Guest Editor's desk



Medical devices

by Claudia Frumento

What do a wheelchair, a magnetic resonance tomograph, a cochlear implant and an infusion pump have in common?

They are all medical devices! The world of medical devices is complicated and not getting easier. Microtechnology, nanotechnology and bionics, among others, are making such rapid progress that one could get dizzy in an attempt to follow all the new developments: new mechanical limbs that can be connected to the nerve endings at the stump of an amputated arm or leg and can be steered just as a normal arm or leg without even thinking; implantable micro cameras that permit the blind to recognise objects in their way; pills that can be swallowed and deliver exact pictures of their journey through the intestinal tract; CT scanners that produce real-time 3-D images of the coronary arteries as the heart beats and make invasive coronary angiography look like a primitive method. The oncologist's dream of delivering chemotherapy only where it is needed and when it is needed is already under clinical testing—want more? You name it and for sure somebody in some high tech company is already working on it!

But why have most of us—medical writers—had little or no contact with this fascinating world? A simple answer *could* be: there was and still is less regulatory control of medical devices by independent authorities than of drugs, not because control is not wanted but simply because of the intrinsic explosive characteristic of new developments: the regulatory and legal authorities cannot respond at the pace dictated by the creative minds of engineers, entrepreneurs and investors. This is not specific to medical devices, we see it often when new technologies, developments, or even life-style fashions are introduced to the market: did anybody think to seriously study the possible negative effects on the eyes (or brain) of sitting for hours in front of a PC screen? Was the use of nano structures ever tested for a negative impact on the environment?

Times are changing though, and demands for more and better clinical studies before market release and more stringent post-marketing surveillance are surfacing. Professor Jerry Avorn from the Department of Medicine at Harvard Medical School reveals some frightening examples of unjustifiable common sense deficits: "...even car manufacturers have better databases to identify who uses their products"[1]. Shouldn't companies or an independent agency keep a register that would enable a targeted recall of some of the implanted devices, just in case there were some faulty electronic components in one of

the production batches? Why should medical device companies have easier marketing release procedures for their new medical-device-based therapies than pharmaceuticals? A new therapy is a new therapy; whether it is based on a medical device or a new drug does not really make a huge difference.

But there are valid arguments for a faster market release of some medical devices, particularly for those that are not used for *new* diagnostic or therapeutic procedures such as a syringe or a clamp and that are not based on *new* technologies. Nobody with a bit of common sense would ask a company that wants to market a 'me too' pacemaker with no new features or technological gadgets to run a double blind controlled clinical trial. We must also take into account that it is not so easy to run controlled clinical trials with medical devices, as Diarmuid De Faoite and Melissa Wilhelmi describe in their article "Ethical and practical problems in clinical research with medical devices in traumatology" on page 81 of this issue and Geert Hertecant mentions in the interview on page 78.

Moreover, the risk of a wide-spread and uncontrolled use of medical devices that have been newly introduced to the European market is quite low, since the market release of a new medical device does not automatically lead to its reimbursement. This is frequently the biggest obstacle to an unlimited use for some devices. In the last decades the Health Technology Assessment (HTA) has developed into a multidisciplinary method to systematically examine the safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal, and ethical considerations of the application of a health technology—usually a drug, a medical device or a clinical/surgical procedure. "HTA acts as 'a bridge' between evidence and policy-making. It seeks to provide health policy-makers with accessible, useable and evidence-based information to guide their decisions about the appropriate use of technology and the efficient allocation of resources" [2].

An HTA of a particular medical device is to some extent comparable with a clinical study in its complexity due to its focus on:

- Clinical effectiveness—how do the health outcomes of the technology compare with available alternative treatments?
- Cost-effectiveness—are these improvements in health outcomes commensurate with the additional costs of the technology?

Thus, medical device companies that have sponsored the HTAs for their products to overcome the reimbursement hurdle are marketing products that have been thoroughly scrutinised for safety, efficacy and cost effectiveness.

The question, though, is still not answered: why have medical writers hardly been involved in this exciting area? Most probably because of a combination of many factors: less stringent controls, recent explosive development, fast life cycles of some medical devices (believe it or not, a 4-year-old neuro-stimulator model is already obsolete) that put a lot of time pressure on the developing companies, and last but not least, as Dr. Reterski explains in his interview (page 76) and Jane Opie describes in her article (page 88) in this issue, because much of the writing is being done by employees who are not only dedicated to writing.

But, as I mentioned before, things are changing. I started with my first regulatory writing project for a medical device company 3 years ago and I was not out there looking for it. I was asked by a big European CRO if I could do it since they were looking for somebody who could understand the technicalities of that particular medical device. After that, many other projects have followed; sometimes regulatory work, sometimes medical communication and never boring!

Something similar could happen to any of us and probably, in the near future, we will have more requests and opportunities to work on biotech products, hybrid products (medical devices combined with drugs) and medical devices. In the meantime if you have an eye to a future in medical device writing and are keen to keep pace with the technology take a look at: <http://www.economist.com/topics/medical-devices>, you might be surprised by some of the content.

Claudia Frumento

Berlin, Germany
c.frumento@icimt.com

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1. Avorn J. Regulation of Devices. Lessons can be learnt from drug regulation. *BMJ* 2010;341:c5730
2. Taylor R and Taylor R. What is health technology assessment? Available at: www.whatissseries.co.uk

Erratum

On page 37 of volume 20 (1) of *The Write Stuff* under the title 'Writer's block' Mark Twain is erroneously credited with having said the words "I am sorry I wrote such a long letter, I did not have time to write a shorter one." The sentence preceding the quote should state "Indeed they can take comfort that a reviewer of one such paper was moved in the spirit of a remark by Blaise Pascal" rather than "a remark by Mark Twain." With thanks to Neville G Goodman for bringing this error to our attention.

Competing interests are greater for medical devices than for drugs

The withdrawal from the market in 2010 of a metal-on-metal hip implant after more than 93,000 patients had received the implant in Europe since 2003 gives serious cause to look more critically at medical device regulation in Europe. For 7 years the manufacturer of the implant ignored concerns raised by surgeons about its high rate of failure and the elevated concentrations of metal ions in patients receiving the implant. Fiona Godlee in her editorial in the *BMJ* titled 'The trouble with medical devices' refers to this case and lists a number of articles highlighting the flaws in the regulation of medical devices and its lack of transparency in Europe [1].

In the same *BMJ* issue, after listing the many competing interests that influence drug prescription, Peter Wilmshurst explains why he believes the situation is even worse for medical devices. The European Medicines Agency is the only authority that can approve drugs sold in the EU but there are many notified bodies in the EU which may issue a CE (European conformity) mark and medical devices are only tested for safety and performance and not for clinical efficacy, which the industry argues is appropriate in most cases. Rather than being based on evidence of effect sales of devices are often based on recommendations from opinion leaders, who may have undeclared interests. If there are trials the principal investigator might have been involved in the development process of the device. Doctors are frequently bound to the manufacturer as the manufacturers train them how to use the device and then pays them to train other doctors or to demonstrate their use at meetings. This brings the doctors income and the kudos of their expertise, which they risk losing if they contradict the manufacturer's message. Wilmshurst also points out, as mentioned by Diarmuid De Faoite and Melissa Wilhelmi in their article in this issue of *TWS* (page 81), that device company representatives are often required in the operating theatre to advise on procedures whereas drug reps. never sit in a doctor's surgery during a consultation. Clinicians are not compelled to report complications directly to regulators possibly, Wilmshurst suggests, because of the fear that the blame will be shifted to them as the operator, to maintain their relationship with industry and in some cases to avoid the risk of a subsequent legal dispute.

Elise Langdon-Neuner

editor@emwa.org

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1. Godlee F. The trouble with medical devices. *BMJ* 2011; 342:d3123
2. Wilmshurst P. The regulation of medical devices. *BMJ* 2011; 342:d2822

Message from the President



Dear EMWA Colleagues,

by Rita Wellens

Greetings!

I hope you are still basking in the afterglow of the terrific 32nd EMWA Conference in fascinating Berlin.

I am delighted with the feedback received—great range of workshops, plenty of networking activities, excellent plenary lectures and discussion panels zooming in on the ‘Globalisation’ theme, great social outings, and, of course, the superb Andel’s hotel setting.

On top of these superlatives, the Berlin Conference welcomed a total of 369 EMWA enthusiasts and featured a whopping 72 workshops and 6 plenary sessions—a record-breaking meeting!

Many volunteers have again generously dedicated their time to make it happen in Berlin and to all of you involved, sincere appreciation and thanks for this achievement.

I am deeply indebted to Laurence Auffrett, ex-president, for passionately paving the way for this pinnacle conference and for graciously taking on my first presidential tasks while I was on bereavement leave. Additional heartfelt appreciation for the efforts of the other members of the Executive Committee (EC): Gillian Pritchard (Treasurer), Andrea Palluch (Public Relations Officer),

Laura Hollyhead (Honorary Secretary), Shanida Nataraja (Website Manager), Sunethra Wimalasundera (Conference Director), Stephen De Looze (Education Officer) and Elise Langdon-Neuner (Editor *TWS*). Congratulations to Elise Langdon-Neuner and Alistair Reeves, both recipients of the prestigious Nick Thompson award for recognition of their long-term commitment to EMWA!

As stated earlier, the EMWA Professional Development Programme (EPDP) steered by the EMWA Professional Development Committee (EPDC) and the dedicated workshop leaders have worked relentlessly to offer a record-breaking number of workshops in Berlin. The EPDP currently has over 100-plus potential workshops and this training ‘treasure trove’ is covering a fascinating spectrum of medical writing opportunities. The herculean long-standing efforts by Stephen as EPDC chair and Education Officer will be continued by Jo Whelan. Sarah Choudhury will assume Laura’s responsibilities as Honorary Secretary, while Farid Khalfi will take over from Andrea as Public Relations officer, and Susan Bhatti will move into the Vice-President’s role.

Please join me in wishing these new EC members—Jo, Sarah, Farid and Susan—the best of luck with their appointments.

EMWA’s increased expenditure and operational costs were discussed at the Annual Meeting in Berlin. I take this opportunity to reassure you that the EC will remain focused on EMWA’s financial health by implementing income-generating as well as cost-saving strategies. I invite you to explore the ‘Sponsorship’ opportunities featured on the EMWA website, a section that was overhauled at the beginning of this year. Don’t be shy, encourage your friends, colleagues, employers, and companies to team up with EMWA!

With the record-breaking attendance in Berlin, continued growth in high-quality training for medical writers, and boundless energy of our dedicated volunteers, EMWA’s future looks bright.

Last but not least—remember that EMWA keeps the momentum going! I look forward to meeting you in November 2011, **at the 33rd EMWA Conference in London.**

All the best

Rita Wellens
EMWA President

Let your colleagues benefit from your publications in other journals too!

Each year *TWS* publishes a list of medical writing articles written by EMWA members in other journals. (*TWS* 2009;18(2):146 and 2010 19(3):213).

EMWA members are invited to send citations to articles relevant to medical writing/biomedical publication or on other topics of general interest to medical writers which they have published in the last 12 months. (Details of articles published earlier, which you might have forgotten to send last time around, are also welcome.) Please send the citations to editor@emwa.org for inclusion in the list which will be published in the September 2011 issue and also on www.emwa.org.

What's news at EMWA ■

The EMWA Spring Conference: Berlin 2011

EMWA held a very successful spring conference with a special focus on globalisation in Berlin between 10th and 14th May. Over 370 delegates attended the conference which included more than 60 workshops offering credits within the EMWA Professional Development Programme (EPDP). Additionally the programme had three excellent plenary sessions, 'Cultural Sensitivity and Medical Writing' presented by Barry Drees, 'Creating a Global Medical Writing Department' presented by Keith Dawes and 'Shift of Clinical Trial Activity to the East: Implications for Europe' presented by Nermeen Varawalla. To gain a closer insight go to Shanida Nataraja's conference blog at www.emwa.org/member-blogs.

New positions were taken up on the Executive Committee by members (whose names are written in bold on the following list of EC members) elected at the Annual Meeting held on Wednesday 11th May.

Rita Wellens

Susan Batti

Jo Whelan

Sunethra Wimalasundera

Gillian Pritchard

Sarah Choudhury

Farid Khalfi

Shanida Nataraja

Elise Langdon-Neuner

President

Vice-President

Education Officer

Conference Director

Treasurer

Honorary Secretary

Public Relations Officer

Web Manager

Journal Editor

The social programme included coach, boat and walking tours as well as the conference banquet amidst the Art Deco in Café Nolle. It was interesting to discover that chicken, salad and baked potato is a Berlin specialty. A toast was raised to Ben Young who died recently and had been president of EMWA between 1996 and 1997. Alistair Reeves and Elise Langdon-Neuner were honoured with the Nick Thompson award for outstanding contributions to the association.



Nick Thompson fellowship awardees

New Associate Editor for TWS

TWS is pleased to announce that Phillip S. Leventhal has joined the editorial board as Associate Editor

Originally from the United States, Phil came to Paris in 2003 after 15 years as a research scientist in biochemical and cellular oncology at the Universities of Wisconsin and Michigan and in drug discovery at two small pharmaceutical companies in California. Although successful as a research scientist, with 30 scientific publications, like many researchers, Phil had a desire to leave the bench and do something new.



After taking a break to learn about winemaking in Italy and to think about his career, Phil discovered medical writing. "I had always loved both writing and science but had never found a way to combine the two. Medical writing was the perfect answer, and I have been truly happy since making the change."

Beginning as a freelancer, Phil eventually joined 4Clinics in Paris where he has been for 3 years. He has since become recognised as a specialist in peer-reviewed manuscripts. He now co-leads two workshops on manuscript writing for EMWA, and he recently served as guest editor for a special issue of *The Write Stuff* on manuscript writing. Since serving as a guest editor, he has become continuously more involved with *The Write Stuff* and is now joining the editorial team as an associate editor. "I'm excited to be a member of the editorial team because I can continue to give back to EMWA, its members, and those new to medical writing."

Call for papers for upcoming issues of TWS

The theme of September's TWS will be **Health writing**. Submissions of articles on topics such as communicating health information to the public, preparing promotional material, and compiling documentation for pharmaceutical representatives to present to doctors are welcome.

The December issue with the theme **Management in medical writing** will be edited by Phil Laventhal. Submissions of articles on this topic should be submitted to Phil at pleven2@yahoo.com.

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 theme are also welcome. Please send articles, letters to the editor and suggestions for individual articles or future issue themes to the editor at editor@emwa.org.

What's news at EMWA

EMWA Professional Development Committee— Call for volunteers

Two vacancies have arisen on the EMWA Professional Development Committee (EPDC). The EPDC supports the Education Officer with the running of EMWA's Professional Development Programme. We're looking for enthusiastic new members who can bring both new ideas and a steady hand to the EPD, which is such an important part of EMWA.

Duties include mentoring new workshop leaders, observing new workshops and recommending them for approval or revision as appropriate, reviewing workshop evaluation forms during conferences, and supporting the Education Officer with administration of the programme. We meet at the end of the spring and autumn conferences, and have a small number of teleconferences in between. You will normally be expected to come to each conference and to run a workshop each time (subject to scheduling, so members with one workshop might not run it twice a year). You will need to stay to the end

of conference to attend the meeting. In return, you will receive two additional nights' accommodation on top of the reimbursement and registration benefits available to workshop leaders.

To be eligible, you must be an EMWA workshop leader and must have attended at least one spring conference in the last three years. The term of office is 5 years. During this time you will be eligible to stand for election as Education Officer (EOs are drawn from the EPDC). This is your chance to get more involved in the running of EMWA, and to help shape the education programme for the future. We would love to hear from you if you would like to be involved. Please e-mail me **by 31 July 2011** (whelan.jo@gmail.com) with a summary of your professional background, including any training or lecturing experience, and a brief statement of why you would like to be appointed and what you feel you can bring to the EPDC. Enthusiasm and commitment to EMWA are the most important requirements, as is willingness to work as part of a friendly and cooperative team.

Jo Whelan
Education Officer

Meeting the new EMWA Executive Committee members

Candidate statements from Jo Whelan and Farid Khalfi were published in the last issue of *TWS* (vol 20 (1) page 6). Susan Batti and Sarah Choudhury would also like to introduce themselves to the membership.

Vice President Susan Batti



Although I have been a member of EMWA since 1997 and a workshop leader since 1999, it is the first time I am assuming an organisational role within EMWA and I must admit this is both an exciting and a rather daunting prospect. My background is primarily in regulatory affairs and I have spent over 15 years working in both the pharmaceutical industry and for CROs. Currently I am European Director of Regulatory Affairs, Pharmacovigilance and Medical Writing at Premier Research and work closely with medical writers on a daily basis. As VP I would like to reach out to other associations worldwide and look for ways in which a mutually beneficial interaction could be established in order to spread the reputation of EMWA and raise the awareness of the medical writing profession across the globe. Another focus of my attention in 2011 will be to work together with our website manager, Shanida, to identify possibilities to implement more direct electronic communication and reduce the need for time consuming and costly individual collection and dissemination of information, such as pre-workshop assignments. I am very much looking forward to representing the EMWA members as VP and hope to see you at the autumn conference.

Honorary Secretary Sarah Choudhury



I have been attending EMWA since the Malta conference in 2005, just after starting a job as a trainee medical writer and after a stint in academia (laboratory assistant and then a PhD student). Coming from a very small medical writing group in both my roles as a trainee medical writer, and my subsequent role as a manager in medical writing, EMWA has provided me invaluable, guidance, friendship, and fun. Throughout my years in this niche profession, I have therefore received support from an organisation which is highly regarded in the pharmaceutical and CRO industry, which in turn has encouraged my attendance at the EMWA conferences every year.

So now is my time to give something back. I have bundles of enthusiasm, am very conscientious, and through my work experiences and general challenges that life brings us, can demonstrate reliability, dedication, persistence, attention to detail, good communication skills, and have always proved to be a great team player. I look forward to the challenge of this role and know that I will be able to give the kind of dedication the role requires and support the growth and continuation of this fantastic organisation.

Are you looking for an exciting new challenge and the right opportunity?

Due to significant expansion we have opportunities for experienced medical writers in our Horsham and Hammersmith, UK offices, which offer exciting challenges in a scientifically stimulating environment.

Ideally, you will have worked in medical communications and have a relevant higher degree (or equivalent). A proven track record of medical writing and editing, plus an exceptional eye for detail are essential.

As a medical writer you will (depending on level of experience) demonstrate excellent writing and quality control, serve as key client/author liaison, champion key therapeutic areas, be responsible for managing your projects and successfully delivering outputs, and have an appreciation of the nuances of publication planning, strategy and implementation. You will be conversant with the many and varied tasks of a scientific, medical communication professional.

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How do medical device industry managers tick?

by Claudia Frumento

When I started my medical writer freelance career, I was surprised by the differences in the two worlds: the pharmaceutical industry and the medical device industry. I had worked for many years for a huge medical device corporation as a training and education manager. I had also worked for the medical device units of Eli Lilly (when they had such a business), but I had forgotten the typical pharmaceutical ‘ways’ of working, thinking, timing and managing clinical research and pharmacovigilance. If I was surprised by the differences (and I had had contacts with both worlds), I assume that many medical writers that have gained most of their experience in the pharmaceutical world do not know how regulatory managers or VIPs in the medical device world tick. Here are two interviews that give a first glance at this fast paced industry: one with a regulatory affairs director of a well established medical devices corporation and a mature business and one with an entrepreneur who helps start up companies to bring their implantable medical devices to the European market—before they are introduced in the USA.

Interview with Dominik Reterski, Senior Regulatory Director Europe, Middle East and Africa (EMEA), Covidien

Dr. Dominik Reterski is a pharmacist by education and is Senior Director of EMEA Regulatory Affairs of the Medical Devices Division of Covidien, a company that offers high quality products in many different areas and has a product portfolio with almost 60,000 items. Covidien has pioneered a number of medical advances including contrast media, pulse oximetry, electro surgery, surgical stapling and laparoscopic instrumentation. Offering an extensive product line that spans medical devices, pharmaceuticals and medical supplies, Covidien serves healthcare needs in hospitals, long-term care and alternate care facilities, doctors’ offices and the home.

Dr. Reterski, I sincerely appreciate that you have taken the time for this interview for *The Write Stuff*. Many people think that medical devices are in a ‘regulatory grey zone’ and that regulations are much more lax than in the pharmaceutical industry. Is this correct?

D.R.: No, it is not correct, actually it is a misperception. Pharmaceutical companies have to prepare a complicated dossier and application that will be reviewed by the authorities, be it the FDA in the United States or the Euro-

pean Medicines Agency (EMA) in Europe. They will then decide whether the new drug can be marketed.

In the case of medical devices the regulatory responsibility lies on the manufacturer. All medical devices have to meet the essential requirements defined by the Medical Device Directive. Manufacturers have to provide evidence that the devices meet the essential requirements, which are slightly different depending on the type and risk class of medical devices. The manufacturer has to carry out multiple tests and create the technical files that demonstrate that the device meets the essential requirements. Only then may such device be Conformité Européenne (CE) marked and placed on the market.

As regulatory director of a company that has different areas, medical devices and pharmaceutical products, which is the area of your work that is most time consuming?

D.R.: It is difficult for me to compare since I’m working in the area of medical devices and I don’t feel at ease describing the work of my colleagues in the pharmaceutical division. What I can describe is what we do: we have to run the tests and prepare the technical files of our medical devices and this is not an easy thing to do. It requires a lot of time and resources to put these documents and tests together.

Is it difficult to bring your medical devices to the market?

D.R.: Having almost 60,000 items listed it is hard to say... each device has its own difficulty. In the case of capital equipment for example, ventilators, which are Class IIB or the surgical equipment which is classified as Class III, the process to demonstrate that they meet the essential requirements is much more complicated than for drapes that are *self certified* Class I medical devices. In this case the manufacturer has to do the same essential requirements assessment, but they are easier, the files stay with the manufacturer and are only required by the notified bodies if they consider it necessary. Notified bodies are independent organisations that are accredited by the European Commission and Member States governments to perform assessment and decide whether a device complies with the essential requirements or not.

In general, how long is the life cycle of your products?

D.R.: I can’t mention a *mean* life cycle for all of our products because they are very different, but for example capital equipment such as ventilators can be running for many

How do medical device industry managers tick?

years, 10, 15 or even more, this doesn't mean that we do not bring new or innovative models in the meantime to the market. Also simple disposable medical devices such as wound dressings might have a very long product life cycle and be in the market for many years. But again, we are always innovating and bringing new products to the market every year. Nowadays with the very fast development in the area of biotechnology and materials this is a must.

Do you need to run clinical studies or trials for your products before you can market them?

D.R.: Yes we do have to run clinical trials with medical devices, but in general they are not as long as those required for pharmaceutical products. But actually, it is not possible to compare the clinical studies required by medical devices and those for pharmaceuticals. The objectives of the study, the endpoints are completely different. Let's clarify with an example: if a pharmaceutical company wants to introduce a new drug for the treatment of prostate cancer the clinical trial to demonstrate that the drug is more effective than others will take years. The patients will have to take the new drug and the comparator and they will have to be followed for years to establish survival rates.

The clinical study to demonstrate that a new device resects the tumour effectively will take much shorter. Actually the study will only have to demonstrate that it does what it says: it resects the tumour effectively and with little or no adverse events. This doesn't mean though that the surgical procedure with the new device will lead to a longer life expectancy of the patients treated with this new method than with other already established surgical methods. But if the new device is easier to use and the procedure is much more comfortable for the patient why should it be denied to the patient?

On the other hand, in some countries, even if a medical device has a CE mark or is approved by the FDA, we have to run clinical studies in their territories and there are also regional differences. If a device has been approved for marketing in the EU it will be recognised by Canada but not by the USA. Even the classification of the medical devices is not the same in Europe as it is in the USA.

In the case where you have to run clinical trials, in general, do you work together with Clinical Research Organisations or do you have your own clinical research department?

D.R.: Covidien is divided into different business units and each business unit has its own clinical research department. These are responsible for the clinical trials required to bring the products of their business unit to the market. But we also work with CROs, particularly when we run clinical trials overseas.

Do you have medical writers in your department or in another department of your company?

D.R.: Yes we do have medical writers in our organisation, but they are not called as such and they have to do other

tasks as well. They are called regulatory affairs associates, specialist etc, and as I said before they are not dedicated only to writing. They work mainly at the manufacturing level preparing all the necessary documentation for the market approval of the products.

What type of educational background do they have?

D.R.: Well it varies quite a lot, we have medical doctors, pharmacists (as myself), biologists, chemists and some engineers, but most of them have a biomedical background. In the USA they are often certified regulatory affairs managers.

And what are certified regulatory affairs managers?

D.R.: These individuals have done special post graduate studies.

Do you think that the regulatory environment for medical devices is changing in the right direction and do you think that it will change dramatically in the future?

D.R.: Yes the regulatory environment is changing a lot but in different ways. In many European countries that have had regulated medical devices for a long time the changes are not so dramatic, but in other countries that do not have a tradition of regulation for medical devices things are really moving fast. One interesting example: Saudi Arabia has created a Saudi FDA to regulate the use of medical devices. They have allocated a multimillion dollar annual budget and have hired 188 staff to manage this new organisation. The problem is that most of those new legislations are not harmonised with each other or with global standards and this will make our work extremely difficult.

Europe is also changing. There is one Medical Device Directive, but there are 27 transpositions of this Directive into the national legislations of the EU Member States. Unfortunately, they often differ from each other, this leads to different interpretations of the law by the Competent Authorities and Notified Bodies which reside in all Member States. Therefore medical devices may be assessed in different states against slightly different standards, which according to the European Commission may allow for easier access of low quality medical devices to European markets.

Another serious issue is related to the common practice of reprocessing or refurbishment of single use medical devices: that means that the medical device is being re-sterilised, a process which is not compatible with the original design of the medical device. Some companies offer this service and sell the products to the hospital and what is even worse, they do not offer any guarantee. The European Commission is aware of these risks and there are serious plans to recast the Medical Device Directive in the next two years to eliminate illegal imports of low quality medical devices from the far east and hopefully put an end to the reprocessing of single use devices. We, as a serious >

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> health partner, support these changes and developments, but we would like to see a better harmonisation process throughout Europe and abroad as well. Solid medical device regulations already exist in the European community, Japan, Canada, Australia and in the US. These should serve as the base for a global harmonisation.

Do you expect an increasing workload for the regulatory authorities as well as for your department?

D.R.: Certainly, just as an example: we doubled our staff over the last two years in our department, which covers only Europe, Middle East and Africa.

Do you find experts easily in the area of regulatory affairs for medical devices or do you have to train your own people?

D.R.: In countries where there is a history of pharmaceutical and /or medical device regulations it is easy to find experts that have been exposed to medical device regulations. In Eastern Europe we find more pharmaceutical experts that can be 'converted' to medical device specialists. But we also hire personnel with a biomedical background and develop and train them ourselves.

Last but not least: what do you enjoy most of your work?

D.R.: I enjoy the constant change and the associated challenge. The work is so diverse, the people and organisations are so different that it is a very mind broadening experience. It's interesting to learn how different medical devices are perceived in different cultures. Most countries outside of Europe have completely different registration systems, but as mentioned before even in the EU there are significant differences between member states due to different transpositions of the Medical Device Directive. In some countries such as France and Italy we still have to go through a full blown registration process. This is also something that will be addressed with the recasting of the Medical Device Directive: a better harmonisation.

Some organisations / experts believe that medical devices should be put under the control of the European Medicines Agency. The Medical Device Industry does not think that this is the right way to go. This could slow the process of bringing innovative technology and new products to the patients that need them. We don't think that medical devices should follow a centralised approval path as pharmaceutical products do, the two worlds are completely different. But we do believe in strengthening the present system based on the CE mark provided by the Notified Bodies.

The aim of not just our but all serious medical device companies is to deliver the highest possible quality, safe and efficient medical devices, to improve the care, health and quality of life of the patients and consequently society as a whole.

Interview with Geert Hertecant, an entrepreneur in the Medical Device Industry

Geert Hertecant has more than 20 years experience in sales management, marketing and market development for new revolutionary therapies based on medical devices. He worked for many years for one of the biggest medical device corporations of the world. He was sales director of two start-up companies that became so profitable under his command that both were bought for very interesting prices by two medical device corporations which operate worldwide. He is now an independent consultant for medical device start-up companies and has a great insight into how these companies work.

Thank you Geert for agreeing to this interview, I know that you are a very busy man....

G.H.: Claudia, you know how the world of medical devices is, fast paced and everything has to be ready by yesterday.

Yes, I'm perfectly aware of this, so let's get started: How long does it take the companies with which you work to bring a new device to the market?

G.H.: It is really very difficult to say. Some companies have invested years of research and development efforts into a particular product with which they come to the market and some others have invested much less time and efforts. One example is a company which developed a particular matrix for bone growth: there were at least 30 years of research behind it. Of course the company did not exist at the beginning of the research process. Part of the development was done at the university, in an academic environment. In general, once the prototype is ready to go to mass production (even though in some cases we can't really speak of mass production) we have to go through a CE mark process, which is not always very easy or clear. But it might take 2-5 years' time to have all the necessary tests done such as biocompatibility, safety and performance tests.

And after the device has a CE mark and is out there in the market the company sells it and reimbursement is automatic?

G.H.: Of course not! This might be the case in the pharmaceutical world, but not in the world of medical devices. The procedures to get a medical-device-based therapy reimbursed depend on the local authorities, the local health insurance structures and policies and many other factors. In countries such as Germany we need real experts to deal with the multiple reimbursement pathways: disease related groups, case by case, hospital use, ambulant use, private health insurances, national health insurance organisations....

Besides reimbursement which are the major obstacles and challenges?

G.H.: One of the problems is local registration of the devices. Even though there is a European-wide CE mark

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procedure that has been implemented some countries like Spain, Italy, Eastern Europe, Russia still request local registrations of the devices on top of the European CE mark. This means a lot of paper work that sometimes can be written in English and sometimes has to be translated to the local languages.

And why is that?

G.H.: Well, actually it is a historic development and should change, but until today it hasn't. There is no reason why it should be this way. An interesting case is China. No matter what type of approval we have, FDA or CE mark, all medical device products have to run through the Chinese approval process and this costs some millions of dollars, more than 2 years and at least 16 free devices, no start up company can pay this.

And why is this?

G.H.: We believe that they are protecting their market and that they ask for the devices for free to analyse and develop similar ones.

Is the regulatory environment an issue in Europe or in the US?

G.H.: Actually in the European Community it is much easier than in the United States. The FDA asks for longer clinical studies and a much more stringent analysis.

What happens with devices that are based on a new revolutionary technological principle?

G.H.: It depends on how different the technology and the therapeutic approach is. Sometimes you can have it approved by showing that it is based on similar principles as other approved devices. In this case the approval procedure is quite simple. You have to present enough clinical evidence from the scientific literature that shows that the equivalent device is approved and that it poses no risks for the patients.

Lately we have seen news in the press about a medical device therapy that is supposed to treat a certain condition and actually might be creating the condition itself [1]. In fact, there have been some deaths reported...apparently this device-based therapy was not tested sufficiently?

G.H.: Yes, the case is known in the industry, but obviously something went very wrong there: apparently the company marketing the device did not report the cases as it should have done. No device or drug-based therapy is exempt from some residual risk and all companies, medical device or pharmaceutical should comply with appropriate reporting procedures for Adverse Events (AEs), Serious Adverse Events (SAEs) and Serious Adverse Device Effects (SADEs). There should be a huge penalisation for these types of 'mistakes'. AEs, SAEs and SADEs should be reported complying with all the regulations. These cases are the ones that will lead to even more difficult approval procedures in the future.

How is the regulatory environment changing for implantable medical devices?

G.H.: It is getting more and more complicated, really complicated. This is already a bottleneck in the development of new medical devices and it is getting worse and blocking the development of new technologies.

How do you see this affecting new companies such as the ones you support as a consultant?

G.H.: There is an inherent contradiction in this process: on one hand we, as a society, want to see fast improvements at all technological levels, on the other hand we want them to be absolutely secure and tested ... and this doesn't always work, for many reasons: if a physician or an engineer has a great idea of a new possible medical-device-based therapy and they do some tests and the therapy shows good results in animal studies, in the lab or wherever, the founder or possible founder of the company will have to raise money and find investors that will give him the money to develop his/her idea further. In this fast pace economy, no start-up company with a certain amount of risk will raise funds to put into 10, 20 or more years of clinical research. In the pharmaceutical world the money is already there, or any of the big companies can easily invest in many drugs for the treatment of lung cancer, but they would never invest in drugs for extremely rare diseases for which there are not enough patients in the world to fulfil the minimal criteria for a controlled clinical study.

Yes, but not all devices are developed for extreme rare diseases...

G.H.: Of course not, but running a controlled clinical study for medical-device-based therapies is extremely difficult. One example: one of the companies for which I worked had a CE mark for a deep brain stimulator for the treatment of Parkinson's disease. This device can be used for the treatment of another movement disorder such as severe dystonia that cannot be controlled with medication. A child affected by a very severe dystonia had to be put into artificial coma so that he didn't suffer the unbearable pain related to this condition and he slept most of his life. The parents pleaded the neurosurgeon to test this device in the child and they got approval from the authorities to test the therapy under a humanitarian exception. The therapy worked and the child is now almost normal after a few years of therapy and rehabilitation. What should the neurosurgeon and company do then? How can a controlled, double blind, placebo controlled study be run in severe child dystonia? There are not enough patients, who would deny these children the chance to test the therapy? Of course we could say the same of new drugs, but running placebo controlled trials with drugs is much easier and the number of patients necessary are achieved faster. The amount of work related to the follow-up of medical-device-based therapies and drugs are by no means comparable. The burden on the patient is also completely different.

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> What were / are the most important documents in which you see medical writers involved?

G.H.: I have worked with professional medical writers more than once: sometimes they have helped us to develop clinical study plans for a new product. Big companies tend to have their own staff, small start-up companies do not have enough resources and they outsource this type of work. Some will outsource the whole study management and work with CROs. Medical writers are also asked to write training manuals for sales representatives, users and training material for physicians.

Have you worked with a medical writer with professional experience?

G.H.: Yes of course, many of the training materials that start-up companies have to develop to bring their products to the market have to be written by somebody.... Sometimes in start-up companies, the first 'material' is written and produced by the founders and the 'first generation' staff. These are people who can do a lot of things and really do a lot of different tasks, from regulatory to clinical, up to managerial decisions and down to courier travel. The problem is that they are not professional writers.

Would you like to work for the pharmaceutical industry?

G.H.: Noooo! By no means. The pharmaceutical industry is too big, too slow, and too bureaucratic for my taste. I like fast developments, short decision-making processes, fast results, and growth... all this I will never find in any pharmaceutical company no matter how small they are... if you allow me a personal question, would you like to be pregnant for ten years and then change diapers for another ten? That is how I perceive pharmaceuticals compared with medical devices.

Interesting comparison and I understand what you mean.

Claudia Frumento

Berlin, Germany
c.frumento@icimt.com

Reference:

1. Lenzner J and Brownlee S. Why the FDA can't protect the public. *BMJ* 2010;341:c4753.

A Commentary on *How do medical device industry managers tick?*

These interviews make it apparent that there are a number of trends in effect in the world of medical devices. Most notably, there has been a transition from a relatively loosely controlled development and marketing approval process to one that more rigorously complies with Good Clinical Practice (GCP) standards. These had historically applied more directly to drugs and biologics. Concerns were expressed that this more strict process will impede the development of new devices. Hopefully, this will be balanced by fewer device failures and recalls, of which there have been a number of recent examples. A relative lack of clinical data supporting commercial applications has been a source of concern in Europe, in contrast to US device approvals based on strong clinical evidence.

While I might take issue with Geert Hertecant's claims about lack of incentive to invest in drugs for extremely rare diseases (consider 'Orphan Drug' incentives to do so); reimbursement issues remain, as surgical hospital formularies and third-parties are often reluctant to add novel devices to their lists. However, the same may be said for drugs and biologics.

Ultimately, developers and manufacturers of devices are experiencing many of the same challenges that apply in the drug and biologic worlds: lack of investment capital; lengthy and arduous development pathways; and an uncertain reimbursement future. Add to these, the lack of consistency among the 27 Member States in the EU. This is a real headache for all medical interventions that must negotiate the myriad of often fuzzy requirements of the licensing bodies. As in the drug and biologic arena, device harmonisation is a wish that has yet to be fulfilled.

Art Gertel

ArtG@beardsworth.com

The risk of embarrassing frozen surfaces

I spotted these signs some time ago on an iced-over lake in the mountains of Austria. (Here's my version of the English translation: "Only the corridor marked by the marker poles has safety checks by the mountain railway/gondola of Turracher Höhe. Walking on the ice surface of the Turrachersee [Lake Turrach] outside of the corridor marked by the marker poles is therefore at your own risk." I cannot work out where the 'embarrassed' came from...)

Pamela Waltl

pwaltl@aon.at

Nur der, durch Signalstangen gekennzeichnete Korridor, unterliegt den Sicherheitskontrollen der Bergbahnen Turracher Höhe. Das Betreten der Turrachersee – Eisfläche außerhalb dieses, durch Signalstangen gekennzeichneten Korridors, geschieht daher auf eigene Gefahr.

Only the corridor which is marked with stacks subjects to supervision of security checks of the Bergbahnen Turracher Höhe.
The embarrassed of the frozen surface of the Turrachersee outside of the corridor which is marked with security stacks happens at owner's risk.



Ethical and practical problems in clinical research with medical devices in traumatology

by Diarmuid De Faoite and Melissa Wilhelmi



Introduction

While the medical device market is a huge one in absolute terms (valued at US \$336 billion in 2008) [1], it is usually overshadowed by the much larger pharmaceutical industry. This article will be of interest to those readers who would like to have an overview of the medical device market and specific problems we have encountered in the conduct of clinical trials for medical devices in orthopaedic / trauma settings.

Let us begin by examining some of the differences between pharmaceutical trials and ones designed to investigate medical devices for trauma patients.

Table 1

Pharmaceutical trials	Trauma studies
Large multicenter trials → huge number of patients	Small number of patients → some fracture types = rare disease
Patients are conscious, no problem to sign informed consent	Unconscious patients, problem to sign informed consent
Intervention: e.g., 1 pill per day. Intervention can be done by nurses, relatives or patients themselves	Intervention: Surgical technique, bone status, soft tissue damage, quality of the surgeon, cooperation
After treatment → no / low influence	Rehabilitation protocol is critical
	Effects of comorbidities: e.g., ~30% hip fracture mortality in old patients → low follow-up rate

What is so special about traumatology?

Trauma is unique with respect to the mechanism of injury and future outcomes compared with chronic disease or injury. Patients can transition from otherwise healthy to severely disabled individuals in an instant.

Information management

It should be borne in mind that huge amounts of data are usually produced from such trauma studies—not only patient demographics, but fracture details, surgery details, different outcomes regarding fracture healing, function, quality of life etc. By necessity, there should not only be good monitoring practices in place, but also strict data management practices due to the large volume of data generated by such trials.

Recruitment is a continual problem in the medical device industry for a number of reasons. For example, in a multicenter clinical study, patients with pilon fractures have to be enrolled. Most medium-sized hospitals see only about 10 cases with this indication a year, making recruitment difficult and by necessity elevating the number of clinics that need to participate in the study (with the concomitant increases in costs and administration).

The importance of how patients are recruited should not be underestimated. During a recent study conducted in Spain, the problem was adequate recruitment, but not because the patients couldn't be found. An unfortunate lack of appropriate support for the study by the hospital staff (properly enrolling the patients and documentation) led to a lot of patients not being included in the final data set. Many of these patient exclusions were due to protocol violations.

In comparative studies where the conservative (non-operative) treatment is compared with the surgical intervention—this can affect recruitment. In some cases the problem is adequate recruitment for the conservative group. This is at times difficult when the patient (particularly a sports person who seeks a rapid recovery) knows that the surgical treatment would be better in terms of faster recovery than having a cast for a longer period. This issue overlaps with ethical aspects in treatment and blinding in trials.

Informed consent also vexes us in the medical device world. A particular problem is that patients may be unconscious from their accident—making informed consent difficult! Proxy consent may be obtained in some specific circumstances but this is obviously not ideal. In addition, even if the patients are conscious, they are often whisked away to be operated upon almost immediately giving us little time to enrol them on the study (or even to explain what it is about)!

The intervention itself is much more complicated than in pharmaceutical trials. There are many issues surrounding and impacting upon the intervention such as having to wait for swelling to disappear before internal fixation can be attempted or whether a fracture is open or closed.

Preoperative interventions (like osteoporotic prophylaxis) and more importantly, postoperative interventions (such as cast immobilisation, time to weight bearing etc.) can have a massive impact upon the outcomes. The interventions need to be clearly described as well as uniformly practiced among the clinics (which can also prove to be difficult in multicentre studies with the negative effects felt when it is time to compare the data). A major criticism by reviewers of trauma publications is often that there is no information on what the postoperative intervention was, and if it was similar among the different clinics.

Baseline and follow-up data can be problematic. Trauma patients present themselves for treatment when they already have an injury so there is no baseline data and no

Ethical and practical problems in clinical research

> possibility to collect any. Trauma surgeons are victims of their own success—patients may be lost to follow-up because they recover well and do not return to be assessed. In Switzerland many trauma patients are tourists who have suffered an injury while skiing. Once they are well enough, they return to their home country and never present for any late stage follow-ups. For those with an eye on publication, the *Journal of Bone and Joint Surgery* (American edition) and a number of other high-ranking trauma/orthopaedic journals require a minimum follow-up period of 2 years.

Bones themselves play a role. In an elderly population there is a greater risk of fracture. In certain studies patients can be quite old and death as a complication stemming from the general health of the patient can influence the follow-up rate.

Complications and SAEs

Regulators are interested in complications which are defined as serious adverse events (SAE) because they cause severe harm or occur at a rate higher than expected in the population studies. Therefore, all SAEs in medical device trials need to be reported. This situation is confounded because reporting of complications /adverse events is often not uniform among surgeons and there is currently no accepted standardisation of this part of a medical device trial.

A surgeon's perspective can often be different to that of the patient in terms of complications. The doctor generally focuses on events related to the surgical technique and the implant used. Any deviation from the planned surgical intervention such as imperfect anatomical reduction of a fracture may be listed as a complication. This may have no impact on the patient's healing though and these 'complications' may not be reported.

The patient's perspective on complications generally relates to events that are harmful because they have a negative impact on the normal healing process or trigger additional treatment such as a reoperation.

Legislation

"The collection and evaluation of sound clinical data are the basis of the approval process for many medical devices."
- *U.S. Food and Drug Administration, January 1996* [2]

"Regulation has added ~2 years and up to \$20 million to the cost of developing and launching a medical product in the US market."
- *MCRA Fact book, 2010* [3]

The medical device market is heavily regulated with a plethora of laws and guidelines which must be adhered to. While these of course are designed with patient safety in mind, they can seriously add to a CRO's workload and the duration of a clinical study.

Over 500,000 medical device models are regulated by the FDA [3]. At the start of 2011 it announced a long heralded overhaul of the 510(k) process (whereby a new model of a device can be released if it is found to be 'substantially equivalent' to currently marketed products) which

involved 25 changes to the 510(k) process to improve transparency and predictability for industry participants [4]. This process is substantially faster than any other approval method in the USA.

In Europe, the applicable EU legislation includes the Active Implantable Medical Device Directive 90/385/EEC and the Medical Device Directive 93/42/EEC. Both of these were amended on 21 March 2010 through the 2007/47/EC Directive. Other legislation may also apply, depending upon the device in question, e.g., the Low Voltage Directive 73/23/EEC for active medical devices [5].

Ethics

Getting ethics committee approval is generally a long process. This approval is required from every site where the study is to take place. Principal clinical investigators who want to make a change to the already accepted protocol trigger a re-submission to the ethics committee. Considering that the average cost is €1,000 for ethics submission to a clinic in Germany, changes can be an expensive and time-consuming.

A real difficulty is blinding in surgery (double blinding is impossible—the surgeon quite simply has to know what treatment they are doing). Patient and independent outcomes assessors can, however, be blinded.

While pharmaceutical trials have placebos, the concept is harder to implement in trauma cases. Sham operations have been carried out but the ethical issues involved means that their use is extremely rare [6].

The science behind the medical device may not be the real reason for the study. The study could be serving a marketing purpose to get the device into the surgeons' hands. In addition, technical personnel from the sponsor may be physically present in the operating room, providing advice on the use of complex machinery. Having the sponsor's representatives so close to the frontline is unacceptable in pharmaceutical trials [5]. In addition, the medical devices provided for surgeons may also be used for non-study surgery in some clinics.

Outcomes

Measuring 'success' needs to be patient relevant. However, many validated outcome measures are based on surgeon (and not patient) assessment, e.g. Constant shoulder score, Neer shoulder score, Gartland and Wesley score for wrist/hand, Harris hip score, Knee Injury and Osteoarthritis Outcome Score.

Patient-oriented outcomes are currently a hot topic with ministries of health and healthcare providers from various countries shifting their focus from clinical processes to outcomes, i.e. the quality rather than quantity of healthcare [7-9]. How much hospitals get paid for a procedure may soon depend in part on such measurements of outcome [10]. Furthermore, patient reported outcomes in addition to clinical quality indicators [11] are becoming more popular [12-14].

Ethical and practical problems in clinical research

Summary

Medical device trials, although sharing some similarities with other areas of medical research, bring with them their own unique challenges and rewards. We hope that this article has triggered your interest in our relatively small but complex world.

Diarmuid De Faoite and Melissa Wilhelmi

AO Clinical Investigation & Documentation, Dübendorf, Switzerland.
aocid@aofoundation.org

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A publication writer's reference library

Recently, my supervisor asked me to come up with a list of key references for our publications writing team. Here's a list of the references that I keep on hand. EMWA also has a very complete 'Useful Reading List' at <http://www.emwa.org/Home/UsefulReadingList.html>.

- **Lang TA (2010) How to write, publish & present in the health sciences: a guide for clinicians & laboratory researchers. American College of Physicians, Philadelphia.**
This is an excellent quick resource of information for writing and planning manuscripts. Available at <http://www.tomlangcommunications.com/>.
- **Iverson MA (2007) American Medical Association manual of style: a guide for authors and editors, 10th edn. Oxford University Press, New York.**
In my opinion, all medical writers should have a copy of this. This is a detailed reference on standard medical writing style. Available at <http://www.ama-assn.org/>
- **Council of Science Editors (2006) Scientific style and format: the CSE manual for authors, editors and publishers 7th edn. Rockefeller University Press, New York.**
This reference can provide answers when the American Medical Association manual of style does not. Available at <http://www.councilscienceeditors.org/>.
- **Matthews JR (2008) Successful scientific writing: a step-by-step guide for the biological and medical sciences 3rd edn. Cambridge University Press, Cambridge (UK).**
This book provides practical guidance on how to organise a manuscript writing project. Available at <http://www.cambridge.org/>
- **Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *Ann Intern Med* 154: 1-8.**
This is an essential document for helping determine what should be included in a manuscript on randomised clinical trials. It is also a good place to start for other types of manuscripts. Available on line at <http://www.consort-statement.org/consort-statement/>.
- **International Committee of Medical Journal Editors (2010) Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication.**
Available on line at http://www.icmje.org/urm_full.pdf. This publication provides guidelines for writing a manuscript including definition of authorship, discussion of ethics, and descriptions of what should be included in each section of a manuscript.
- **Strunk W and White EB (1918) The elements of style. W.P. Humphrey, Ithaca, New York.**
A well-known book that gives solid and simple advice on English grammar, punctuation, and how to write clearly and concisely. Admittedly, this book has received a lot of criticism for being too rigid and obsessive (it is), but it is short, funny and good place to start for any writer. Available at <http://www.bartleby.com/141/>.
- **The September 2010 issue of *The Write Stuff* (issue 3, number 3)**
This issue of *The Write Stuff* has several useful articles on manuscript writing. It can be accessed by EMWA members on line at <http://thewritestuff.emwa.org/article/1/43/categories/>.
- **American Medical Writers Association (2001) Essays for biomedical communicators: selected AMWA workshops, volumes 1 and 2. American Medical Writers Association, Rockville, Maryland.**
These two volumes contain a collection of essays based on AMWA workshops. They are an excellent desktop reference for biomedical communicators. They cover English usage, manuscript writing, and a wide range of other topics useful to medical writers. Available at <http://www.amwa.org>.

Phil Leventhal
pleventhal@4clinics.com

Classification of medical devices

by Claudia Frumento

If you were asked to organise a school hockey competition and put together the teams, you would define some criteria that would enable you to classify your players without overlap, which is the basis for a correct classification. Most probably you would classify them by age and playing experience and then you would build your teams either completely mixed to give all teams a fair chance or very homogenous and you would organise the matches within categories and in both cases you would have a great sports event.

Classification of any entity, hockey players, cars or medical devices, is always done with an objective in mind. In the case of medical devices, these are classified to know how hazardous their use is for the patient, the user and for third parties (e.g.: a fluoroscope, poses a radiation risk not only for the patient but for the physician using it and for others in the operating room), therefore how they should be tested before they are introduced to the market and how strictly they should be controlled after market introduction needs to be considered. Four classes have been defined¹ to date: Class I (not really 'dangerous'), Class IIa (a bit more 'dangerous'), Class IIb and Class III which is the most 'dangerous' type of device. Still, the criteria for classifying a device as moderately, fairly or quite dangerous are not very well defined. How hazardous the use of a device is, depends on multiple factors and a clear classification according to a few clear cut criteria is almost impossible. Let us discuss an example:

A cardiac pacemaker used to treat an intermittent cardiac bradycardia on demand may fail to stimulate for a few minutes and most probably the patient will not notice it. If the

same pacemaker is used to treat complete atrioventricular block and it fails, most probably the patient will collapse quite soon. Does this mean that the best criterion is the indication for which the device is being used? This doesn't really make a lot of sense considering the enormous amount of indications for which medical devices are being used, and that not all medical devices are used to treat a particular condition but for diagnostic procedures instead.

What has developed over time following the rapid development of new medical device technologies, is a classification that lists medical devices according to their 'contact' with the body, body fluids or skin, how long this contact is, with which organ systems they are in contact and other criteria such as energy needs and source. Today the classification has become more of a list than a real classification, and when companies try to classify their new medical devices they sometimes need the help of experts.

Before we take a look at the accompanying table, the duration of the use of a device should be understood:

Transient use	normally intended for continuous use for less than 60 minutes.
Short term use	normally intended for continuous use for less than 30 days.
Long term	normally intended for continuous use for more than 30 days.

The classification also includes different categories of devices (remember the hockey team categories?) and there are 7 different categories:

Category 1 Non-invasive devices (e.g.: blood bags)

Class I	Class IIa	Class IIb	Class III
All non-invasive devices unless they are listed in any other higher class.	Devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. Devices that may be connected to an active medical device in Class IIa or a higher class. Devices that are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues. Devices intended for modifying the biological or chemical composition of blood through filtration, centrifugation or exchanges of gas or, heat.	Devices that are intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body and do not use filtration, centrifugation or exchanges of gas or heat.	

¹ The classification is based on the Annex IX of the Medical Device Directive (also called Council Directive) 93/42/EEC from 1993 and amended by the Directives 98/79/EC, 2000/70/EC, 201/104/EC and 2007/47/EC as well as the Regulation 1882/2003 of the European Parliament.

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Category 2 Non-invasive devices which come into contact with injured skin (e.g.: adhesive bandages)

Class I	Class IIa	Class IIb	Class III
Devices intended to be used as a mechanical barrier, for compression or for absorption of exudates.	Devices principally intended to manage the micro-environment of a wound.	Devices that are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent.	

Category 3 Invasive devices—a device which, in whole or in part, penetrates inside the body, either through a body orifice¹ or through the surface of the body. (e.g.: cannulae, ear drum tube)

Class I	Class IIa	Class IIb	Class III
All invasive devices other than surgically invasive devices and which are not intended for connection to an active medical device and are intended for transient use. Devices that are intended for short-term use if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity.	Devices intended for short-term use. Devices intended for long term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane. All invasive devices other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class.	Devices intended for long-term use.	

Category 4 Surgically invasive devices—an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. (e.g.: balloon catheter to expand coronary arteries)

Class I	Class IIa	Class IIb	Class III
Reusable surgical instruments	Devices intended for transient use unless they are listed in a higher class. Devices intended for short-term use unless otherwise specified. Devices intended for short-term use to undergo chemical change in the body or to administer medicines and the devices are placed in the teeth.	For transient use and intended to supply energy in the form of ionising radiation For transient use and intended to have a biological effect or to be wholly or mainly absorbed For transient use and intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application. Devices intended for short-term use to supply energy in the form of ionising radiation. Devices intended for short-term use to undergo chemical change in the body or to administer medicines.	For transient use and intended to specifically diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body. Devices intended for short term use and specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body. Devices intended for short term use in direct contact with the central nervous system. Devices intended for short-term use and to have a biological effect or to be wholly or mainly absorbed.

Category 5 Implantable devices and long-term surgically invasive devices (e.g. knee prosthesis)—any device which is intended:

- to be totally introduced into the human body or,

- to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

Class I	Class IIa	Class IIb	Class III
	Devices to be placed in the teeth.	All implantable devices and long term surgically invasive devices are in Class IIb unless otherwise specified. Devices to undergo chemical change in the body or to administer medicines if the devices are placed in the teeth.	Devices used in direct contact with the heart, the central circulatory system or the central nervous system. Devices intended to have a biological effect or to be wholly or mainly absorbed. Devices to undergo chemical change in the body or to administer medicines.

¹ Body orifice - Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

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- > **Category 6 Active devices**—any medical device operation that depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change are not considered to be active medical devices.
- Active therapeutic device**—any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.
- Active device for diagnosis**—any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

Class I	Class IIa	Class IIb	Class III
	<p>All active therapeutic devices intended to administer or exchange energy are in Class IIa unless otherwise specified.</p> <p>Active devices intended for diagnosis if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum.</p> <p>Active devices intended for diagnosis if they if they are intended to image in vivo distribution of radiopharmaceuticals.</p> <p>Active devices intended to allow direct diagnosis or monitoring of vital physiological processes and not specified otherwise.</p> <p>All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body unless otherwise specified.</p>	<p>All active therapeutic devices intended to administer or exchange energy and their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy.</p> <p>Active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices.</p> <p>Active devices intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity or of the CNS.</p> <p>Active devices intended to emit ionising radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance.</p> <p>All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application.</p>	

Category 7 Special cases

Class I	Class IIa	Class IIb	Class III
	<p>All devices intended specifically to be used for disinfecting medical devices.</p> <p>Non-active devices specifically intended for recording of X-ray diagnostic images.</p>	<p>All devices used for contraception or the prevention of the transmission of sexually transmitted unless other specified</p> <p>All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses.</p>	<p>All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 65/65/EEC, and which is liable to act on the human body with action ancillary to that of the devices.</p> <p>Devices used for contraception or the prevention of the transmission of sexually transmitted diseases that are implantable or long term invasive devices.</p> <p>All devices manufactured utilising animal tissues or derivatives rendered non-viable.</p> <p>Breast implants, shoulder, knee and hip implants.</p> <p>Active implantable devices.</p>

Lets us try to classify two devices and see if it is easy to do: Cardiac aortic valve: this is an easy one! It is an implantable device and it is in direct contact with the heart therefore Class III.

Pocket monitor of blood glucose (used by all patients with diabetes): this one is not so easy...it is an active device because it uses energy from the batteries to measure the

blood glucose (*remember: Active device for diagnosis—any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities*). But the patient has to prick a finger and draw some blood: Is this an invasive device or is the needle to prick the finger another device? Is the measurement of

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blood glucose so critical that it could be Class IIb or is it not so critical and it belongs in Class IIa?

In this case we can't really give a definite answer and an expert with some experience in similar devices might be required. It is not us though, medical writers, who are expected to classify medical devices. However, medical device companies bringing new products to the market are often small and not very experienced in introducing new products in the market. As a freelance medical writer for

medical devices I was once faced with a delicate question: "What do you think, Ms. Frumento, could we find a way to classify this device as Class IIa and save some costs in the dossier?" The intent of the question was clear, the correct classification of the device was not... my answer was simple: please ask an expert!

Claudia Frumento

Berlin, Germany
c.frumento@icimt.com

Are we bugged about superbugs?

There are lots of things to worry about but some are more interesting than others, for instance superbugs and what to do about them. As a child I suffered from tonsillitis regularly and was pumped full of penicillin until it failed to have an effect, but there was a simple solution. I had my tonsils taken out. There are also of course alternatives to penicillin, but only 7 new antibiotics have been licensed by the FDA since 2003. I had not known until I read an article in *The Economist* that Alexander Fleming warned in his Nobel lecture in 1945 that ignorant men might become resistant to antibiotics by exposing themselves to non-lethal doses [1]. James Hughes writing in *JAMA* in February contended that 50% of antibiotic use is unnecessary or inappropriate and this leads to antibiotic-resistant infections which are currently costing the US \$20 billion annually and resulting in more than 8 million additional days in the hospital [2]. According to the BBC over 25,000 people die in Europe each year from untreatable bacterial infections [3]. The risk of infection during surgery is still low and is outweighed by the benefit of non-essential surgery but if the balance tipped we would for example have to live with painful hips rather than undergo replacement surgery.

The main cause of antibody resistance *The Economist* states are convenience and laziness. Doctors pander to patients by prescribing antibiotics too readily, not to mention that antibiotics in some countries can be bought over the counter. The problems of over prescription in India seems to have been responsible for the antibiotic-resistant New Delhi NDM-1 gene found in bacteria, but there was more reaction over its naming than its cause [4]. A new study published in *The Lancet* has found the gene in drinking-water samples in New Delhi [5]. Superbugs are also encouraged by patients failing to complete a prescribed course of medication or cheap meat procured by giving antibiotics to livestock to make them grow faster (a bill is currently going through the US Congress to restrict this use). As pointed out by Hughes, resistant bacteria have the unwelcome consequents of illnesses that take longer to cure and increased treatment costs. They also give rise to diseases that cannot be cured. A strain of tuberculosis which is drug resistant causes death in a third of the patients who succumb to it each year.

The Economist discusses possible ways of combating superbugs starting with 'doing nothing'. In this scenario drugs would continue to be used as they are now and the problems of resistance set off against the benefits of taking the drugs, i.e. a few deaths against the many cures, bearing in mind that resistance is hard for an organism to develop and can only really thrive in hospital environments. Another possibility could be to rein in overuse and develop more rapid and portable diagnostics to evaluate when antibiotics are really required. Reining in would require cooperation between governments, manufacturers and healthcare providers. China would certainly have to change its ways as currently it links financial reimbursement to the amount of drug dispensed. Counterfeit drugs would also need to be combated as they often contain less active ingredients than are required for the effective dose. Big Pharma could put more effort into developing new antibiotics. But there is a problem here: profits are viewed in the short-term. Resistant infections are not yet a large market and much of the bacterial resistance is emerging in poor countries, not to mention that the financial prospects for drugs that cure are less attractive than those requiring repeat treatments. Some small companies are developing antibiotics. Cubist Pharmaceuticals have developed the antibiotic daptomycin which had been dropped by Eli Lilly because it produced side effects but Cubist developed the drug further adjusting the dose and turned it into a commercial success. The Infectious Disease Society of America are keen to promote the development of more antibiotics and to this end have proposed providing financial incentives and tax credits with the aim of having 10 new drugs developed by 2020.

In conclusion *The Economist* recommends that the rise of superbugs is best tackled by guaranteed purchase arrangements for new drugs, rapid diagnostic systems, and stricter dispensing guidelines.

Elise Langdon-Neuner

editor@emwa.org

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Life as a medical writer for a medical device company

by Jane Opie

Once upon a time in the late 1960s in New York City's Greenwich Village, a tall, grade-school teacher with long blonde hair, love beads and bell-bottom pants, leaned far over a little girl and asked her, "and you, Jane, what would you like to be when you grow up?" The girl cheerfully replied, "why, I want to be a medical writer for a medical device company, of course!" Oops, sorry, no, that is not my reality, and it probably isn't yours either, nothing like it. So, how did I wind up as a medical writer for MED-EL GmbH, an Innsbruck-based medical device company that makes hearing implants for people with moderate to profound hearing loss? Luck, chance, destiny, or determination and hard work?

Well, as it turns out art does inspire science, or so it did for me. As a twenty-year-old college language and business student kicking around the 'City', I went to the theatre (inexpensive on Wednesday afternoons) and was prompted by a play I saw to think more about hearing loss: how it affects people's lives and their relationships with others, and how they communicate. At the time, New York University required all students to take several writing courses (yes, even in America, we must sometimes learn how to combine nouns and verbs), and I began writing about hearing. For my creative writing course, I wrote from the perspective of a young deaf girl; for my research writing class, I wrote about the then hot topic of whether deaf children should be taught to speak or whether they should learn sign language. That controversy has since been put to rest thanks to the cochlear implants made by our company: deaf children now learn to hear.

All that writing inspired me to study audiology so that I could work with hearing impaired people, working with them encouraged me to get a PhD so that I could study their hearing systems and work on solutions to improve their hearing. MED-EL, the company for which I work, lets me do all three: I work on clinical studies of hearing-impaired people using hearing implants and write about the findings. Luck, chance, destiny, or determination and hard work?

Now you have a general idea of how I got here from there, but what do I actually write? Honestly, I write a lot of different stuff. MED-EL is a small company with about 700 people at headquarters, including manufacturing staff.

That means that I, like almost everyone here, wear many different hats. Since I began at MED-EL six years ago, I managed a regulatory clinical trial and wrote almost all documents related to it: the clinical investigational plan, the subject informed consent, the ethics committee application, proposed labelling, the final study report, the clinical evaluation submitted to the TÜV (Technischer Überwachungs-Verein: a notified body that checks that medical devices comply with the safety and performance standards required) to obtain marketing approval, parts of the surgical manual, website content, the publication describing the study and its outcomes, and, finally, the press release announcing the product's approval. When we decided to take the study to the US, I wrote much of the application for an Investigational Device Exemption from the FDA. Sounds interesting and wide spread? It is!

More recently, I have moved away from regulatory writing and toward scientific writing and an interest area of mine: hearing implants in older adults. I edit manuscripts from external and internal authors. In addition, I gather evidence, develop studies and write publications and mar-

I managed a regulatory clinical trial and wrote almost all documents related to it

keting materials so that more elderly people will feel comfortable undergoing a two-hour surgery to get effective hearing help that will improve their communication skills and quality of life.

This year, I have written a couple of press releases and marketing brochures, prepared a manuscript for submission, and replied to reviewers' comments on a manuscript. Writing a protocol for a study on music listening in older adults using our hearing implants is in my to do list as well as writing the text for an online hearing test that we plan to post on our website, www.medel.com. Where does all this work initiate? Since I report directly to the company's CEO, I'm to blame!

I am in a privileged situation, my work is varied, not only in what I do but also in my colleagues' backgrounds and professions. External colleagues are researchers, surgeons, audiologists, rehabilitation therapists, engineers, ethics committee members, and regulatory agency personnel. Internally, I work with a similarly trained team in R&D, sales, marketing, clinical research, clinical support, regulatory, and reimbursement. Both external and internal

Life as a medical writer for a medical device company



From left: Vibrant Soundbridge middle ear implant and sound processor, cochlear implant remote control and two sound processors, and two versions of the MED-EL cochlear implant.

colleagues are located throughout the world, which makes my work even more interesting, if somewhat more challenging. Sometimes international conference calls take place while my colleagues in Asia are brewing their morning tea and while we here in Europe are falling asleep at our desks. Because of my work, I travel quite a bit around the world to congresses and to meet with colleagues. Although I have learned how to say ‘good morning’ and ‘good evening’ in only a few languages, I have mastered the translation of the word ‘receipt’ in many languages!

Travelling to interesting places and working with interesting people are just two of the many things that I like about my job. I also am enthusiastic about the company itself and its owners. MED-EL is a relatively small company that, even after 30 years in the medical device industry, remains privately owned by two pioneers in the field, Dr. Ingeborg Hochmair and Prof. Erwin Hochmair. Both of them



Professor Erwin Hochmair and Dr. Ingeborg Hochmair, founders and owners of MED-EL, GmbH.

have strong backgrounds in engineering and physics, and Dr. Hochmair is the CEO of MED-EL. About twenty years ago, the Hochmairs entered into a business partnership with 3M; however, they severed the agreement when they realised that board members wanted them to make changes to the cochlear implant that would have compromised its scientific integrity. The Hochmairs, therefore, developed the company in Tirol and have added several new hearing implants to their product line. Over the years, cochlear

I edit manuscripts, gather evidence, develop studies and write publications and marketing materials

implant technology has improved and results have been so good in both children and adults that today not only profoundly hearing impaired adults but also severely hearing impaired ones, as well as very young children, use cochlear implants. In 2004, MED-EL acquired a middle ear hearing implant, the Vibrant Soundbridge, which is used as an alternative to hearing aids and for people who have problems with their middle ears. We also make an implant that combines a hearing aid with a cochlear implant.

All in all, I would not change anything about my job! There is no routine day, and I very much appreciate the variety.

I also am enthusiastic about the company, which remains privately owned by two pioneers

In addition, our products have helped many hearing impaired children and adults throughout the world, which motivates me to get out of bed even on the darkest and coldest of winter mornings. I have no plans to leave the company before I retire, and I do not expect that there will be any need to do so. The amount of work never decreases, it just accumulates and I doubt that we will ever contract our writing to a CRO because we believe that we benefit from an exchange of information amongst professionals within the company. In addition, our field is relatively small and specialised, and there are benefits to having our employ-

There are benefits to having our employees stay at the company for several years

ees stay at the company for several years: accumulated knowledge, stable relations with customers and partners. Because our hearing implants are implanted and used in patients for decades, there is a great need for trust amongst patients, surgeons and audiologists, and other professionals. We have received much positive feedback that surgeons and patients trust us because our staff have been in the field for a long time.

Would I recommend working as a medical writer at a medical device company? Yes, no doubt! And especially at a small one like MED-EL. The work is very satisfying.

Jane Opie
MED-EL GmbH
Innsbruck, Austria
Jane.opie@medel.com



Take as directed: Has the recommended cautionary and advisory labelling for dispensed medicines been improved?

by Wendy Kingdom

The standard wording for cautionary and advisory labels for dispensed medicines in Great Britain has been revised to make them more easily understood [1,2]. This labelling does not refer to the specific dosing instructions for individual patients (e.g. Take one tablet every morning) but to the additional wording such as “Spread thinly” or “Do not take with any other paracetamol products.” It is recommended that pharmacists add these additional labels when dispensing medicines. In reality, the computer labelling system automatically adds the recommended additional

wording to the relevant labels so the wording appears on dispensed medicines without the pharmacist having to look up the applicable cautions in the British National Formulary (BNF).

The depressing reality is that between 30 and 50 per cent of prescribed medication is not taken as recommended. This is not a uniquely British problem but is found consistently across disease states and countries [3]. Fitzsimmons et al have researched the subject of ‘health literacy’ of consumer-orientated webpages for patients with Parkinson’s disease [4]. Health literacy is defined as “the ability to perform basic reading and numerical tasks required to function in the healthcare environment.” The researchers found that only 1% of the webpages were fully comprehensible to the average adult. It is recommended that patient-orientated literature should be pitched at or below the literacy ability of children 11 to 12 years of age because, it is asserted, poor health literacy leads to poor treatment compliance. But what is an average adult? Whether we understand something or not, some of us will do exactly as our doctor tells us, others of us will do exactly the opposite and everyone else will do something between the two extremes. Our individual reasons for our behaviour are likely to be complex and unique. So we shouldn’t confuse failing to follow instructions due to lack of understanding with a conscious choice not to do what we are told. It is obviously a good idea to maximise the probability of important instructions being understood but it is also important not to pitch the language at such a low level that people with average intelligence and above do not take the information seriously.

Call it concordance, adherence, compliance, dyslexia, whatever you like, a substantial proportion of patients do not take their medicines as the prescriber intended. Therefore, any

change that might help to improve this situation is to be welcomed. This is the first time in 30 years that the labels have been revised, although minor changes have been made during this time. However, it is clearly time for change.

Professor Raynor of the University of Leeds was commissioned by the editors of the BNF to conduct user testing on the standard wording and to recommend revisions. Almost 200 participants were involved in three rounds of testing, which resulted in changes to 29 of the 32 standard labels. Although the wording has changed, the intended instruction in the original labels remains the same [1].

Some of the revised wording is undoubtedly an improvement. For example:

Before	After
Avoid exposure of skin to direct sunlight or sun lamps	Protect your skin from sunlight - even on a bright but cloudy day. Do not use sunbeds.
This medicine may colour the urine.	This medicine may colour your urine. This is harmless.
...swallowed whole, not chewed	Swallow this medicine whole. Do not chew or break.
Contains aspirin	Contains aspirin. Do not take anything else containing aspirin while taking this medicine.

It is reassuring to see that the language has been revised from indirect (“Avoid exposure of skin...”) to direct (“Protect your skin...”). Explanations have been added (“This is harmless”), and instructions have been extended.

Interestingly, user testing identified that the word ‘drowsiness’ is not always readily understood but the word ‘sleepy’ is less troublesome. Hence the following changes:

Before	After
Warning: May cause drowsiness	Warning: This medicine may make you sleepy
Warning: May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink.	Warning: This medicine may make you sleepy. If this happens, do not drive or use tools or machines. Do not drink alcohol.
Warning: Causes drowsiness which may continue the next day. If affected do not drive or operate machinery. Avoid alcoholic drink.	Warning: This medicine makes you sleepy. If you still feel sleepy the next day, do not drive or use tools or machines. Do not drink alcohol.

There are two issues with these changes, most notable being the use of the word ‘warning’ before the caution about sleepiness if the medicine is a hypnotic. The whole point of taking the medicine is that it is supposed to make you sleepy so it doesn’t make sense to warn people that the drug should have the desired effect. This raises the question of how the user testing was done. How were the



subjects selected and what questions were asked? Just as we want to know exactly what was asked if we are sceptical about results of a survey, so the same scepticism applies to user, readability or consumer testing.

The second issue with the change from drowsy to sleepy is that many preparations can produce a slowing of reaction time and a loss of mental concentration that can have the same effects as drowsiness [2]. In these cases, warning someone that the medicine can make you sleepy could be misleading. I have a personal experience of this side effect. A long time ago, before the labelling was changed on a second generation antihistamine, I took a single tablet just before driving home; a journey time of about 2 hours. During the drive I was aware of feeling rather strange but I wouldn't describe the feeling as either drowsy or sleepy. However, as soon as I arrived home, I decided to lie down for a short while. Two hours later, I woke up and decided that my first dose of that particular antihistamine was also the last. The lesson I learned from this is that a drug can make you drowsy (or sleepy) in ways that we might not recognise. Therefore, the change in the standard cautionary labelling from 'drowsy' to 'sleepy' might not be quite the improvement that it appears to be.

Consider this change:

Before	After
Do not take indigestion remedies at the same time of day as this medicine.	Do not take indigestion remedies 2 hours before or after you take this medicine.

If we want to be picky about it, we could ask if it's alright to take indigestion mixtures 1 hour before or after taking the medicine. Surely it would be better to say "...within 2 hours...?"

This change:

Before	After
Warning. Avoid alcoholic drink	Warning: Do not drink alcohol while taking this medicine

...makes me think that you shouldn't wash the tablet down with gin but once you've swallowed your medicine, you can go to the pub as usual.

And this one:

Before	After
...with plenty of water	Take with a full glass of water

...is clearer in some respects but glasses come in many shapes and sizes. It might be better to say "Take with at least XXXml of water."

On the whole, more words are needed to explain something in patient-friendly than in technical language. Therefore, one possible unintended consequence of the new cautions is that more medicines will need two dispensing labels instead of one. Most manufacturers seem to give little thought to where one dispensing label can be placed without obscuring the name of the preparation or the product details; two labels will cover up all identifying features of the original packaging.

Overall, revision of the cautionary and advisory labelling is a good thing, particularly since the new labels have been

user tested. It would be interesting to see the details of the user-testing methodology.

Wendy Kingdom

Wendy Kingdom Limited
Somerset, England
info@wendykingdom.com
www.wendykingdom.com

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Time tracking

Don't count every hour in the day, make every hour in the day count.

Alfred Binet, French psychologist

During my working life as a medical writer I have worked for a pharmaceutical company, contract research organisations, and, for the last 8 years, freelance. In every role I needed to keep track of how much time I spent working on various projects, occasionally as a fairly vague percentage estimate, but usually in some detail. As a freelance writer, I usually invoice my clients on the basis of the actual time worked, so it's necessary to keep track of my working time. Making a note of when I start to work on something and then making allowances for distractions/lunch/phone calls seems a bit haphazard in this day and age, so I recently looked for some more technical solutions (which don't cost anything, but which aren't *too* technical). One is a web-based stopwatch, (<http://online-stopwatch.chrome.com/>) which is a simple stopwatch function that you just start and stop as you work. If you happen to be working on several things at once, you can label each time period and do the sums afterwards (the results can also be downloaded into an excel file). I've also just discovered an open-source, time-tracking software called Rachota (<http://rachota.sourceforge.net>), which enables a more sophisticated tracking of multiple tasks. There are others out there: for example, colorhat.com, or mite.yo.lk/en/ (both €5/month). I've only just downloaded Rachota (duration on this article so far, 47 minutes and 46 seconds), so I will write again in the next issue as to how it's working out.

It would be interesting to hear how other writers track their time, and your experiences of using time tracking applications. My plan is that if I count my working hours, then I will have more hours in my day that really count...

Pamela Waltl

pwaltl@aon.at

Pondering the subtext: Q-tips and toothpicks as putative measures of public intelligence¹

by Jack Aslanian

My dentist will not succeed in getting me to stop using toothpicks. He tells me they can break. *Of course they may. Cars may collide when driven....* “Use floss instead,” he says. How frequently adverse events occur with the use of toothpicks, how dire such events are, and how difficult it is to extract broken tips (if they do break), he hasn’t told me. On the one hand, implicit in his paternalism is a low regard of the average Joe (or Joyce) Dentalgiac. On the other hand, he should know that I have done surgery, and am capable of using tools, and therefore also a toothpick.

I have not yet asked him if it is OK to use toothpicks in connection with meals but not for regular dental hygiene in the bathroom. If toothpicks were to be marketed for the first time today, would they need FDA approval as a medico-dental device? Would the same apply to Q-tips² if they were just invented?

The current texts on Q-tip packages would suggest that the manufacturers and their competitors have voluntarily gone through a process not all that different from the formal and mandated regulatory process for medical devices. But in reality what they have done is to engage in risk management. The marketers of one brand appear to broadcast buzzwords to seduce the buyer into complacency: ‘**COTTON SWABS GENTLE & SAFE**’ in large italic font is under the brand name on one package. A few centimeters below, however, is this: ‘**CAUTION! DO NOT INSERT IN EAR CANAL.**’ Other messages, declarations, and commands, similar in tone and logical reliability, appear on the packages of various other brands.

One manufacturer is so convinced of the illiteracy and untrustworthiness of the average consumer that to protect its (the manufacturer’s) derriere, and perhaps also keep them (the public) from harming themselves, it has taken additional measures such as including the following in the otherwise imaginable writ on the box: ‘**SAFETY SWABS SPECIALLY DESIGNED FOR CHILDREN**’, but ‘**Keep out of reach of infants and young children.**’ This brand has been redesigned (‘improved,’ to use marketing lingo) with the addition of an extra ring of cotton about

half a centimeter from the tip, which will prevent all but the extreme 0.4 – 0.5 cm of the bud from entering not just a baby’s ear canal but also an adult’s. The problem with this design (aside from the insinuations underlying its conception) is that it is hard to imagine how it might effectively be used (intelligently or otherwise) for any of the other purposes for which cotton buds have been used.

Q-tips were actually developed and eventually successfully commercialised in the 1920s by Leo Gerstenzang with the aim of improving the safety of otic hygiene, specifically of babies^{3,4}. He had observed his wife using a pinch of cotton impaled at the tip of [alas!] a toothpick to clean their newborn’s ears. As happens with most initially single-purpose products that succeed in their original mission (and also many that fail in one arena), corporate interests pushed forward advertised suggestions for other extra-aural uses for cotton swabs⁵; to the point that now they are being advanced as tools for cosmetic pursuits⁶.

It would be foolish to assert that cotton swabs are absolutely harmless. There is no such product. Who among us has not had a paper cut? Next to the packaging of cotton swabs, however, the warnings on boxes of cigarettes appear mild, and even surreptitiously permissive—not unlike the playful admonitory shaking of a raised index at a friend. (Can we not quickly guess why? And why in fact tobacco is still being cultivated and sold?) Based on personal and professional experience and observations, I have no problem asserting, however, that the opposition to the otic use of cotton swabs is exaggerated and extremist. They could and may properly be used inside the ear canal by the general public: not every day, however, not inattentively, and especially not to remove accumulated, impacted, and occlusive amounts of earwax (in which latter instance the swab will act as a ramrod—a ‘plunger’).

The prohibitory messages against the original, and probably still-most-common use of cotton swabs have political and social (possibly even social engineering) overtones. It is very likely that most citizens comprehend such

1 A word of caution: Nothing in this essay should be interpreted as reflection on or assessment of any but US society. My familiarity with other cultures is that of an occasional traveler, superficial and patchy.

2 The trade name ‘Q-tips’ is used, at least in the USA, to refer to cotton swabs in general (a.k.a. cotton bud, ear bud, domestic cotton applicator, etc.—and even ‘ear-plungers’ [sic]).

3 ‘Q’ standing for quality.

4 The primary source for general background information is <http://en.wikipedia.org/wiki/Q-tips> and the links provided by it and a Google search of ‘Q-tips’ and ‘cotton swab’. Another site is www.qtips.com.

5 I still recall my serendipitous discovery in a user’s manual that a cotton swab could serve to clean tape-recorder heads. And many similar uses in hobbies.

6 Its corporate web site has pictures of women touching eyes, cheeks, and lips with Q-tips.

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messages but do not heed them. If they do follow the label commands, they probably use an index or little finger instead—which may not penetrate as far as a swab, but which may traumatise the ear canal much more than a cotton bud (especially if fingernails have not been trimmed for some time, or have just been trimmed).

Anybody with a little imagination and acquired knowledge (the underpinnings of ‘native intelligence’) can be certain that cotton swabs may do harm. But there are numerically and qualitatively more serious injuries to the eye from flying fragments than to the ear from anything, including swabs. Should everyone be commanded to wear protective eyeglasses? The case against the use of cotton swabs is not watertight. In fact, the arguments for it, at least in the public arena, are muddled. In the context of one debate (with potentially regulatory consequences), attributed to a specialist is the statement that “... he sees 10 to 15 cases a year of eardrums ... broken by improper use of cotton swabs or hairpins⁷.” How many of each? We don’t know. Is there a ‘proper’ use of hairpins in ear canals?

Apparently there have been ‘... four or five... cases...’ of deaths, admittedly rare occurrences, attributed (either evidentially or presumptively) to perforations of eardrums by a cotton swab. Is it 4, or is it 5? In how many years, i.e. incidence? Could those who died already have had an infection, for example, in the ear before the presumed swab-induced perforation? Could the swab simply have been an *added* insult? Coincidental? Might the eardrum have ruptured anyway on its own from another underlying cause? The knee-jerk response to a problem, probably real but rare, is disproportionate, in my opinion. Should we take seriously the public official’s suggestion to add to the already required (in Canada) label warning a ‘... pictogram ... that showed a small ear with a red X painted over it.’? Will that pictogram need clarification so that it is not interpreted as an interdiction against eavesdropping or as a command to turn a deaf ear to...?

Some may argue that Q-tips and toothpicks are small fry in the wide arena of medical devices, too small to deserve elaborate discussion. The point to be considered, however, is not simple products, but perceptions or validations of public intelligence. The current labeling of those simple products indicates the magnitude of the reaction to a ‘rare’ potential danger and product safety taken to the extreme. Implicit in the labeling of cotton swabs is a devaluation of public intelligence. If they do not insult the thoughtful, such communications as the instructions on a pack of cotton swabs could engender and fortify public debility, the disuse atrophy of critical thinking and certain mental faculties and functional capacities. If you repeatedly tell people outright or by implication that they have a limited capacity in a certain area, most are apt eventually to take

the message to heart—especially if it comes from a figure with authority or power (e.g. parent, media, government).

When you don’t or can’t ban tobacco outright and have to resort to easily negligible package warnings and piecemeal smoking bans in designated locations, that is a failure of upbringing, reason, and common sense in the face of profit-motivated fashion-mongery. When you have to tell people not to use a simple and well-designed tool (a product that has considerably less potential harm than does tobacco use) for the purpose for which it was devised, that too is escapist, but also a failure of public health education. Not all of health care should be exercised as an exclusionary, absolutist priesthood of medical professionals and public health regulators. In some matters, the public deserves empowerment, education and trust—and after being educated should be charged with responsibility for themselves. The public does not need edicts and fear-mongering. How do you use Q-tips? Or a toothpick? Just like everything else. Mindfully and carefully. That is where educators and writers come in; and with respect to the use of cotton swabs and toothpicks in personal hygiene, that is where public health educators and medical writers come in. Writing thoughtfully and well about medical devices is part of our responsibility.

Jack Aslanian

Freelance Medical Editing
Oakland, California, USA
jaclanian@earthlink.net



Here lies a Proof that Wit can never be Defence enough against Mortality.

Aphra Behn (1640-1689) was the first woman to earn her living from writing! She was a poet, playwright, novelist—and spy. Her best known poem was a coronation ode to Charles II and she spied for the king during the Dutch War. Her novel *Oroonoko* is considered one of the first anti-slavery works in the English language and is about an enslaved African prince. Behn is buried in the east cloister of Westminster Abbey, London (<http://www.poetsgraves.co.uk/behn.htm>).

With thanks to Ursula Schoenberg for sending this photo.

⁷ <http://www.cbc.ca/canada/story/2008/02/06/swab-warning.html>

What price quality?

A summary of the Society for Editors and Proofreaders' report on the overseas outsourcing of editorial services

by Kathleen Lyle and Helen Stevens

“So there’s a British publisher outsourcing to an Indian outfit who outsources to a British editor. Something wrong here, surely?”

In September 2008 the National Union of Journalists (NUJ) held a meeting in Oxford on quality in academic and educational publishing. One of the issues raised was the overseas outsourcing of editorial services and its effects on standards in academic publishing.

The use of overseas suppliers, freelance or corporate, is well established throughout the United Kingdom’s publishing industry. British publishers have routinely and successfully used overseas typesetters (mainly in India, Singapore, Hong Kong, and the Philippines) for many years.

With the increasing availability of fast internet access in many countries, geographical location seems increasingly irrelevant. What remain relevant are linguistic ability and editorial skills. The concern is that some overseas suppliers whose staff do not have English as a first language are now offering editorial services, often based on a rigid, rule-based approach. At present this seems to occur most often in scientific journals. In this context it is important to remember that many of the authors of these papers do not have English as a first language either, and may require considerable editorial help.

Although it is difficult to quantify the effects of this development, the anecdotal evidence is not encouraging. Following the NUJ meeting on the general issue of quality in academic publishing, the Society for Editors and Proofreaders (SfEP) requested members to report their experiences of this type of editorial outsourcing. Over 40 replied, and this article presents a selection of their comments, giving perspectives from freelance project managers, proofreaders, in-house desk editors, and freelance copy-editors. The full report, written by Kathleen Lyle, is available on the SfEP website (<http://sfep.org.uk/pub/news/outsourcing.asp>).

Extra work for in-house editors (and freelancers)

A major issue highlighted by respondents was that in-house staff often had to carry out additional work on material that had been edited overseas. The use of freelancers for additional quality control or proofreading comes ‘above the line’, and can be set against the savings derived from outsourcing. This is not the case for additional work by in-house staff, whose costs are counted as overheads. Presumably the additional workload will decrease their

in-house productivity and therefore their profitability in real terms.

“In-house staff complained to me about poor work done in the Far East that they had to spend much time correcting.”

“Management found that money saved out of house was being spent in-house instead and that turnaround was slower. In-house editors had to do more work.”

“The strength of overseas suppliers is supposed to be their ability to throw any number of bodies at work to get even large projects completed quickly. However, their great weakness is that these bodies can only work with very precise rules and instructions, which leaves the slack to be picked up by someone in the UK.”

Disenchantment

Some UK publishing companies have experience so many problems with overseas outsourcing that they have become seriously disenchanting.

“The quality was so poor, and the complaints from the journal editors so great, that it was all brought back to the UK after a year.”

“I learn [*sic*] that there are regrets in some quarters that this [overseas outsourcing] route was ever taken; the cost savings have not been as great as expected and the hassle has been considerable.”

While the return of editorial work to the UK may mean more work for UK-based freelancers, sometimes the rates of pay are unfavourable (see below).

Poor-quality editing

Language editing

Various issues were raised concerning the lack of quality in language editing: inadequate knowledge of English, lack of appropriate subject knowledge, an inability or unwillingness to do anything that is not strictly rule-based, an over-reliance on pre-editing clean-up macros, and sometimes unnecessary changes that may alter the sense or introduce errors. There usually seems to be a lack of the kind of lateral thinking that a good editor requires—perhaps because there is no time for it, or because it does not fit in to the script-based approach generally adopted by these suppliers.

“Frankly, I am astonished that ... a high-profile publisher of medical texts favours low costs over quality, and the hazards of potentially introduced errors are obvious in the

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context of medical texts ... the risks for introducing injurious and possibly fatal results in the medical community as a result of erroneous text are vastly increased.”

“They could not tell whether an author’s abstract was written in good English or bad and were liable to convert good English to worse.”

“One problem with these editorial agencies is that they require rigid house styles and don’t have the skills, experience or judgement to know when not to apply the rules. Having the wisdom to know when not to follow house style is, in my book, one of the most important signs of a good editor.”

Other aspects of editing and page layout

Sometimes there seems to be a mismatch between what the clients expect and what overseas suppliers offer. It may be convenient to call this ‘cultural’, but it probably reflects the way in which UK editorial freelancers have tended to undersell themselves and their services. We do lots of things because we think they are part of the copy-editing/proofreading job, but if they aren’t explicitly specified in the brief an external supplier will not do them.

“Apparently little effort had been made at the editing stage to impose any uniformity on the chapters in the way the text features were handled, and the headings were graded in an almost random way. There were also a lot of small typos that the authors hadn’t noticed and that should have been cleaned up by the copy-editor.”

“There were illogically graded headings, and any number of inconsistencies of hyphenation and spelling.”

Insistence on first-language input

In what seems to be a relatively recent development, some publishers and their overseas suppliers are attempting to have the best of both worlds: they are requiring their overseas suppliers to use native-English-speaking editors. It’s an advance over the kind of ‘non-editing’ mentioned above, but its consequences for UK-based freelancers are questionable (see the following section).

“I have had two or three assignments per year from an outsourcing company in India for proofreading or copy-editing; the client is a large academic publisher and they insist that this part of the work is done by an English native speaker.”

“Both of these [UK publishers] outsource some project management to companies overseas, with explicit instructions that they hire UK freelancers, so keeping the language work in the UK.”

Financial consequence of outsourcing for UK freelancers

Experiences here are mixed so far. For many large UK publishers and their overseas suppliers this is a new way of working, which may not yet have had time to settle down into a general pattern.

“The fee might not look particularly good at first, but I find I can work fairly quickly as all the technical and formatting work is done in-house by the outsourcing company.”

“I and several other British freelancers have seen a drop in the page rate for editing because we in the UK were previously doing this pre-editing work (as well as the on-screen editing), and this drop in rate has not been commensurate with the reduction in work required for each text.”

“I worry that such competition is driving down UK rates. Last week I turned down a job that would have equated to £7/hour, the lowest rate I’ve been offered in 20 years!”

Working practices

The good

Traditional practices in the UK publishing industry are far from perfect. There is scope for more efficient business practices that can be learned from overseas suppliers.

“The representative I was dealing with was very responsive, dealt with queries quickly, even when taking into consideration the time difference. His English was extremely good, which meant we never got at cross purposes.”

“They were well organised on the financial controls side, and gave me a proper works order, plus had me sign a form to formalise the position on tax.”

“I have to say that the organisational side is very good, including feedback, keeping freelancers informed of any changes, etc. and invoicing procedures.”

“The outsourced suppliers are excellent at balancing workloads, dealing with chaotic manuscript transmissions, and doing the actual typesetting.”

The not so good

“Often, the work we’re offered is from Asian companies—and there are problems: poor communication, lack of editorial knowledge by the client, incomplete material. In short, a lot of the clients seem to be ‘pen pushers’ with little knowledge of publishing nor ability to resolve problems: all they want is to pay as little as possible and get the job back on time, and don’t want to hear about problems that need resolving.

“However, the major STM publishers seem happy enough with this state of affairs. They seem to operate on a ‘good enough’ principle, and presumably the product meets needs even though STM books and journals may, overall, be produced to a lower standard than, say, 10-20 years ago. If the customers (academics) are happy and costs can be pushed right down, then the STM publishers are happy too.”

The bad

Done well, pre-editing can save the copy-editor’s time, allowing him/her to concentrate on important features of the text rather than small details of style. Unfortunately, the way it is done at the moment is often far from perfect, so that it sometimes has to be undone or redone by the copy-editor. >

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- > Copy-editors commented on lack of communication with the author, which led to queries having to be repeated for chapter after chapter—this is frustrating for both author and editor. Queries inserted by the typesetters can also be a source of irritation. They may be inappropriate or badly worded, perhaps as a result of an inflexible protocol adopted by the typesetter.

“Each chapter had to be returned individually, as soon as it was finished. I hate not being able to go back and revise a decision, based on later evidence!

“I couldn’t raise queries directly with the author, but had to send them back with the chapter, so I wasn’t getting any feedback and ended up raising issues again and again, which may have been avoidable.

“Queries had to be inserted in the file using the comments feature and repeated as a separate list, which was awfully time-consuming.

“The file had been ‘pre-edited’ in India and all the comments and markings left in, meaning I had a really ugly and messy file to deal with. I couldn’t switch to the ‘show final’ version, because I needed to see what all their comments and edits were.

“The pre-editing wasn’t well done, which meant I was raising issues not just on the author’s work, but on that of the pre-editors.”

The ugly

We have all heard of freelancers being suddenly left without a source of income, sometimes with no warning. This seems cruel, although it is one of the risks of freelance life. However, a great deal of valuable expertise has been jettisoned in this way, and there is often no one left in-house who knows the details of the editorial process. The publisher is at the mercy of suppliers who may not be adequately briefed, may not understand the brief, or may not be capable of providing the quality they promise.

This may be partly the fault of freelancers themselves: we are not good at blowing our own trumpet and we could and should probably do more to sell ourselves to the decision-makers in large publishing houses.

“About five years ago I lost four medical journals for which I had been sole copy-editor for several years (one of them for over 14 years), when the publisher decided to send them to India for copy-editing (and typesetting as well I think). This was a large proportion of my income and left quite a gap in my client list as well.”

“It is becoming increasingly clear that many in-house editors do not know what it is they are asking freelance copy-editors to do.”

“A major publisher I worked for outsourced typesetting to India, and it thus became logical to do the proofreading there as well.”

Where do we go from here?

Editors are traditionally accustomed to being in the background. Although the focus in large publishing houses has moved from editorial to marketing in recent decades, editors have continued to assume that everyone understands the value of the work they do, and is prepared to pay them (although usually not very well) to do it. That is no longer the case. If publishers, ever aware of the bottom line, now think that substandard but cheap editing is ‘good enough’, that’s what they will use. It is up to anyone who is interested in editorial quality—including members of organisations such as the SfEP and EMWA—to demonstrate what good editing is, and the value it can add to their publications.

Kathleen Lyle

*Freelance editorial consultant
Oxford, UK
Advanced Member of the Society
for Editors and Proofreaders
kathleen.lyle@ssep.net*

Helen Stevens

*Freelance editor and proofreader
Bradford, UK
Marketing and PR director of the Society
for Editors and Proofreaders
marketingpr@ssep.org.uk*

It is a critical issue, the topic of outsourcing: Commentary on “What price quality?”

I am an Indian but I lived in Europe over the past ten years, which was a major time for the emergence of outsourcing. I can understand that decisions taken by publishing houses in the UK to outsource their work to India can be difficult for freelance editors and writers in the UK to tackle and can have an effect on the quality of the work produced.

I would like to first set my commentary on the findings of the SfEP reported by Kathleen Lyle and Helen Stevens’ article against the background to the use of Indian as an outsourcing destination for copyediting. 200 years of colonial history led to English becoming the major language in primary education and the only language for higher education in India. It was also practical as otherwise it would have been difficult to create a centralised education system for a country where the population of every region speaks and writes a different language. Keeping English as a language of education helped Indian students and workers to hop from one state to another, a criterion needed to maintain a country. I, being a ‘Bengali’, can think science only in English.

Having said that, it is important to point out that English is not the mother tongue of any Indian (by birth). It is a second language for an educated Indian and the influence of our mother tongue and culture is evident in the English we write. If you read a fiction piece from any Indian author who writes in English you can see this difference. While this is no barrier for creative writing and can secure the Man Booker and Pulitzer prizes, it is a flaw we Indians face in medical and science writing.

Also, whereas English in the UK and USA has evolved over the years, we are taught an ‘old ornamental form’ of

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English in most schools, as the teachers are non-native English speakers. The education system is still mostly of a 'blackboard to notebook' type based more on memorising than exploring, where students have rare chances to get a feel for the language. The Plain English campaign is only at its nascent state in India. So although technology has improved online working between the UK and India, the mental wiring of writing professionals working in the two countries is very different. Publishing houses therefore provide strict protocols for the jobs they outsource to India, which precludes the lateral thinking which Kathleen Lyle and Helen Stevens state in their article is needed to be a good editor.

Another issue is that in India the fields of humanities and science/engineering are considered as two different worlds. Science students are rarely encouraged to develop their language skills and humanities students remain bound in fiction. Research-based non-fiction was rare in Indian bookshops until recently, but now popular science articles, travelogues, memoirs and political literature are available in English and people are interested in reading about these topics. This I hope this will bring a genuine shift in the writing style of Indians as a whole.

Finally, freelancing rates in India are really low. It is common to get £7 for a 500-word write-up, which requires moderate research and one to two editing cycles. This means a freelance writer must seek out other sources of income to cover living expenses and consequently the quality of articles suffers. I would like to emphasise that in the quest for cheap prices very little money trickles down to the freelancers in India.

The best option in my view would be to create a bridge, where writers and editors from India and the UK become more involved with each other and produce the quality work which is essential for medical and science literature as a whole. Associations like EMWA could come forward and play an important role in the meshwork of medical writing and editing outsourcing so that not only the multinational companies but also freelance writers and editors from both countries can benefit.

Chandrima Pal

pchandrima@yahoo.com

Another Indian viewpoint on outsourcing

In an article published in *European Science Editing* [1], Yateendra Joshi also comments on the SfEP's report (<http://sfep.org.uk/pub/news/outourcing.asp>). He distinguishes between on the one hand proficiency in English at the level of a native speaker of the language and on the other hand copyediting tasks such as matching text citations and references, ensuring consistency in heading format, stylistic changes (e.g. litres to L) and inserting text coding to indicate the text format for typesetting (italic print, headings

etc.). He points out that according to a survey, which he quotes, references alone account for more than 40% of editing changes in an article. Non-native English speakers, he argues, can perform these tasks as well as native speakers of English but he accepts the latter are at an advantage in checking English usage and grammar, adding that many readers are not native speakers themselves and have low expectations, so will probably not be concerned about the occasional incorrect preposition.

He concedes that Indian editors rarely attempt to make text more readable, which he suggests stems from a lack of domain knowledge and short turn-around times demanded by publishers, contending that this could equally apply to native speakers who are not experts in the topic or are strapped for time.

Yateendra believes there must be trade-offs between paying more for high quality and paying less for quality acceptable to customers. Customers fall into three categories, the largest of which is the authors for whom "cost is obviously an important criterion." [It is not clear here if he is exclusively referring to the author pays publishing model.] Publishers form the second category and "probably demand higher quality, which native speakers are more likely to supply," but publishers are also interested in keeping costs low. The third category is the readers, who Yateendra considers the least influential customers.

Availability and speed are other justifications Yateendra offers for outsourcing to India. Given the time difference, overnight services provided by the outsource companies may [as well as price] trump quality.

Reference:

1. Joshi Y. Native and non-native speakers of English as copy-editors of research papers. *European Science Editing* 2011;37(2):37-8.

Discovering research misconduct: When the going gets tough

Patricia Keith-Spiegel, Joan Sieber, and Gerald P. Koocher have produced a user-friendly guide on how to act when you suspect research misconduct. They explain that the guide is for scientists who want to do the right thing, but are unsure how to go about it or are concerned about negative consequences for them or their junior colleagues.

http://ori.hhs.gov/documents/Responding_to_Research_Wrongdoing.pdf.

Joining forces to address the global challenge

CRO markets are growing in Europe by 8.7% p.a., in the US by 11.9% and in India by 41.4%. These were some of the figures given by Nermeen Varawalla during her plenary lecture at the EMWA conference in Berlin titled, 'Shift of Clinical Trial Activity to the East: Implications for Europe'. Nermeen is the founder and CEO of ECCRO, a company based in Europe that offers outsourcing services exclusively in India. The services offered are study start-up, trial monitoring and site management.

Nermeen began her presentation by outlining the serious risk to European pharmaceutical revenue posed by generic competition. On average 44% of top company sales are at risk of being lost to generics. A wave of drug licences are running out opening up the market for generics and India is also rapidly establishing a strong base in the manufacture of generic drugs.

Innovation to develop new drugs is critical for Big Pharma but while R&D investment has tripled since 1996 FDA-approved medicines have declined by two-thirds. Nermeen demonstrated with the statistics how Big Pharma is becoming increasingly reliant on biotechnology companies for innovation. However, since 2008 these companies have experienced a downturn in available finance. Interestingly most recent deals between pharma and biotech have been in the field of oncology followed by CNS and infectious disease. The problems facing the pharma industry are further exacerbated by a greater focus on drug safety accompanied by ever more complex pharmacovigilance and risk management. At the same time more intense scrutiny is being directed towards the economic and social value of treatments by health authorities.

In the light of these factors and a background of falling clinical trial participation in Europe and the US, (e.g. in the UK currently only 2% of the population are enrolled in clinical trials), Nermeen presented India as the most attractive emerging country in which to conduct phase II-IV clinical trials. India has a population of 1.15 billion facing a huge unmet medical need, low healthcare delivery costs, highly productive hospital sites, a growing track record of successful FDA audits, English as a second national language and acceptable regulatory timelines (see Box).

Cost savings are also a primary reason for clinical trials to move eastwards. The saving is as much as 60% of the cost of running trials in the US or Europe because, for example, investigator and site fees are 50% of those in the West. Fees for translation and medical writing services are also considerably lower.

In one slide Nermeen presented the following attractions and challenges of placing clinical trials in Europe:

Attractions	Challenges
500 Million Caucasian Population	Harmonisation not Complete
Skilled Investigators & Respected Opinion Leaders	Administrative Burden
Organised Healthcare Infrastructure	Inefficient and thus Expensive
Experienced Clinical Research Environment	Poor Patient Recruitment
Important Commercial Market	Non-Productive Clinical Trial Sites

Taking the advantages offered by Europe and by India and joining forces to address the global challenge was the forceful note upon which Nermeen ended her presentation.

Slide below presented at the 32nd EMWA Conference. Reproduced with permission from Nermeen Varawalla



India is one of the world's most attractive clinical trial locales

Key Growth Drivers

- Access to clinical trial subjects
 - India has 20% of the global disease burden
 - High prevalence of developing & industrialized world disease
 - Huge unmet medical need
 - Patients travelling to centralized hospitals for healthcare
- Cost savings of 60% as compared to the West
 - State of art diagnostics & therapeutics at one third US costs
 - Motivated, able investigators with relatively modest fees
 - Productive, cost effective hospital based sites
- Data quality
 - Growing volumes of Indian data accepted by FDA & EMEA
 - 14 FDA inspections, no "Official Action Indicated" verdicts
- Favorable clinical trial environment
 - Stable, progressive regulatory framework
 - 10,000 GCP trained clinical research professionals and 1500 GCP trained investigative sites
 - English for clinical research, healthcare & business
 - Robust IT infrastructure with an IT savvy workforce
- Commercial Potential
 - 12% p.a. growth in domestic pharmaceutical sales

- No. of international clinical trials conducted in India up by 30% p.a. for past 3 years
- Global trials with India up 15% in 0.5 yr www.clinicalTrials.gov
 - In 6 months ending August 2010, no. of global trials with India up from 1,191 to 1,366
 - 25% & 55% of these are Phase II & III, respectively
 - Oncology, Infectious Disease, Diabetes & Cardio-respiratory disease are the commonest therapeutic areas
 - Represents only 1.5% of worldwide clinical trials as compared to 52% US participation





PubMed: Scientific literature panacea?

by Andrea Rossi

What do medical writers do when they initiate a new publication? Like all good scientists, they look at the most up-to-date literature! In the era of the Internet, this would seem a simple task as scientific information available in the World Wide Web is, theoretically, never ending. Most of the available sites contain unchecked information and the systems created to certify their reliability are not enough to provide the same scientific value as the process of peer-reviewing.

Thus, peer-reviewed journals remain the gold standard reference for scientific literature. To date only about 4,000 have full text open access; they are a small number compared with the estimated total of more than 25,000 peer-reviewed journals [1]. This is why literature databases remain a fundamental source for scientists. When a medical article has to be written, most authors start smiling and think “let’s go on PubMed: all medical literature is there!” But, how many of them know what PubMed is and what it contains?

Generally, PubMed gives access to the US National Library of Medicine’s (NLM) premier bibliographic database and

“access to more than 20 million citations for biomedical literature from MEDLINE®, life science journals, online books.... and.... links to full-text content from PubMed Central and publisher web sites” [2]. PubMed’s search interface seems simple and there are clear instructions to refine searches if they are not satisfactory. There are some tricky things in the instructions. For instance, over 18 million references to journal articles belong to the MEDLINE database but it’s not reported how many belong to other, unspecified, sources. Furthermore, the search term entered in the ‘search’ window is recoded through an automatic term mapping [3] that could strongly influence your search outcome. The MEDLINE database can also be searched for free via other search engines such as MedlinePlus (<http://www.nlm.nih.gov/medlineplus>), NLM Gateway (<http://gateway.nlm.nih.gov/gw/Cmd>), Dematel (<http://www.dematel.com>), Medical Matrix (http://www.medmatrix.org/_spages/medline.asp) and many more. There are other search interfaces, including OVID and Dialog, where access requires payment. Each of these sites uses a different search algorithm. As a consequence, the results

Table 1: Medical literature databases—main features (NB all data are updated to April 2011)

Database	MEDLINE [4]	Embase [5]	Biosis [6]	Current Contents [7]
Owner/manager	U.S. National Library of Medicine’s®	Elsevier	Thomson Reuters	Thomson Reuters
Types of journals indexed	Life sciences with a concentration on biomedicine	Biomedical	Every life sciences discipline	Scholarly journals, websites, electronic journals
Number of references/journals indexed	Over 18 million references from 5,516 journals	Over 24 million indexed records from more than 7,500 journals. More than 260,000 conference abstracts from 800 conferences	18 million records from over 5,000 journals and journal literature	More than 7,000 relevant evaluated websites
Indexing system	NLM Medical Subject Headings (MeSH)	Emtree - Elsevier’s Life Science Thesaurus	Specialised indexing, including taxonomic data and terms, enhanced MeSH disease terms, Sequence Databank Numbers, and Major Concepts	Cover-to-cover, expert indexing
Journals indexed from (year)	1946	1947	1926	N/A
Frequency of updating	2,000-4,000 completed references added each day Tuesday through Saturday	Over 3,000 records every day	Weekly	Daily
Geographic distribution of journals	About 45% articles published in the U.S.; about 91% in English. 39 countries; 60 languages	51% from Western Europe, 30% from North America, 5% from Asia, 4% from Eastern Europe, 3% from Japan, 2% from Middle East, 2% from Central and South America, 2% from Australia and New Zealand, 1% from Africa	100 countries	N/A
Access	Paid or free	Paid	Paid	Paid

PubMed: Scientific literature panacea?

- > of the same search are often inconsistent when using different search engines.

Table 1 gives a brief summary of the main databases where scientific literature is stored and indexed. Frequency and indexing methods are reported too.

The various databases contain different journals (a list of indexed journals is available on each database's website) with different geographical and linguistic distributions; some include abstracts from congresses and other selected websites. Different indexing methods and dictionaries for coding articles' descriptors (rendering them searchable using standard words) are used, as the professionals who index the material have different backgrounds and standards. Databases are updated daily or weekly but the delay between article publication and their inclusion in databases is not reported. Descriptors used for indexing each

article together with title, authors, source and abstract can be checked in the output reporting search results but only a few journals have full text links. Selection and identification of review articles is possible when searching any of the above databases but the Cochrane Database, which is accessible through the Cochrane Library, with more than 4,000 systematic reviews from 1993 onwards, is the most comprehensive one. In addition, Cochrane Systematic Reviews include information from studies available only in trial registries [8].

What PubMed contains

MEDLINE is the largest component of PubMed that is freely accessible and is indexed through the Medical Subject Headings (MeSH). PubMed also contains:

- in-process or pre-published citations which provide a record for an article before it is added to MEDLINE,
- citations to some additional life science journals that submit full text to PubMedCentral and receive a qualitative review by NLM,
- citations to author manuscripts of articles published by NIH-funded researchers,
- citations for both the books and each chapter or section of a subset of books available on the NCBI Bookshelf.

PubMed provides links to many sites providing full text articles, links to other information or citations (such as those to related articles), a single citation matcher and a spell checker [3].

Conclusion

All of the above characteristics make PubMed a simple and comprehensive site where relevant medical references are available for free, but it is clearly limited in terms of indexed journals and search engine. Even in the Internet era, where literature searching is simpler than ever before, any comprehensive systematic literature search should be performed by an expert professional accessing the main medical literature databases.

Andrea Rossi

*Scientific Writer Eli Lilly Italy
Florence, Italy
rossi_andrea_a@lilly.com*

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EMWA member receives Pfizer award for excellence in writing patient-focused clinical trial information

The work of medical communicators—who usually rather act in the background—rarely gets officially recognised. It was therefore a very special event when, in March of this year, Susanne Geercken, long-standing EMWA member and workshop leader, was selected to receive the Pfizer REICO award as one of 11 winners across the Pfizer Development Operations organisation in the developed markets of Europe, Korea and Australia. REICO stands for “Recognizing Excellence in Clinical Operations.” Susanne received the award for her achievements in continuously improving patient-directed materials in clinical trials over the last years.



Left: Ermanno Patern , Speciality Care Medical Director, EU Regional Medical Teams, Pfizer
Middle: Susanne Geercken, Manager Translations & Procedures, Pfizer
Right: Dennis Joseph, Area Head, Clinical Operations in Developed Markets, Pfizer



Science writers and editors hijack software designed for management consultants

by Daniel Heuman

On a romantic walk in the park, a medical editor told me about her terrible week. “It was awful. I left the letters ‘xxxxxxx’ to fill in the details for an address, then I forgot about it until after they were printed.” The date in the park didn’t end so well, but I made a mental note to add a new function to a piece of software I had started to develop which was eventually to become PerfectIt (an add-in for PCs that finds difficult-to-locate mistakes in documents). I couldn’t salvage the date, but the typo was a problem I could solve!

During the initial development of PerfectIt, that was the only time a professional editor influenced its design. The software was actually intended for use in management consultancies. My background is in economic consultancy, and I designed the product to be useful to my former employer.

Not a spell checker or a grammar checker

To understand how PerfectIt was developed specifically for management consultants, consider the underlying challenge of all editing software. All editing software must balance the need to ensure documents are perfectly correct with the danger of false positives. Everyone wants their document to have no errors. However, computers don’t know what’s correct, so the computer actually alerts users to possible errors. The problem is that each possible error could be a false positive. And if there are too many false positives, users think the software is a waste of time.

To design a product that would help management consultants to proofread documents, I had to make the balance of accuracy and false positives suitable for a professional audience. There are exceptions of course, but management consultants write research reports for a living and (mostly) know how to write well and have good spelling and grammar skills. So if the software alerts consultants to possible grammar mistakes, there is a high probability that the software will be wrong.

For example, the grammar checker in MS Word is turned on by default. When management consultants use it, the checker interrupts them with a message such as “Fragments, consider revising.” They look at the supposed fragment, decide that it’s perfectly good the way it is and shut the grammar checker off. Knowing that the intended audience consists of professionals like these, the program focuses on errors that are likely to be mistakes. It especially focuses on consistency mistakes. For example, PerfectIt spots if the spelling ‘advisor’ is used in the same document as ‘adviser’. It could be intentional (for example in a quote), but most of the time that is an error and users will want to be notified of it.

My chequer tolled me sew

There is always a balance and PerfectIt is also prone to false positives. Two examples show the dilemma:

- **Hyphenation:** PerfectIt locates if a word is hyphenated in one place but not in another (e.g. ‘short term’ and ‘short-term’). However, it can be correct to use both in the same document depending on context (e.g. ‘the interest rates are short term’ and the ‘short-term interest rates’)
- **Capitalisation:** PerfectIt locates if a word is capitalised in one place but not in another (e.g. ‘Government’ and ‘government’). It understands (and does not prompt) if the word appears at the start of a sentence. However, even in the middle of a sentence, this could be intentional and in that case, PerfectIt wouldn’t know. This happens where the word is used as a substitute for a name in one place but not in another (e.g. the French Government may be referred to in capitals in ‘the Government decided that...’ However, the same document may use the phrase ‘some government documents show...’

Knowing those possibilities exist, it can reasonably be asked if software has a role to play in the solution. However, the speed at which the program can find these possible mistakes is incomparable to anything a human editor can do. It takes at least one read-through for an editor to find and correct hyphens and capitals. However, a computer can compare every hyphenated phrase to every single other phrase across hundreds of pages in a matter of seconds. Capitalisation is more challenging for a processor, but it’s still only a matter of seconds to get through hundreds of pages. That speed difference between man and machine suggests that software can be valuable. PerfectIt offers users a far faster, far more accurate method of editing. However, it relies on users who understand technical points about grammar and language. A user who doesn’t understand these, and who just assumes that all hyphenation must always be the same regardless of context, could actually make a document worse with PerfectIt.

Professionals don’t read the manual

Designing for management consultants requires that the software be easy to use. I have yet to meet a consultant who reads the help section before diving right in, so PerfectIt had to have an interface that could find and demonstrate complex errors in a way that’s easy to understand. It does so by showing the results of two searches (with an ability to switch back and forth between them). For example, it checks whether numbers in sentences appear as numerals or are spelled out (split between 1-10, 11-20 and 21-100 to cater for a wide variety of style guides). Users are given a choice. They select either ‘words’ or ‘numerals’ and the search results (containing all the possible errors) appear instantly with the ability to move up and down to select each location in the document.

Science writers and editors hijack software designed for management consultants

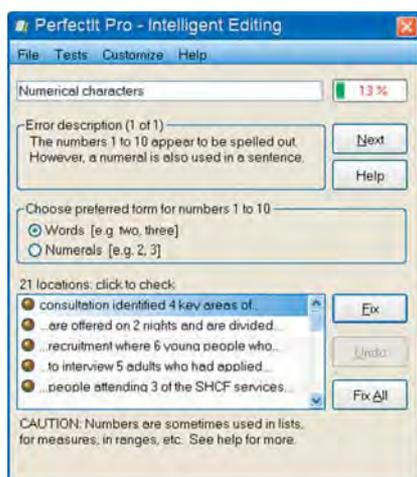


Figure 1: Users choose between words or numerals, and the search adjusts, allowing users to choose which to correct.

Multiple authors mean exponentially more mistakes

One author may struggle to maintain consistency. However, management consultants work in teams, with documents coming together from across departments and even across countries. The result is that PerfectIt has to find all sorts of mistakes that would be less likely with one author. These include:

- consistency of bullet punctuation and capitalisation;
- the order of table numbering; and
- use of title caps in headers.

However, perhaps the most important check on multi-author documents is the test of abbreviations. PerfectIt checks if:

- presentation is consistent (not 'NASA' in one place and then either 'N.A.S.A.' or 'Nasa');
- there are undefined abbreviations (each author expecting another to have defined it, or perhaps just forgetting entirely);
- abbreviations are defined twice (each author assuming they need to define it);
- abbreviations are spelled out in full even after they are defined (one author using an abbreviation, but another spelling the phrase out in full);
- abbreviations have more than one definition ('ITT' should not be used to mean 'International Trade Team' in one place but 'Invitation to Tender' in another); and
- abbreviations in use are defined when they first appear (not on their fifth appearance).

PerfectIt can also automatically generate a table of abbreviations for the document.

The hijack

Since its release, PerfectIt has had far more success with other users than with the consultants it was originally designed for. Sales have been dominated by writing and editing specialists. For example, more than 80 editors from the Society for Editors and Proofreaders in the UK and more than 30 from the Society of English Native Speaking Editors in Holland have purchased it in the past 12 months. It never occurred to me during the initial development, but perhaps this should be no surprise. Writers and editors have better

language and grammar skills than management consultants, they spend even more time dealing with consistency mistakes and multi-author documents, they are well versed in the limitations of computer editing, and they spend more time writing and editing reports than consultants do.

The strong response from the editing community has made a big difference to the development of the product. Editors writing in with suggestions have guided improvements to the software, and it has quickly become a product geared to their needs. For example, management consultants don't usually need to juggle two style guides. However, editors made clear that this was essential and there is now an ability to switch between different preferences when PerfectIt opens.



Figure 2: The PerfectIt opening screen now has a drop-down menu that allows editors to select a style guide. Styles can be customised by the user and shared online.

The scientific and medical writing community has also been instrumental in developing the product. In particular, one user in Australia has delivered a tremendous resource for writers and editors around the world. With a little help from us on formatting, she created a style sheet for PerfectIt that checks the preferred spelling of over 1000 different words in the WHO Style Guide. Thanks to her effort, everyone who uses PerfectIt can download the style sheet and automatically check documents for WHO preferences.

It took a while to recognise that our customer base is not the one we originally had in mind. However, now that we have, we're developing specifically for writers and editors.

Daniel Heuman

Intelligent Editing Ltd
London, UK
daniel@intelligentediting.com
<http://www.intelligentediting.com>

Daniel Heuman is managing director of Intelligent Editing Ltd. and a former research consultant. For more information about PerfectIt, see <http://www.intelligentediting.com>. EMWA members interested in purchasing can use the coupon code 'EMWA-Member' at checkout to obtain a 15% discount.



The personalised medicine revolution: New opportunities for medical writers

by Sanja Pavlica

“Personalized medicine is a young but rapidly advancing field of healthcare that is informed by each person’s unique clinical, genetic, genomic, and environmental information” [1].

The recent DNA revolution has opened up the possibility of personalised¹ (or individualised) medicine. In the age of the Internet, examples of drugs and diagnostic treatment options to cure patients according to their unique determinants are increasing daily. Contemplating the exciting possibilities arising after obtaining a small finger-prick or even a few urine drops led me to consider the developments in medical writing careers this medical model could bring.

About personalised medicine

The information garnered from the Human Genome Project, finished in 2003, opened a window on a new world of personalised medicine with the potential to transform healthcare. Each patient can potentially receive the treatment that will work best for them, rather than the treatment that works best for most people with the same disease. Recent discoveries of a range of molecular profiling methods, including genetic testing, proteomic profiling and metabolomic analysis, could be used to tailor patient-centred healthcare. Screening for diseases to which we are prone may help us to reduce our biological risk by making appropriate lifestyle choices. Further, personalised medication brings the major benefits of determining the optimum dosage of appropriate drugs and reducing unwanted side effects.

By guiding patients according to their unique circumstances and characteristics before, during and after occurrences of a disease, personalised medicine is predicted to be very cost-effective.

Harnessing the power of personalised medicine: Collaboration and communication challenges

Let us imagine a future doctor’s visit going well beyond the traditional parameters of sex, age, height, weight, temperature, blood pressure and pulse rate [2]. Routine data measurements and physiological images might expand colossally to include, for example, (epi)genome, transcriptome, proteome, metabolome, signalling and transcriptional

networks, and perhaps even social network and pedigree obtained from integrated medical records of friends and relatives. Currently, this sounds like science fiction.

We should endeavour to reap the potential benefits of developments in this direction. To achieve tailoring of medical treatment and delivery of healthcare according to the individual characteristics of each patient, the most important and critical step is overall collaboration between scientists, clinicians, pharmaceutical/biotechnology companies, patients and healthcare service entities.

Scientific discoveries could be translated almost overnight into real benefits for patients. Basic scientific findings could be used to trigger further development of new drugs and treatment options. This can perhaps be achieved only by speeding up the publication process by paying publication charges.

We have already seen a recent boom in scientific communications to underpin the successful launch of new drugs, devices or treatments onto the market. Researchers should develop the communication skills needed to translate their knowledge to the stakeholders involved in developing personalised medicine. Special interview and ‘breakthrough’ news sessions in top magazines and newspapers in the mainstream press will be needed to shape public opinion and trust. Enhanced collaboration and communication could circumvent current obstacles to improved health delivery.

Rapid development of disease models, software programs and databases should accompany scientific discoveries. Unrestricted and open-access platforms for sharing data, models and tools will be a rule [2]. Today, scientific innovation in the areas of ‘omics’, imaging and computing is too far ahead of public policy. Companies race to announce and put new diagnostic products onto the market. But there is still a lack of interoperability, standards, data sharing, privacy, predictive modelling and rapid learning feedback models [3].

Further, improvement of health information technology will enable the model of personalised medication to be realised. Healthcare systems will require an efficient and rapid flow of digital information, including genomic, clinical outcome and claims data [3]. In addition to improved healthcare, preventive and personalised medicine will create high-value medical technology jobs, which will have economic benefits.

¹ Synonyms for personalised medicine: molecular medicine, genomic medicine.

The personalised medicine revolution

> Clinical trials in the era of personalised medicine: Collaborative?

Discoveries related to preventive and personalised medicine will bring more drugs and devices but with smaller populations needed to test them. Selective clinical trials, approved for genetic subgroups who are less prone to side-effects, might reduce the duration and expense of the drug regulation process. Some previously failed medications may then be recognised as effective and safe for subgroups of patients with specific genetic markers. For further incorporation of new beneficial approaches and treatments into clinical practice, more efficient clinical trials should be undertaken based on an advanced understanding of the 'omic' basis of diseases.

At present, the clinical trial system is facing a crisis due to rocketing costs, burdensome regulatory requirements, extended trial completion and enrolment problems. Urgent reform is essential. To revitalise the testing of new therapies and devices, the members of the Multicenter Research Group suggested that clinical trials should be planned and conducted in a collaborative manner [4]. Such a trial system could involve similar therapies or devices from different companies targeting the same disorder. Or, it could examine combinations of therapies, launched by different companies, designed to target unique mechanisms or pathways involved in a complex disease. The main advantage for companies coming together to conduct a single collaborative trial would be the reduced number of patients required, and consequently reduced time and costs. Such trials could directly compare several new therapies, or new vs. old treatment options, in the same defined patient population with a uniform set of rules, designed to measure the same set of outcomes. To be effective and realistic, it may be possible to perform such collaborative studies only when several similar or relevant options are available at the same time. Because of the race to the market, new regulations may be needed to guide trials of competing products [4]. Antitrust and patent issues, arising from collaborative trials, will need negotiations and new legislation ('Personalised Law'). Consequently, 'the world of drug discovery will no longer be filled by the top ten pharmaceutical giants of the present day' [2]. They will be 'complemented by a distributed chain of groups who each build a given tool or product'.

Rapid laboratory discoveries of potential treatments will demand rapid testing in humans even before animal testing for safety or efficacy. Despite the warnings [5], unproven therapies will be tested first in patients in countries with lower regulatory or ethical approval standards, similarly to early stem cell tourism in Russia when physicians tried experimental stem cell therapies in patients even before approved animal testing, as in the case of the Israeli boy who developed tumours after treatment at a Russian stem cell clinic in 2001 [6]. The promise of tested treatments will demand rapid publication of cases (case reports), and a large demand for translation, editing and medical writing services.

Similarly, requirements for translators are likely to be enhanced with the introduction of collaborative clinical trials, involving patients from different countries. On the other hand, high quality automated translation services are likely to be increasingly available in the future via the Internet.

Case reports will be a more frequent form of publication than today. New forms of patient reports will probably be developed.

Target market sectors for personalised medicine: Opportunities for medical writers

En route to personalised medicine, identifying the market areas most relevant to medical writing careers is important.

Particular interest in successful individualised treatments exists in the fields of oncology, diabetes, and neurodegenerative and cardiovascular diseases. Emerging advances in new technologies and biomarker discoveries will very soon enable the application of personalised treatments in these market sectors.

An additional prime target for personalised medicine is repair after injuries of skin, bone and cartilage. In particular, personalised stem cell therapies using the patient's own cells for regeneration hold great promise.

Generally, as diseases are defined by specific genetic and molecular markers, new chances for careers in pharmacogenomics, pharmacometabonomics and similar disciplines will arise. Writing in the pharmacoeconomic area will be of particular importance since the goal is a healthier population receiving medical care at a more reasonable cost. Such developments, coupled with expanding regulatory requirements, will provide new challenges in regulatory medical writing in the era of personalised medicine, offering many job opportunities.

The nutrition, alternative medicine and wellness markets are additional targets for revolutionised preventive and personalised medicine, with a commensurate growing need for medical writers. Potentially increasing job opportunities exist beyond these core products and services—particularly in consumer-oriented areas such as telemedicine, electronic medical records, disease management services and health technologies embracing even direct marketing to consumers.

Educating for personalised medicine for all involved stakeholders: Extensive medical communication

Advanced and continuing training for doctors and nurses should support rapid transition of scientific and technological discoveries. Training opportunities for the whole healthcare sector via the Internet are becoming more popular, as are Internet coaching sessions. A new class of primary care physicians, proficient in biostatistics, networks, data modelling and integration, will be required to engage patients [2].

The personalised medicine revolution

In general, new skills are needed to motivate the various stakeholders involved to become partners. In particular, physicians need to provide new services and to take new approaches in order to become efficient motivators of their patients and conduct preventive and personalised medicine.

Since 2008, the European Association for Predictive, Preventive and Personalised Medicine (EPMA) has held regularly workshops in Brussels aimed at ‘Contributing to creation of Guidelines in European health care with the accentuated role of prediction, prevention and personalised patient treatment in favour of improved life-quality of the European population’ [7].

In addition to traditional medical education and teaching, special training in the field of organisation and medical communication will be required. Companies will employ more public relations managers for activities such as on-line education and communication with patients, enhancing visualisation, active dialogue, incorporating animated graphics and use of video podcasts. Generally, only improved healthcare communication flow among all stakeholders will encourage greater participation by the public in collaborative biomedical research and its transition from laboratory to clinic and individual patient. Overall, the upcoming age of personalised medication will create an increasing demand for brilliant scientific and medical communicators.

Conclusion

Altogether, personalised medicine will bring manifold changes in the healthcare market and have a significant impact on medical writing strategies and tools. It will bring new business opportunities, and I am optimistic about my writing career in the upcoming decades of individualised medication. Personalised medicine is likely to affect the quality of our lives, increasing our longevity. We should also be prepared for professional challenges.

Sanja Pavlica

Biotechnological Biomedical Center
University of Leipzig, Germany
pavlica@rz.uni-leipzig.de

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Is publication planning ethical?

Is selling medicine no different from selling cornflakes? According to a British medical writer who works for medical communication agencies there is no difference. Mushrooming of “New guidelines [to avoid ghostwriting] work very nicely to permit the current system to continue as it has been.” The medical writer is quoted in an article in *The Guardian* which contends that nothing has changed since 2004 when Richard Horton, editor-in-chief of *The Lancet*, said “journals have devolved into information laundering operations for the pharmaceutical industry.” The article also describes a flow-chart drawn up by Eric Crown, publications manager at Merck, in which the authors who are to appear on an article are decided by company employees after they have “presented clinical study data, discussed the findings, finalised “tactical plans” and identified where the article should be published.” I suppose therefore when Kimberly Goldin, head of the International Society for Medical Publication Professionals (ISMPP), is quoted in the article as saying “I feel that we’re doing something good for mankind in the long-run,” she could equally well say the same about selling cornflakes.

Elise Langdon-Neuner

editor@emwa.org

Source: <http://www.guardian.co.uk/science/2011/may/20/drug-companies-ghost-writing-journalism>





Medical writing for the veterinary pharmaceutical industry, take two: Pharmacovigilance

by Gina M Dungworth

I was very pleased to see Susanne Goebel-Lauth's article in the March 2011 issue (*TWS* 20(1):29-30). We veterinary medical writers (and veterinary regulatory affairs professionals) sometimes find ourselves a little 'out on a limb' when it comes to recognition by the industry as a whole.

I came to medical writing by a slightly convoluted route which included both veterinary practice and veterinary pharmaceutical sales. Apparently that makes me an ideal person to write about pharmacovigilance from both sides of the fence! I know first-hand how the products are intended to be used, and how they are actually used out in 'the real world'—where veterinary surgeons and animal owners don't always follow instructions as precisely as the manufacturer intended.

Working mainly on the vaccines side of the industry, I don't see many reports relating to residues, which were touched on in the previous article. Residues can be detected in milk or meat because a withdrawal period has not been adhered to, or may indicate that the withdrawal period for a product is not long enough. Fortunately for me, most vaccines for food-producing species do not find their way into either product and so have a withdrawal period of zero.

What I do see frequently are two common varieties of 'off-label use' in species other than those for which a product is authorised. Firstly, we see the product being used in the wrong species deliberately because no similar product is licenced for that species (goats being treated with sheep vaccines, donkeys being treated with horse products, llamas being treated with who knows what, etc) or because someone has picked up the wrong vaccine vial or tablet packet. Cats and dogs seem to regularly receive a vaccine intended for the other species with apparently no ill effects beyond missing out on receiving the correct product if the veterinary surgeon fails to notice in time.

Where an animal has received the 'wrong' product and afterwards suffered an adverse event, it is important to consider carefully whether that event is specific to the product and species, or whether it is similar enough to what is seen in the correct species or when the correct product is used. Goats aren't physiologically identical to sheep, donkeys aren't physiologically identical to horses, and llamas bear little resemblance to any of the species whose intended products get given to them. On the other hand, a post-injection lump is remarkably similar in most cases, regardless of the species it occurs in.

There are also breed-specific issues, some scientifically recognised, some anecdotal. Anyone who has worked in veterinary practice will be able to regale you with stories

of cat and dog owners convinced that their breed is uniquely sensitive to just about any product on the market. A real problem, however, is that collie dogs, and crossbreeds with a lot of collie in them, (popular pets for horse owners) are well-known for being highly sensitive to the avermectins found in many horse wormers. This leads to a small number of serious, and potentially serious, adverse reactions being reported every year in collie-type dogs after they have consumed only a small quantity of product. Similar cases also result from small terrier-type dogs, also popular with horse owners, consuming what for them is a massive overdose (5kg dog vs the 500 or 600kg horse that one syringe of wormer is intended to treat).

From all this we need to work out which reports in our Periodic Safety Update Report (PSUR) may lead to a change being required to the warnings on the Summary of Product Characteristics (SPC). Does that one lumpy goat justify a 'do not use in goats' being added to the contraindications? Do four ill collies mean that we need to make the 'keep away from dogs' warning more descriptive? What about the humans administering the product? Do they need to be warned about potential side-effects?

A variety of products that are highly useful medicines in the species for which they are intended pose risks to the humans treating the animals. This can be either because of the nature of the active ingredient or because of other substances found in the carrier, especially in the case of injectable products. Without knowing much about how humans work (except that some of them are very good at accidentally injecting themselves while trying to inject their animal patients), we have to assess whether they have been sufficiently warned to take care with a particular product or whether their reported injury comes not so much from the product as from jabbing a needle into their own (or their



Pharmacovigilance

assistant's) finger after sticking it into a muddy farm animal. As with the example of the small dog consuming the dose intended for a large horse, problems can also arise if humans are accidentally injected with the entire dose intended for an animal ten times their weight or more.

I particularly liked the part of the previous article which discussed potential linguistic errors. While I'm yet to encounter any pulverised cows, I have on occasion encountered cows and sheep suffering from 'meteorisation'. This condition commonly occurs in France and is not, as I at first idly wondered, the result of animals being hit by space debris, or indeed taking off into space themselves. The word does in fact translate more accurately as 'bloat', the condition whereby ruminants experience a build-up of gas in their stomachs. I think I prefer my version...

Not that I'm perfect when it comes to mistranslations. I have on occasion been presented with an SPC in a language

I'm not familiar with for a product with no UK equivalent, and have attempted to work out what it says while waiting for a translation to arrive. I greatly admire my colleagues in mainland Europe, who produce Suspected Adverse Reaction (SAR) reports in English with only the occasional instance of 'meteorisation' in 'sheeps'.

To summarise, you don't need a veterinary qualification to work in veterinary pharmacovigilance writing, although it may help to know a few details about some of the species that are commonly kept. But it does present a unique set of writing challenges, not to mention some good stories to share with your colleagues at conferences!

Gina M Dungworth

Biologicals Registration Manager (Pharmacovigilance)
Portsmouth, UK
gina.dungworth@vetsurgeon.org

Definitions box

Drug Names

All drugs have at least two names, the chemical name and the International Non-proprietary Name. The chemical name describes the chemical structure of the compound, for example: *(RS)*-1-(isopropylamino)-3-(1-naphthoxy)propan-2-ol (one of the shorter names) and *(3R,4R,5R)*-2-[[[(1*S*,2*S*,3*R*,4*S*,6*R*)-4,6-diamino-3-[[[(2*R*,3*R*,6*S*)-3-amino-6-[(1*R*)-1-(methylamino)ethyl]oxan-2-yl]oxy]-2-hydroxycyclohexyl]oxy]-5-methyl-4-(methylamino)oxane-3,5-diol.* These names follow the IUPAC (International Union of Pure and Applied Chemistry) convention on naming chemical structures.

Chemical names are not particularly useful for everyday purposes, so drugs are usually known by their (recommended) International Non-proprietary Name (rINN or INN, also known as the generic, approved or official name). The INN system was set up by the WHO in 1950 and now includes over 7,000 names. INNs are issued by the WHO, which in collaboration with national nomenclature committees: "...selects a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical. To avoid confusion, which could jeopardize the safety of patients, trademarks should neither be derived from INNs nor contain common stems used in INNs" (<http://www.who.int/medicines/services/inn/en/>).

Since the 1970s the WHO has standardised suffixes of INNs so that all drugs in a particular pharmacological class have the same suffix. For example: -mab for monoclonal antibodies; -olol for beta-blockers; -pril for ACE inhibitors; -statin for HMGCoA reductase inhibitors (cholesterol-lowering drugs); and -vir for antivirals. When a company or academic institution invents a new class of drug, it is encouraged to suggest a name to the WHO committee. It is rumoured that several suggested

names have been rejected because they are obscene or otherwise inappropriate in some languages!

When a pharmaceutical company starts selling formulations of a drug, it will assign it a new proprietary name or trade name. This name is chosen by the pharmaceutical company and is usually registered as a trademark and cannot be used without the owning-pharmaceutical company's permission. When other pharmaceutical companies have the right to sell their own version of the drug, they must come up with their own proprietary name. For long-established drugs that no longer have patent protection, there can be a huge number of trade names for products that contain only one active ingredient. When I last counted there were over 40 proprietary names for products that contain only propranolol.

Note that INNs are never capitalised (except at the beginning of sentences) whereas proprietary names must always be spelled with an initial capital letter.

In the early days of development, many pharmaceutical companies refer to drugs by an internal code name or number. These code numbers often stick when such drugs are used as tools in further pharmacological research, particularly when the drug never receives marketing authorisation or fails to become a commercial success. For example, MK-801 has the INN dizocilpine, but is very widely referred to as MK-801 in research publications. Some pharmaceutical companies have strict rules about how drugs should be referred to in internal and external communications. Some insist on the code number being used until marketing approval is granted, some insist that the INN be used externally, whereas some insist that the proprietary name be used at all times in internal and external communications (if allowed by the publisher).

*Their INNs are propranolol (a beta-blocker) and gentamicin (an antibiotic), respectively.

John Carpenter

john.carpenter.medcom@btinternet.com



Quis custodiet ipsos custodes?

Getting away with publication misconduct: A ghostly tale

by Adam Jacobs

In January 2010, a paper appeared in the *Journal of Bioethical Inquiry* entitled “From Evidence-based Medicine to Marketing-based Medicine: Evidence from Internal Industry Documents,” by Glen Spielmans and Peter Parry [1]. The paper was of a genre that is no doubt familiar to those who follow the literature on industry-sponsored publications.

In the paper, the authors describe various ways in which the pharmaceutical industry allegedly distorts the scientific literature. One section of the paper describes ghostwriting. It alleges that ghostwriters insert messages into papers “to maximise the marketing power of the publication,” with a clear implication that this is putting marketing concerns ahead of science and safety.

No-one should be working in that way. The EMWA guidelines for medical writers involved in publications, which I co-authored (<http://www.emwa.org/Mum/EMWAGuidelines.pdf>), make it clear that those kinds of behaviours are unacceptable. However, for all I know, perhaps there are some unscrupulous companies out there who do work like that.

Spielmans and Parry give examples of two companies who they allege engage in such evil behaviour. Now, given that this is a scholarly article in a reputable peer-reviewed journal, you might think that they would have good evidence of the evil deeds of those companies, and would present the evidence in the paper, wouldn't you?

Well, you'd be wrong. One of the companies they describe is my own company, Dianthus Medical Limited. I happen to know, because I run the company, that we do not work like that. We do not ghostwrite, and we do not allow marketing messages to over-ride the science in the papers we write. The allegation that we do those things was simply untrue. All this is rather ironic considering the title of the journal. Publishing untrue and damaging allegations is hardly ethical, and it was clear that the authors had just made stuff up instead of attempting any form of inquiry to get at the facts. It is a further irony that the article itself was about the integrity and accuracy of the scientific literature.

This was totally unacceptable to me. Here was a paper in the peer-reviewed literature making serious and untrue allegations against my company. It is not the sort of thing that should happen in a peer-reviewed journal. So I wrote to the editor to point out the mistake, and asking that they print an apology and a correction, which I thought was a perfectly reasonable request.

The editor of the journal, Kate Cregan, disagreed. She refused to correct the article, and wouldn't admit that there was anything wrong with it, stating in her reply to me “We see the differences of opinion on what ghost-writing con-

sists in, and some of the risks encountered in writing for others, as important issues to debate fully and openly.”

I really don't see how making specific allegations about a specific company could be simply a “difference of opinion.” Nonetheless, Cregan did agree to publish a letter from me in reply, in which I explained that the allegations were completely untrue [2]. That hardly seemed satisfactory, however, as the original article remained uncorrected, and most people who read an article do not also read the accompanying correspondence.

To make matters worse, Spielmans and Parry wrote a letter in response to my letter, in which far from admitting their mistake, they simply repeated the allegations against my company [3]. I was not permitted to reply to that letter.

I contacted Spielmans and Parry and explained that we really don't engage in the sort of behaviours they describe, and asked them to request that the journal publish a correction to their article. In e-mail correspondence, they appeared to be reasonable about this, and did offer to do so. They agreed that a correction, which included the text “To be clear, we found no evidence that Dianthus Medical [*sic*] writers fail to properly acknowledge their role in drafting and editing various manuscripts,” would be appropriate.

Again, I asked Kate Cregan to publish this correction, but despite apparent agreement from Spielmans and Parry that the correction was warranted, she still refused to do so.

It seems to me extraordinary that faced with an article which even the authors appear to agree is incorrect, she still refused to publish a correction. By this stage, I was sufficiently frustrated with these damaging and untrue allegations against my company being printed, and remaining printed, in a peer-reviewed journal that I decided to contact some libel lawyers. I spoke to several lawyers specialised in the field of libel, and the advice I received was absolutely consistent: yes, the article was almost certainly defamatory under English law, and I would have a good case against the publisher if I decided to take action, but they strongly recommended that I didn't pursue the case. Libel is a rich man's game, the costs of court actions typically running into hundreds of thousands of pounds. The simple fact was that there is no way in practice that a small company such as my own could realistically take on a major international publishing company like Springer (the publisher of the journal).

Clearly, authors and editors have little need to worry about being sued for libel when they chose to make untrue allegations against a small company such as Dianthus Medical. However, if such allegations had been made against a

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large multinational company, the journal would have been far more likely to have ended up as the defendant in a libel action. Spielmans, Parry, and Cregan could well have been aware of that, which perhaps explains why they chose to make the allegations against my company rather than a larger and better known one.

Having accepted that legal action was not open to me, my final hope in requiring the journal to publish a correction to the article was the Committee on Publication Ethics (COPE). According to the COPE website [4], “COPE aims to define best practice in the ethics of scholarly publishing and to assist editors, editorial board members, owners of journals and publishers to achieve this.” They publish a code of conduct for journals, and they state “Editors who are COPE members are expected to follow this Code of Conduct and COPE will consider complaints against those who have not followed the Code.”

Section 12.1 of the COPE code of conduct states “Errors, inaccurate or misleading statements must be corrected promptly and with due prominence.” It seemed clear to me that the journal had broken that part of the code, so I submitted a complaint.

Although I knew that COPE was likely to have an editor perspective as it consists largely of journal editors, their response to my complaint shocked me. What I found shocking, in view of the stated claim of COPE to be a guardian of publication ethics, was not the decision *per se*, but the total lack of transparency in their decision.

I was hoping for a detailed explanation of how they had reached their decision that the journal had done nothing wrong. Did they believe that the article was not inaccurate, and if so, why? Or did they believe that the letter from me counted as a correction “with due prominence”? If so, did they think it appropriate that I was not permitted to reply to the further letter from Spielmans and Parry repeating the allegations? And if they did believe my letter to be an adequate correction, why did they think that a formal bibliographically linked correction wasn’t necessary? Or did they believe that there was some reason why section 12.1 of the code wasn’t applicable in this case, and if so, why? What weight did they give to the fact that Spielmans and Parry had themselves agreed that a correction was appropriate?

I do not know the answer to any of those questions, because the reasons COPE gave for their decision were so miserably lacking in detail that it is impossible to know what their reasons were. Their response was, in fact, so short, that I shall reproduce it in full here:

COPE has now looked into this complaint against the Journal of Bioethical Inquiry. The Vice-Chair and two Council members have looked at the evidence provided and we have agreed that the journal has satisfactorily dealt with the issues at hand. COPE will only comment on the processes of a journal and not on the actual facts of the case. Given the nature of this complaint, we feel that it was sufficient that the journal allowed discussion of the relevant issues in the correspondence section, which allowed readers to understand the different sides and arguments.

The most extraordinary part of this is the statement that “COPE will only comment on the processes of a journal and not on the actual facts of the case.” This suggests that they didn’t even consider the question of whether the article was inaccurate. Without considering that question, it is impossible to see how they could determine whether the journal had breached their code. It sounds (although given the lack of transparency, it is hard to be sure) that they simply trust the journal’s judgement in determining whether the code has been breached.

If that is true, you have to wonder what the point of COPE is.

I did e-mail COPE and ask them to explain the reasons for their decision, but they refused. I had an e-mail from Sabine Kleinert, the vice-chair of COPE, which simply paraphrased the original response and ended with “We regard this case now as closed.”

The integrity of the peer-reviewed literature is important (in a deep, deep irony, that was the point that Spielmans and Parry were trying to make in their article). There need to be various mechanisms to ensure that what is published in peer-reviewed journals is reliable. Obviously peer review itself is the first line of defence, but that doesn’t always work. Clearly it didn’t work here: an alert peer reviewer might have seen that the article was making some serious allegations and queried what the evidence was for those allegations, but that didn’t happen (or if it did happen, the peer reviewer was over-ruled by the journal).

So what should happen if an inaccurate article makes it into press? Often, when the inaccuracy is noticed, contacting the journal will result in a correction being published, or in extreme cases, a retraction. However, all this assumes good faith on the part of the journal editor. What happens if that good faith is lacking? In this case, it is clear that the journal editor, Kate Cregan, had not simply been guilty of an inadvertent omission. She was perfectly aware that the article was inaccurate: even the authors of the article agreed with this. She never attempted to claim that the allegations in the article were true. But despite that, for whatever reason she may have had, she chose to let an inaccurate article remain uncorrected in her journal.

It appears that COPE’s processes assume good faith on the part of journal editors, as they were unwilling to get involved and investigate the facts of the case.

If COPE, the supposed guardian of publication ethics, are not willing to investigate acts of misconduct by journal editors, then what line of defence is left when editors act in bad faith?

Adam Jacobs

Dianthus Medical Limited
ajacobs@dianthus.co.uk
www.dianthus.co.uk

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4. <http://www.publicationethics.org>

COPE response to Adam Jacobs

I am writing on behalf of the Committee on Publication Ethics (COPE) to respond to Adam Jacobs.

COPE is primarily an advisory body for editors on publication ethics. It is not a regulatory body. We have a procedure for investigating complaints about COPE member editors but we accept that our complaints procedure has several limitations and that this procedure may not be able to satisfy some individuals who have a grievance, which either falls outside our remit, or where we do not uphold their grievance.

We appreciate that Adam Jacobs is unhappy about the outcome of our investigation. We understand that it is unlikely that we will be able to assuage all his concerns but perhaps by explaining how we investigate complaints we can make it clear how we come to decisions and reinforce how seriously we take all complaints against editors.

We can only consider complaints specifically about our Codes of Conduct (for Editors and Publishers). COPE does not seek to arbitrate in disagreements (i.e. it does not act as a Court of Appeal if someone has a dispute with a journal) but it does seek to ensure that its members follow its Code of Conduct. The complaints procedure therefore considers only whether the COPE member broke the Code, not on the actual arguments in the specific case. This distinction may appear arcane, but it is important. However, when we feel that a journal does not have good systems in place, or has not followed them, we will issue a judgement.

In this case, as in all others, we carefully reviewed the details of the complaint supplied by Adam Jacobs. We then contacted the journal concerned. We received a detailed reply to our queries from the Chair of the Editorial Board. Three council members then assessed all the documentation from Adam Jacobs and the Chair, first individually and then in person together. To ensure impartiality, complaints are handled by Council members without links to the publisher, editor or complainant concerned and always by at least 2 people. Since Liz Wager (the Chair of COPE) has worked and published with Adam Jacobs in the past, she took no part in the process.

Without allowing the journal the right to respond here it is not appropriate for us to go into extensive details. In addition, decisions about publishing corrections and about allowing criticism of published material are not always clear-cut. However, in this case, we did not feel that the journal had broken the COPE Code of Conduct and therefore informed Mr Jacobs of this in an initial e-mail and in two further e-mails in response to his request for more detail.

The e-mail sent to Adam Jacobs was brief and thus may have given no sense to him of how carefully we had investigated his complaint and we are sorry for that impression. We will look again at how we should report back to complainants in future. However, we stand by our decision here.

Virginia Barbour

Secretary, COPE
Chief Editor, PLoS Medicine
vbarbour@plos.org
<http://publicationethics.org/>

A meeting of editors and peer reviewers in Turkey

Acta Orthopaedica et Traumatologica Turcica (AOTT: www.aott.org.tr), the official international journal of the Turkish association of orthopaedics and traumatology has a driven editorial team lead by its editor in chief Mehmet Demirhan. AOTT is published not only in English but aspires to a readable English of the style that we are used to reading in the *BMJ*—and not many speciality journals—making it a pleasure to read. The impressive approach behind its production is to the credit of a dedicated team of technical editors lead by Askel Seyahi, who is an EMWA member. The team meet in the evenings after they have finished their day jobs—Askel is an orthopaedic surgeon—to translate, edit and discuss the articles to be published by the journal.

The AOTT journal, on the initiative of Mehmet Demirhan, held its annual meeting in Istanbul on 4th May 2011. The meeting was attended by the journal's editorial board and peer reviewers and took place in association with a conference held by the Turkish Association of Orthopaedics and Traumatology (TAOT) which attracted some 400

participants. I gave a presentation on peer review at the pre-conference meeting and attended enjoyable social activities arranged for conference participants, giving me also the opportunity to meet the association's members. It was a great honour to receive a placard by which the journal and TAOT expressed their gratitude for my contribution to the editorial community and the AOTT journal. My thanks though go the editorial board for the insights I gained into the hard work and commitment behind the production of their journal.



Elise Langdon-Neuner

editor@emwa.org



Going home

by Chandrima Pal

After spending 10 years in various parts of Europe I am now back in India, my homeland. I wrote to the Editor of *TWS* about the challenges to resettle myself, and she asked me to write a personal account about 'going home'. Many medical writers work as expats and one day we might return to our native country and find that things have changed. In the 'global village' we are living in today, moves and relocations are not rare, but on a personal level, first moving out of my country, then living in Europe and now coming back, has been a life-altering experience for me, and not just once but many times.

Expat life

In the year 2000, I knew that I would be moving out of India to Germany as my then boyfriend (and now husband) obtained a PhD offer in the south west of Germany. No, he did not ask, but at the age of 23 this decision came naturally to me. With my master's degree in chemistry I luckily found a position at the same university in Ger-

Many medical writers work as expats and one day we might return to find our native country has changed

many—and so we started our expat life. This was an adventure, which we naively thought would end in the next 5 or 6 years. In the meantime we got married and were busy working on our PhDs. We were adapting to the very independent mode of research in Germany, as well as to a foreign country, culture, language and people. Our PhD groups were, however, a good source of support. As we were finding our ways in our research fields, we became parents too. With two PhDs and a child to take care for, we went through many struggles such as maternity leave, rejoining work, a sick baby, sick leave, no family help, and over work. But the days whizzed by.

During this period I realised the immense challenge of benchwork science as a profession, and so started thinking of other avenues my education and transferrable skills might take me to. Reading, presenting and writing about science was what I thought I would like to continue to do even if disconnected from benchwork. Whilst Googling for various options I found that EMWA provides courses for professional and wannabe medical/scientific writers. I was impressed by the topics that EMWA covers, and so enrolled in their certification programme.

The first EMWA conference that I attended was in summer 2007 in Vienna. My mentor in the certification programme

gave me an insight into the world of medical writing and answered all my queries with great patience. I must say that it was one of the best conferences I have ever attended: friendly surroundings, people extending their arms to welcome newcomers, an extensive coursework programme and evening events. Each and every bit was perfect. To sum up, the certification programme and two further EMWA conferences boosted my confidence, and I started looking for medical writing options in Germany whilst writing the last pages of my PhD thesis. I attended many interviews, but things were not falling into place, owing perhaps to my background in chemistry rather than biology, a lack of post-doctoral experience, and being considered as a non-native English speaker as an Indian in Germany. Finally, I was offered part-time work, but then my visa and financial status did not support me in this post. Anyway, the time was approaching for us to decide on 'going back home' or maybe somewhere else. 'Going back home' was always there in the back of our minds, and in spite of living eight years in Germany, and feeling like having a second home there, we did not think we would live there for rest of our lives.

By now my husband had substantial postdoctoral experience, and we decided to search separately: he in India for a faculty position and I anywhere in Europe for another postdoctoral position. I shelved my medical writing ambitions for the time being. In 2008, I went to Scotland for a postdoctoral stint, together with my German-speaking daughter, and my husband returned to India with a faculty position in hand.

We thought that this period might be the toughest for us, but things went fine. In that respect, I am thankful to the childcare system in Europe, and the family-friendly mentality of Europeans. Two years in the UK was another revelation to me. Upon reaching the UK I understood how much we had got used to 'German perfection'. But the English language was all around, we were in a small university town, and the history between the UK and India helped me to settle down easily. I was delighted by the easy access to books in English. We had lived in small towns in Germany where English books, whether about chemistry or fiction, could not be found easily. My daughter had to struggle for at least 3 months and then slowly

Going home

- > she picked up English with a Scottish accent, but she forgot German along the way. To keep my passion for scientific writing going I started working as a freelance medical writer for a company based in India which specialises in providing premium editing services and producing clearly written web-content and I began to network with Indian medical writers.

Return to India

In 2010 I was sure that we would come back to India to reunite as a family. I always wanted to come back, but as the day approached I was getting cold feet. I was not sure whether I knew my country anymore. I found that unknowingly I had become used to the safety and security of European roads, as well as the work culture and social security in Europe. I was anxious for my daughter. This was the third country she would have to live in and get used to. As an Indian I know that India can be quite intimidating for someone who has lived only in calm European countries. I decided to take some time off the career track to help her to settle down.

During the last six months we have been living in India and enjoying our togetherness. My parents and I are not in the same city, but we are at least in same time zone. They could not come to visit me for last 10 years for several reasons, but here they came after just one request. I celebrated Diwali—the festival of lights—with my neighbours this year, a ritual I solemnly followed inside my home in previous years whilst living abroad. My daughter, for whom I was worried, was hesitant at first, but she slowly started to make friends and has been learning yet another language



(i.e., Hindi). She has already lost her Scottish accent and is fast incorporating an Indian accent to her English. She sometimes gets tired of the academic pressures of a very conventional mode of education, where teachers teach mainly on the blackboard and students copy in a notebook. Group activities, field works, friendly discussions are rare, but she always wants to go to school.

From time to time we bake European breads at home, and we yearn for European crisp and cold weather when it is too hot and sunny here. In the last 10 years India has undergone immense changes in terms of its economy and the mindset of its people, so it is really a new home we have returned to. I keep complaining about the new-found consumerism in India, as well as road rage and the old-fashioned examination system of education here. But then we say that this is our country; so we try to settle ourselves, try accepting the new ways to live in India, like learning to drive again.

At present I do freelance medical writing for companies based in India. I am trying to get a better hold as a freelancer and am open to writing directly for clients based in Europe or the USA. Regulatory writing is still a hard nut to crack for me with no experience of working in the industry beforehand. Case reports, manuscripts and synopses writing are coming my way. In India, medical writing is very much in vogue, but it is not as organised as in Europe and being a non-medical person I am again an outsider. But writing about science as a whole is one of my skills and with many new scientific institutes being founded, people are needed who can communicate science in plain English. Although proper networking, which I am trying to hone, is very important, my extensive research background with a certification from EMWA is coming very handy.

One thing I can say is that though I have come back home, a part of my soul will remain in Europe, and given a second chance I will again go to Europe to re-visit, re-touch and re-live our expat lives.

Chandrima Pal

Pune, Maharashtra, India
pchandrima@yahoo.com

Medicalisation makes me sick!

Ray Moyihan points out in an editorial in the *BMJ* that more and more healthy people are being redefined as sick because panels that lay down diagnostic criteria are widening disease categories and thus lowering treatment thresholds. The recent revision of the threshold for diagnosis of gestational diabetes for example has more than doubled the number of women considered to have the disease to almost 20% of pregnant women. As a result of the lowering of thresholds many people who have mild problems are exposed to side effects with no or little benefit. Overdiagnoses also put pressure of public health systems. Moyihan lists a variety of panels the majority of whose members are in the pay of the pharmaceutical industry which stands to gain from the lowering of thresholds. He suggests that panels should be independent of industry and comprise not only physicians and researchers but also biostatisticians, epidemiologists, health economists, non-health professions and other members of the public.

Source: Moyihan R. A new deal on disease definition. *BMJ* 2011; 342:d2548

In the bookstores ... ■

How the lure of money corrupted the US medical system



Carl Elliott. *White Coat, Black Hat: Adventures on the Dark Side of Medicine*. Beacon Press, 2010. ISBN: 978-0-8070-6142-8. US \$24.95. 213 pages.

“Medical care is neither a right nor a privilege: it is a service provided by doctors and others to people who wish to purchase it.”

Robert Sade, then a practising heart surgeon, writing in *the New England Journal of Medicine* in 1971. Today he is a member of the AMA Council on Ethical and Judicial Affairs.

In a sting operation they wrapped up in March 2009, the US Government Accountability Office invited three institutional review boards to review a proposed clinical trial that involved storing a litre of a proprietary gel in surgery patients' abdominal cavities for up to 5 months, led by a principal investigator with a forged and expired medical licence. Anyone shocked to discover that one of the three IRBs approved the trial may be even more horrified to learn that the FDA declined to criticise its actions at the resulting congressional hearing.

If you were to ask bioethicist Carl Elliott what he feels is wrong with the pharmaceutical industry, his reply could well be along the lines of “What isn't wrong with it?” In his latest book, *White Coat, Black Hat*, he describes some of the changes medicine has undergone over the past few decades, changes that he argues have, in the US at least, turned medical care into a consumer product, physicians into drug reps, and participation in Phase I clinical trials into an occupation. In the dystopian picture he paints, money is the only thing that matters and morality a commodity that even many of his fellow bioethicists have ceased to value.

Chapter by chapter he takes aim at the bad guys—unscrupulous drug reps, vain thought leaders, venal doctors, ethics-shy IRBs. His ammunition is a combination of scandals, some widely publicised (the Tuskegee syphilis studies, Vioxx), others less familiar, and the testimony of industry insiders who had epiphanies or became jaded and got out.

He variously describes the use of homeless alcoholics and illegal immigrants in clinical trials; the withdrawal of treatment from patients in order that they may participate in placebo-controlled trials; the promotion of new products via ‘fake journals’; marketing pieces masquerading as news items; the ghostwriting of articles to sell unsafe drugs; and the corruption of GPs' judgement by a constant stream of freebies.

And what's to blame for all this? Yep, money. Elliott argues, with some conviction, that the commercialisation of

everything from publishing to institutional review means that you can't trust anyone anymore, that industry's collaboration with (read buying of) academics and hiring of (read exploitation of) bioethicists in order to create a façade of legitimacy leaves no-one untainted. Little wonder, he suggests, that public approval for the pharmaceutical industry has nosedived in recent years.

Elliott reserves his greatest scorn for medical writers, in a chapter emotively entitled ‘The Ghosts’. To him, your typical medical writer is a failed researcher who retains a certain uneasiness with the commercial nature of the business and is therefore unhappy and unfulfilled. “Ghostwriting pays the mortgage, but it wears at the soul,” as he puts it. In contrast, he describes the reprehensible actions of others, including some of his fellow doctors, in a somewhat matter-of-fact way. The message seems to be that while drugs reps, say, are what they are, and we shouldn't be surprised if they buy their clients tickets for sports matches or take them to strip clubs, medical writers really should know better.

According to Elliott,
Medical writing = Ghostwriting

There is no difference. He supports his argument with tales of draft manuscripts whose authors are listed as “TBD”, and physicians being paid thousands of dollars to read and put their names to pre-written articles. Noting that the writers themselves are obliged to please their employers, he goes on to claim that they are thus forced to disregard any concerns they may have about what they are doing. He subsequently quotes an unnamed ex-writer who describes the work as “ethically dubious and soul-crushingly dull.”

Elliott fails to mention the ICMJE requirement that authors acknowledge the contribution of (named) medical writers to the preparation of their manuscripts. However, it is doubtful that he would consider it adequate, writing in a subsequent chapter that financial conflicts of interest are often concealed, and when disclosed, according to him, largely ignored.

The role of the bioethicist—a subject close to the author's heart—is considered in some detail. Elliott bemoans their use as advisors and justifiers rather than regulators, and questions their ability to halt unethical actions. In referencing Benjamin Freedman's “Where Are The Heroes of Bioethics?”—which queried whether bioethicists were really speaking their minds on the basis that few or none of them ever seemed to face censure or dismissal—he goes a step further, intimating that some may not even be trying.

Elliott invites the reader to ponder several other intriguing questions. Are certain journal editors favourably disposed to industry-sponsored manuscripts because they anticipate huge revenues from reprints? Does informed consent really protect cash-strapped individuals from exploitation by the pharmaceutical industry? If career ‘guinea pigs’ are lying in order to qualify for clinical trials, how can we trust the results?

White Coat, Black Hat is laced with humorous anecdotes, some dark (the doctor who didn't notice that his patient's legs had been amputated), others bizarre (a reported plan to publish a novel about poisoned drugs with the aim of >

In the bookstores ...

- > scaring people from hopping over the Canadian border to buy cheap medicines). In debunking the popular myth that individuals who participate in Phase I trials are primarily motivated by altruism, the author quotes a former crack addict: “The only reason I came here is to do a study so I can buy me a car and a new pair of shoes.”

Though his book has a clear US perspective, anyone wishing to completely disregard its relevance to Europe should note that one of Elliott’s key sources is a professor of psychiatry at Cardiff University. Another is an anonymous British medical writer who until recently worked in the UK offices of an unnamed medical communications agency.

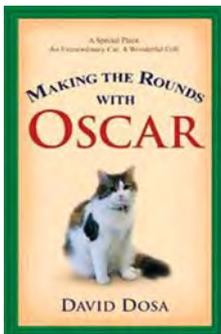
A number of the book’s revelations will be shocking to some: the fact that guinea pigs in US trials are often uninsured and can thus never hope to benefit from the drugs that are being tested on them; that they are often not covered for medical expenses arising from trials and sometimes not paid if they have to drop out because of side effects. Others may find some of the author’s assertions questionable: that accepting credit for ghostwritten articles is not seen as unethical because medical writing is not an intellectual pursuit; that as well as signing up key opinion leaders, the pharmaceutical industry actually creates them. Though his book includes a generous bibliography, he doesn’t quite succeed in substantiating all of his claims.

White Coat, Black Hat is rather one-sided—there are all too few good guys in the world Elliott describes—but nonetheless highly enjoyable. Still, those seeking balance may be advised to steer clear, likewise anyone who is overly sensitive to criticism of the pharmaceutical industry. Otherwise, Elliott’s easy writing style, accessible, jargon-free vocabulary and restrained use of human interest stories should appeal to anyone with any sort of interest in the course medicine has taken in the US, and what might happen if we in Europe were to adopt its model.

Stephen Gilliver

Science Editor, the Center for Primary Health Care Research,
Malmö, Sweden
stephen.gilliver@med.lu.se

Cats, death and the horror of dementia



David Dosa. *Making the rounds with Oscar*. Headline Publishing Group. 2010. ISBN: 978 0 7553 18117 (Hardback). 12.99 GBP. 248 pages.

Steere House is an old people’s nursing home on Rhode Island in the USA. It has a policy of keeping small pets, among them cats. One of the cats is called Oscar. Oscar made it into the *New England*

Journal of Medicine when David Dosa, an attending physician at the home, had an essay published in the journal about Oscar’s habit of sitting with patients when they were

dying. ‘Making the rounds with Oscar’ is an expansion of Dosa’s essay. The style of writing is unsophisticated and will not win him any prizes in literature and it’s a bit too ‘American’ for my European taste but it’s worth reading.

Although this is a book for cat lovers and we follow the trail of Dosa’s search for an explanation of Oscar’s unusual talent, the main force of the book is the insight it gives into the tragedy of dementia. More than 5 million people in the USA have Alzheimer’s and this is only one form of dementia.

David Dosa comes from a family of paediatricians. He was expected to enter the same discipline. He gives his reason for choosing to care for old rather than young people by describing children as a blank canvas, their lives just beginning whereas older people are like a rich painting with stories to tell. He has a touching empathy for his patients “it’s particularly hard to tell someone they have dementia, even when the person intuitively knows already.” He relates a poignant interview with the daughter of one patient “A few years after my father was diagnosed, he called me in the middle of the night, he was anxious. “There’s a strange woman here with me,” he said “I want you to come over here and take me home.”” She spent almost an hour on the phone trying to convince her father that the woman in his bed was her mother and his wife.

Dosa was prompted to take on his investigations of the cat by Mary, the nurse in charge of the home. It was she who brought Oscar to the doctor’s attention. ““This is Oscar” she said, as if introducing me to someone at a dinner party.” One of her recollections was that a member of staff had brought Oscar into a patient’s room when the patient had seemed to be close to death but Oscar quickly scurried out of the room. She continued “Ralf actually hung on for another thirty-six hours. But sure enough, four hours before he died, we found Oscar pacing in front of the patient’s closed door. We opened the door, he dashed in straight to the bed and leaped up next to Ralf... A few hours later Ralf was gone.”

Dosa relates his interviews with people whose relatives had died at the home with Oscar present. The interviewees were all positive about the pet policy, seeing the animals as a comfort for their relatives. One said of her mother “as she got worse and worse with dementia she seemed to take more comfort from the animals on the unit.” The relatives had often been comforted themselves by the cat’s company at their relative’s death bed “with Oscar at my side I felt less alone.”

In considering why Oscar goes to people when they are dying and seems to sense impending death before it becomes apparent to the medical staff, Dosa refers to studies that suggest dogs can be trained to detect chemicals excreted by cancer cells on the breaths of lung and breast cancer patients and to melanoma-sniffing dogs. Perhaps, he thinks, Oscar can smell elevated levels of a chemical released by the body shortly before death but this does not explain the occasions when Oscar was able to sense death at a distance.

Elise Langdon- Neuner
editor@emwa.org



Multiple sclerosis

by Karin Eichele

Multiple sclerosis (MS) is a disabling disease affecting the central nervous system. Autoimmune processes target the myelin sheath which protects nerve fibres. It is usually diagnosed in young adults of 20 to 40 years of age and it is the most common non-traumatic cause of neurological disability. It has a huge impact on the lives of patients and their relatives.

Different courses of the disease have been described. The relapsing remitting form is the most common. It is characterised by relapses which are accompanied by neurological symptoms like numbness, fatigue, spasticity, pain or cognitive impairment, just to mention a few. These symptoms can either resolve completely or partly. Periods between two relapses lack disease progression. About half of the patients with relapsing remitting multiple sclerosis will develop a secondary progressive form within 10 years. This form is accompanied by increasing disability independent of relapses. Apart from these both expressions of multiple sclerosis, a primary progressive form and a progressive relapsing form exist.

In general, progression of disability is partly due to incomplete remission of relapse symptoms which are mainly caused by inflammatory processes. Direct neurodegenerative effects also contribute.

Multiple sclerosis is rather complex and the webpages on this topic are practically countless. Learn about the epidemiology, the symptoms, diagnosis and treatment options of this disease with the following collection of useful links.

<http://www.nationalmssociety.org/multimedia-library/ms-learn-online/ms-learn-online-treatments/index.aspx>

The National MS Society is a US organisation which offers a great deal of information on multiple sclerosis. Especially, the MS Learn Online Section, which you can find in the multimedia library, offers a series of video tutorials on different aspects. Key-opinion leaders in this field explain basics of the disease or pros and cons of current and emerging treatment options.

<http://www.nlm.nih.gov/medlineplus/tutorials/multiplesclerosis/htm/index.htm>

Medline Plus offers patient education tutorials either viewable as an interactive multimedia version, self-running presentation or just as a pdf-download, whatever you prefer.

<http://www.acceleratedcure.org/downloads/bcp-ms-whatsnext.pdf>

This is a further example of patient information on multiple sclerosis especially designed for newly diagnosed

patients. Thus it gives a complete overview of the disease and its treatment. And it contains a section on the impact the disease has on the social lives of the patients. The diagnosis often frightens patients, their families or colleagues. This piece of information offers some guidance on how to cope with the situation. It is worth reading, as it helps to view the disease from a patient-specific point of view.

<http://www.youtube.com/watch?v=K8R5N7ZMINK>

<http://www.youtube.com/watch?v=qgySDmRRzY&feature=related>

<http://www.youtube.com/watch?v=DvaJ9py-vOc>

The first two links above are both animated videos explaining the mechanisms of multiple sclerosis. The third link leads you to a complete episode of 'Health Matters', a health series by University of California Television. An expert explains the disease and patients tell their stories, again allowing insight from different perspectives.

If you have any further questions or you have any comments or suggestions, please e-mail me at: karin.eichele@novartis.com.

Karin Eichele

*Novartis Pharma GmbH
Nuernberg, Germany*

Vital signs

Dear TWS

I had read about the Ig-Nobel Prize (*TWS*;19(4):280) some time ago and, in a conversation last year with my mother, I mentioned the physics prize about the socks over the shoes in order to slide less/not to slide.

My mother burst out laughing because she said there is absolutely nothing new in that: this is indeed what they were all doing during the war when it was icy outside. They found out it was less slippery to have socks outside their shoes (and inside too to keep warm).

Françoise Salager-Meyer

francoise.sm@gmail.com

Journal watch



Populations, funded trials, and careful reading

by Sam Hampson

Differences in study populations between protocol and subsequent articles

A paper from the Cochrane Centre in Germany questions whether the study populations, prespecified in the protocols of randomised trials, are reported consistently in subsequent articles [1]. A precise definition of a trial's study population is important for the clinical reader in assessing whether, or not, the results of that trial can be applied to other patients with the same condition. 141 randomised trial protocols were submitted to the ethics committee of the University of Freiburg in 2000; 103 became completed studies and, surprisingly, only 54 of these resulted in peer-reviewed publications. Of these, one protocol was excluded because it was based on devices and another because it referred to a substudy. The remaining 52 trials were evaluated to see if the reported study population matched that pre-specified in the protocol. The study population was then classified as matching, missing from (the population was not mentioned in published articles), modified, or added to, the study population of the protocol.

For each missing, modified, or added eligibility criterion, the authors determined whether the difference would broaden or narrow the study population the reader assumed from the eligibility criteria provided.

A total of 1299 eligibility criteria were identified; inclusion criteria were twice as common as exclusion criteria. The mean number of eligibility criteria for each trial was 25 and the mean proportion of matching eligibility criteria, specified in both the protocol and subsequent paper(s), was only 50% per trial. In all 52 trials there were differences between the protocol study populations and the populations in subsequent publications. In 44 trials (85%) the criteria had been modified and they had been added to in 21 (41%). The mean proportion of criteria suggesting a wider study population was 85%, and the proportion suggesting a narrower study population was 9%. This has clinical implications, as an apparent widening of the applicability of a trial's results could lead to inappropriate treatment in some individuals.

The authors acknowledge that the trial protocols analysed were all written over 10 years ago and that the reporting of eligibility criteria may have subsequently improved. Indeed some journals now request the trial protocol be submitted along with the manuscript at the time of review.

(T)Read with caution

Science is based on writing. So starts an interesting, and very eloquent, article pleading for greater clarity in

scientific writing [1]. The importance of technical writing skills in the communication of scientific results dictates that they should be a larger part of the biomedical curriculum than is currently the case. The author suggests that, consequently, many medical papers contain simple, straightforward sentences presenting an 'illusion of certainty'; complex statements written dogmatically can produce an illusion that what is being presented is correct. However careful reading and interpretation is needed before the 'certainty' is questioned, and the 'illusion' is apparent.

This paper provides advice on critical reading and the author leads the reader through 11 questions which address the interpretation of a scientific article. These vary from the qualitative and simplistic, "Who and what were studied?", "How was the objective measured?", to quantitative questions about statistics. There is some excellent advice on the interpretation and questioning of statistical results; "Results expressed as percentages are *always* suspect," "What does the author mean by significantly?"

Ultimately, the value of good writing is that it reduces the reading time of the article and that simultaneously reduces the effort required to analyse that writing. Treading the path of good writing and careful reading can symbiotically improve biomedical communication.

Does pharmaceutical cash influence trial results?

A report from a multinational group demonstrates that industry funded, randomised, controlled trials without significant primary outcomes have a greater number of subgroup analyses than those trials which demonstrate a positive primary outcome [3]. In this systematic review, 469 randomised, controlled trials were studied, of which 207 reported subgroup analyses. Subgroup analyses were more common in high impact journals, non-surgical trials, and trials with a large sample size. This may be due to the sponsor looking for a 'return' on his investment, and it is noteworthy that funded trials are less likely to pre-specify subgroup analyses than those that are not industry funded. Earlier the same group of authors had made some recommendations on how to optimise the reporting of clinical trials [4]. Strangely the later report disregards some of their own recommendations. Some analyses are carried out with no pre-specification, and other promised analyses are mentioned in the 'Methods' section, but subsequently ignored.

The ethical behaviour of drug companies is also called into question in an article in *The Journal of Occupational and Environmental Medicine* [5]. Previous research has shown that company funded research is much more likely to yield positive outcomes than research with any other sponsorship; this, largely negative, article by Lexchin investigates the ways bias can be introduced into clinical studies, other than by simply not publishing negative results. This bias is often introduced with the methodological quality of the trial or by inappropriate choice of comparator drug, its dosage, or route of administration. The bias can be reinforced by the serial publication of positive trials and the non-publication of negative results. Ghostwriters putting a positive ‘spin’ on a drug’s success (as discussed in this column recently), or on the lack of side effects, can further bias the presentation of the results. No measures taken have thus far influenced the ‘biasing’ of company-sponsored studies and the onus must be on clinicians and scientists to

carefully evaluate the evidence (literature-based evidence? [1]) arising from studies where there has been significant, corporate investment.

Sam Hampson

Dianthus Medical Limited
shampson@dianthus.co.uk

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Ar-google

One of the landmarks in a child’s development, eagerly awaited by parents, is ‘the first word’. I’m not good on remembering numbers in general, and dates in particular. I am, however, rather good at recalling most things to do with letters. So I don’t remember exactly when my daughter uttered her first word, but I do remember what it was: “Ar-google.” I see your raised eyebrows as you think: That isn’t a word. Well, let me set something straight. ‘Ar-google’ is a word. It is actually two words. As it turns out, they were very prescient words. Why? Because nearly ten years later, I am experiencing how much we who are present and active in the online world need to come to terms with the fact that parts of us ‘are’ determined by the power of ‘Google’.

This was brought home to me when, after two years in the relative obscurity of wordpress.com, I decided to move my website to wordpress.org. This decision was actuated in part by a consultant, who, when questioned as to the advantages of wordpress.org, said: “Imagine your website is a virtual office in the Internet world. At the moment it’s like an office at the top of a very large building—without a sign on the door. If you want people to find you, you’re going to need to move that office down to floor level and change the decorations in the window once in awhile.” I appreciate pithy metaphor, so I’m busy moving. And on the way down the stairs to my new office, I’m learning lots about how search engines work.

One epiphany of this learning process is: Words really matter. This, frankly, fills me with delight. The whole system of computing, which as far as I have understood is based on unending streams of zeros and ones, comes to a cropper at the point of the ‘machine-user-interface’. You may be on the Internet, but if you want to be found and read there, you need to use the right words. What constitutes ‘right’ is entirely up to you, based on who you want to reach and what you are offering. But once you have got those strategic marketing decisions straight, a good deal of creativity and work goes into finding appropriate keywords, so that search engines (and thus people) find your site.

You can spend a few amusing hours in the presence of Google AdWords and Roget’s Thesaurus dreaming up all the words a prospective client might use to find you. Unfortunately, not everything is amusing. The feminist in me bridled instinctively when I realised that German clients are out there looking for the male ‘Texter’ and not for the female ‘Texterin’. If you type in ‘Texter’, you get over 6 million hits. With ‘Texterin’: about 100,000 hits and the question ‘Did you mean: Texter?’ No you stupid so and so, I didn’t.

To add insult to injury, in its 32-page search engine optimisation manual (and that’s just the starter guide), Google blithely recommends that you ‘create content for users, not search engines’. Where does this leave me? Lying to prospecting clients about my gender in order not to compromise my page rank? I might start calling myself a ‘copywriterette’ just to make a point. A futile point, though, since no one is going to search for a word that does not, to date, exist. Google will just inform you that: “Your search—‘copywriterette’—did not match any documents.” And German clients won’t look for me under that term anyway. I guess that leaves me only to build up a devastatingly amusing or informative blog to beat the almighty Google at its own game.

Google itself is, of course, privy to the power of words, or why else would it have changed its name from ‘BackRub’? Apart from the slightly seamy undertone of the word itself, can you imagine anyone today saying: ‘I’ll just go and quickly backrub that term’? As the company proudly reports on its corporate site, the American Dialect Society voted ‘google’ the most useful word of 2002—the very year in which my daughter made her first utterance. Of course, in future we may all become increasingly impatient with Google’s power and the dictate of the page rank. The result might be that we start entering the vastness of the Internet through the security of network-driven platforms like Facebook or whatever may succeed it. I can only say: Ar-google to that.

Ursula Schoenberg

u.schoenberg@t-online.de
www.ursula-schoenberg.de

■ Good writing practice

Abbreviations (2)

It is not advisable to use abbreviations in section headings, table titles or figure titles in documents that have tables of contents, lists of tables and list of figures that are automatically generated, i.e. most regulatory documents. This also applies to documents that are compiled using electronic publishing software because a high-level table of contents is usually prepared. Again, this applies to most regulatory documents. The problem is that your tables of contents and lists of tables and figures then contain unexplained abbreviations. Some common sense is necessary, and here you also have greater licence to decide that the readers of such documents should be aware of what a 'common' abbreviation means. An example is *DHEA*, which is hardly ever referred to as *dihydroepiandrosterone*, and many other well known substances and diseases which would make reading headers and titles cumbersome and very wearing, such as *lower respiratory tract infection* written out in full in every heading and title in a study protocol or report, instead of *LRTI*. There will always be a grey area here and we just have to live with that. It is unlikely that your device or product will not be approved because of inconsistent use of abbreviations. It is more likely that time will be wasted unnecessarily in internal company review processes because we all have colleagues who cannot resist pointing out that you forgot to put an abbreviation in the list of abbreviations or that you did not abbreviate at first mention, or who insist that 'USA', 'EMA', 'FDA' or 'contd.' have to be put into the list.

Journal articles are very different from regulatory documents, but I still think that the article title, section headings and subheadings are not the place for abbreviations. I don't think you need to be so fussy here about abbreviations in table and figure titles. But again, you should use your common sense—abbreviations should not be overdone. In a journal article, the wider the possible audience, the less licence you have to decide that the readers of such documents should be aware of what a 'common' abbreviation means. However, it must surely be possible to use the abbreviation ECG in the title of an article in a cardiology journal or EEG in the title of an article in a neurology journal without explanation, because the audience will probably be limited to specialists. Refreshingly, some journals provide lists of abbreviations that can be used without explanation. More journals should do this.

Alistair Reeves

a.reeves@ascribe.de

"We made too many wrong mistakes"

American baseball legend Yogi Berra

Pleasing the reader (1)

The golden rule of writing, we are reminded, is to remember the reader. It doesn't matter whether we are writing a few lines in a birthday card, a formal letter, a newspaper article, or a scientific paper; if we are taking the trouble to sit down and write something, it is because we have something to communicate. We want to be understood, both for our own sake and the sake of the reader. We don't want to be misunderstood, we don't want to offend, and we want to get our message across. Equally, we have a responsibility towards our reader. If someone is taking the trouble to read what we write, the least we can do is to make it as pleasant an experience as possible.

Before we start writing, we have to consider who the reader is. A medical writer can have many different types of reader, well beyond the standard 'regulatory writing', 'scientific writing' and 'medical communications' categories that we often recognise in our profession. Even regulatory writing is not always aimed at the same readers—consider the difference between writing for authorities, investigators, researchers, or patients and their families. These rarely have to be considered in the same document, so before we start writing we can already narrow down the style we need.

Once the reader has been identified, the writer needs to put himself in the place of the reader. What would the reader like to read? What will make the reader happy? What will make the reader feel appropriately informed? How can we as writers do our best not to annoy our readers?

We have all felt annoyed as we read and we all know what a negative effect that can have. We don't have to be as passionate about language as Lynne Truss [1] or John Humphrys [2], who rant about the irritation caused them by misplaced apostrophes or soap-opera English, but we will find a way to express our disapproval if we are annoyed. If we are reading a novel, we'll put it down, if we are reading a newspaper, we'll be likely to buy a different one the next time. As a patient, would we consent to participate in a clinical trial if a feeling of annoyance crept over us as we read the first page of the patient information? If it left us wondering what it was all about? As an investigator, would we be inclined to take care of study data as punctiliously as we should if the protocol contained a contradiction about how often to collect the data in the first place? As an authority reviewer, would we read past the synopsis if we were left feeling exhausted, confused or annoyed by the first few pages?

So, what does annoy readers? How can we be kind to them? People are annoyed by many different things. Everyone has their pet hates (although it would probably be fair to say that medical writers are more picky than most). I suggest that the following are likely to annoy many readers, regardless of who they are:

- Clearly identifiable mistakes or typos, especially on the first page
- Mistakes in the header or footer

Good writing practice

- Misspellings
- A title that is too long or that needs to be read several times to be understood
- Typefaces that are too small, too large, mixed, fancy or loud
- Over-capitalisation
- Ambiguity leading to misunderstanding
- Not understanding (long words, jargon, long, involved sentences that have to be re-read to be understood)
- Abbreviations that aren't explained
- Too much, too little, or wrong punctuation
- Too many or too few paragraphs
- Repetition
- Excessive cross-referencing
- Patronising the reader e.g. by oversimplifying the text

We shall look more closely at these issues and ways to avoid them in future 'Good Writing Practice' columns. Readers might also like to tell us about their own pet hates.

Of course, mistakes aside, it is impossible to consider all individual preferences. Even in the medical writing community there are many differences of opinion that have been discussed in the pages of *The Write Stuff* and elsewhere, but it is probably less the use of 'subject' or 'patient', a comma before an 'and' or the hyphenation or not of 'cooperation' that will actually annoy most readers, as long as their use is consistent.

Sometimes, it is possible and appropriate to pander to the whims of the reader. For example, if we know we are writing for a British audience, it is appropriate to use British English. Those of us who are used to working with 'International English' every day are much less annoyed by different styles of writing, and are more forgiving, even of grammatical errors, than native English speakers and readers who read only texts written by other native English speakers. Non-British people might well be surprised by the degree of annoyance caused by American spelling in the UK!

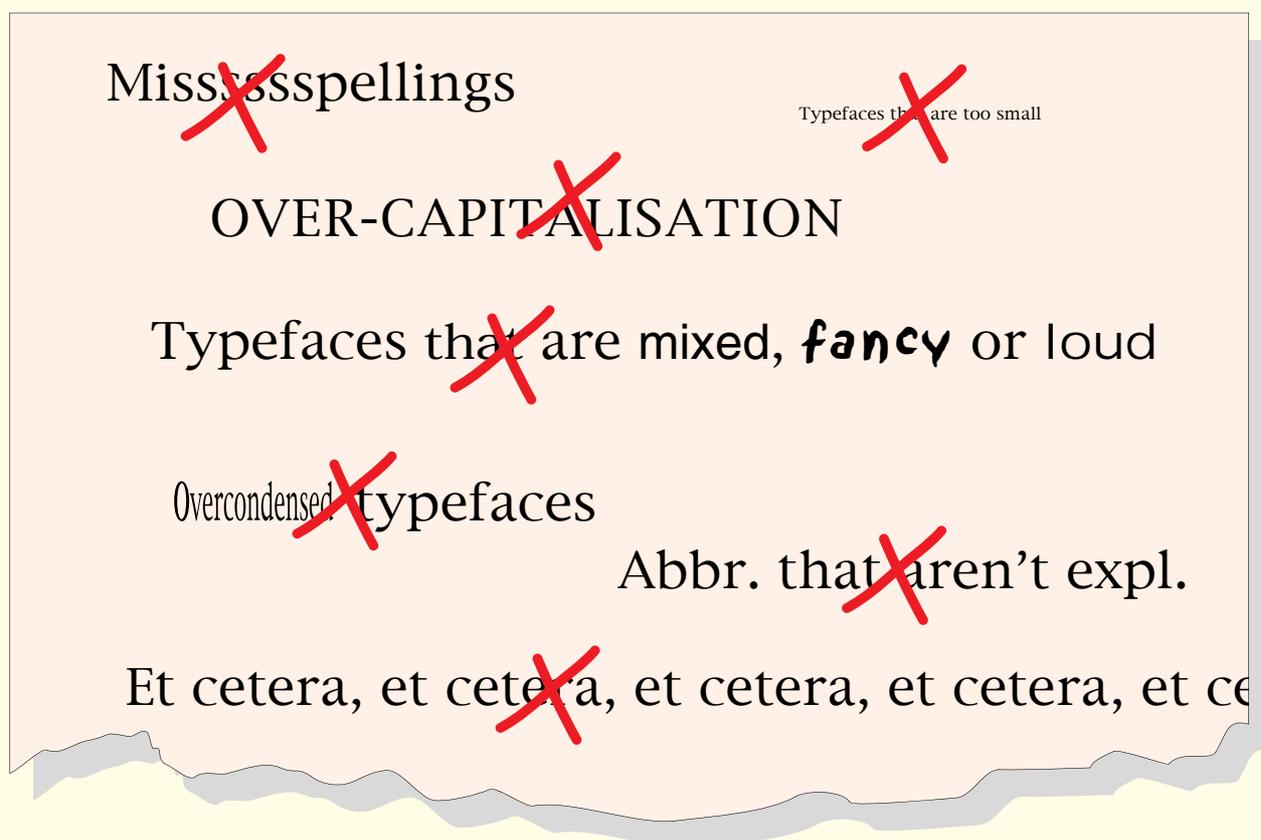
So, in writing as in life, let us be kind to those with whom we interact! It's a matter of courtesy to consider our readers, no matter who they are, and generally, it is also more satisfying to please than to annoy. It can also be more profitable for everyone concerned. The Plain English Campaign in the UK has estimated that sloppy writing costs the nation millions as a result of mistakes, inefficiency and lost business [3]. In our case, writing habits that annoy our readers can result in lost patients, useless data and rejected submissions and manuscripts.

Pamela Haendler

pamela.haendler-stevens@bayer.com

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Out on our own



This editorial comes to you, hot off the press, from beautiful Berlin! The 2011 spring conference was inspiring, informative, thought-provoking and fun, with a wonderful energy and buzz borne of a common desire to share—after all, EMWA is run by the members for the members and the conference is the best place to experience this

first hand. This was the best-attended conference to date with 367 delegates, many first-timers meeting together to learn, share experiences and forge and strengthen those all-important relationships that form the basis of so many of our working alliances. At the freelance business forum (FBF) we were pleased to see so many new faces. Some of you were considering making the leap into freelancing, so we hope the FBF highlighted some of the issues that affect us as a group and provided useful insight into common challenges from the other side of the fence. Given that the members are the lifeblood of EMWA, it was disappointing that a mere 50 or so delegates made it

to the Annual Meeting (AM), the meeting that informs us all about our association, and enables us to elect our new Executive Committee for the coming year. Keep a slot in your diary for the Cyprus 2012 AM! The conference banquet was great fun and rounded off perfectly with two very special people being awarded the prestigious Nick Thompson award for special dedication to EMWA over many years. Elise, *TWS* editor, who has given our freelance contingent a voice in the journal, and Alistair Reeves, Freelance Advocate until November 2010, were the well-deserved and most gracious recipients of this award. Many congratulations from all your freelance colleagues and friends! So, what do we have for you this issue? Ta-da! The OOOO logo is here! We thank the 13 members who submitted a total of 24 entries. Claudia Frumento shares with us the story behind the winning design. Greg tackles the hot topic of indemnity insurance with a fresh and balanced approach. Diana continues with her freelancer interview series.

Sam Hamilton
sam@samhamiltonmwservices.co.uk

Raquel Billiones
medical.writing@billiones.biz



Going freelance: The second of a series of interviews

by Diana Raffelsbauer

I started my freelance career because I had no other choice of finding an adequate job in a radius of 100 Km from the city in Germany I had to live in for family reasons. My first client, an international pharmaceutical company, fully booked my time for the first six months with writing and editing of package leaflets for a variety of indications. I then turned to medical communications and became the official science writer of a large not-for-profit research organisation for whom I have been working since 2007. But it is not always like that. While a few colleagues decided to leave a salaried position due to restructuring and changes in their working environments, which ultimately led to rationalisation of the workforce, others—and they are probably the majority—made this decision consciously and planned long before starting.

The reasons for choosing a freelance career vary. Some of them are personal or due to family circumstances, while others have a more rational nature towards career development. Flexible working hours, compatibility of career and family, being able to choose the tasks and topics they want to work on, avoiding management and staff responsibility, having no bosses, and earning a higher income are the most common reasons. In any case, relevant experience and a list of potential clients are absolutely necessary

for success. Read more about the experiences of four freelance colleagues: **Sam Hamilton**, a regulatory writer from the UK, **Lisa C. James**, a medical communications specialist from the UK, **Tom Lang**, an expert in medical editing from the USA, and **Jason Willis-Lee**, a medical translator based in Spain.

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

S.H.: I am a regulatory medical writer and write across the full spectrum of clinical regulatory documents for both individual clinical studies as well as drug submission dossiers. I additionally write manuscripts for submission to peer-review journals, and am happy to take on preparation of ad-hoc documents, such as literature reviews or bespoke reports, to maintain variety in my work.

L.C.J.: My company provides a full medical writing service, which means that we can produce almost any kind of document. If I had the luxury of choosing my favourite types of document to work on, it would be meeting reports, patient information (especially for children), educational pieces, or pieces for the press.

T.L.: Mostly I provide high-end analytical editing services to authors, especially those submitting clinical research manuscripts. I also do chapters, abstracts, posters, and the

The second of a series of interviews

occasional grant. (I no longer do books; not cost-effective, given what people are willing to pay for them and the time they require.) I also provide training in medical communications, statistical reporting, and scientific publications to physicians, researchers, medical writers, editorial boards, and pharmaceutical companies, much of it internationally.

J.W.L.: I offer my clients translation, editing and proof-reading services, although I would say I work most frequently as a translator first and foremost and somewhat less frequently as an editor. My work is principally for hospital clinicians, university academics and medical communications agencies. Types of document mainly include research articles for publication in specialised journals and market research surveys used to ascertain opinions from patients and doctors on various kinds of treatments and devices used in medical practice today.

How did you become a medical writer?

S.H.: By serendipity, I suppose! I always loved writing and once I was in the wider field of clinical research, I became aware of career opportunities in the industry, and realised that medical writing could be the niche I had always been looking for. I came into clinical research from academia in 1994, working in contract research organisations (CROs), first as a monitor, then as a project manager. I moved into medical writing in 1999.

L.C.J.: My background is in academia. Following a PhD and postdoctoral position, I decided that I didn't want to lecture or stay at the bench and so applied for a part-time 'communications writer' post in a pharmaceutical company. I trained 'in post' and through EMWA, and then set up my own company with a business partner. The rest, as they say...

T.L.: By accident, of course. My first job out of college was as a technical writer in a major physics/atomic energy lab. Earlier, I failed a martial arts exam for not knowing certain physiological principles and so became interested in sports medicine and athletic training. I decided if I had a contribution to make to the world, medicine would be better than nuclear weapons. I wrote a college text on personal health, became a grant writer, and then became manager of medical editing services at the Cleveland Clinic.

J.W.L.: I studied medicine and physiology as a university undergraduate at Bristol Medical School and I also hold a postgraduate diploma in translation and interpreting from Bath University. I initially came to Spain to add another language to the combination I was already offering (French-English). From the outset, I started to specialise in medical and scientific texts and I now work virtually solely in this area with an emphasis on biomedical research articles for publication in academic journals.

Why did you choose to work as a freelancer?

S.H.: I am freelance now but was employed in CROs for 12 years. When I became freelance, the time was right for me in terms of my experience and confidence. I also needed a little more flexibility in my working life than employment could offer, and thought that freelancing could provide a workable solution.

L.C.J.: I chose to work for myself because I wanted the freedom to choose when I wanted to work, and how I wanted to work. I also have a very low boredom threshold, so I needed to be able to work on as large a variety of projects as possible.

T.L.: By default. I left the clinic for the ideal job in Boston, but housing was so expensive, we never moved there. I returned to Cleveland and began freelancing.

J.W.L.: I worked as a part-time in-house translator for 4.5 years during which time I was fortunate enough to have the working time available to gradually build up a portfolio of sufficient clients to go freelance full time. My freelance work was much more satisfying, better paid and gave me more flexibility over my working life. I have now been working as a full-time freelancer for nearly 6 years.

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

S.H.: Good analytical skills, an objective approach, staying current and attention to detail.

L.C.J.: Aside from the usual writing skills, you must be able to empathise with a wide variety of people and be able to process very complicated scientific information into 'lay terms' quickly and accurately. Most crucially, you must learn to love deadlines!

T.L.: A perverted sense of humor, the ability to go without sleep for long periods, and the desire to drink heavily. (Sort of 'like college', if I remember correctly, which I may not.) In no particular order: 1) a keen sense of audience, 2) an excellent command of the language, 3) the ability to think analytically and critically, 4) the ability to think creatively, 5) a passion for communicating accurately, clearly, and efficiently, 6) visual literacy and graphic design, 7) numeracy, 8) an understanding of the scientific method, 9) good negotiation skills, 10) good research skills, 11) a knowledge of the research into written communication (yes, there is some), 12) flexibility.

J.W.L.: A thorough comprehension of the source text material including the overall context of the work (big picture) and excellent native language writing skills.

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

S.H.: The ever-shifting timelines of multiple clients!

L.C.J.: Convincing clients that one person really can write for different audiences, and that different audiences (even within the same broad field) often need slightly different documents.

T.L.: Isolation; the need to concentrate for long periods; the need to work around the needs of two Golden Retrievers who have to pee every 3 hours or so (sigh ...); the need to be travel agent, computer tech, accountant, librarian, secretary, and so on.

J.W.L.: Upholding maximum quality and working on challenging texts, at times under time pressures. Optimising personal time management: deciding exactly how much work to take on to ensure sufficient income while at the same time ensuring customer satisfaction and without compromising the quality of work.

The second of a series of interviews

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

S.H.: Most: Variety in the writing and delivering what I know is a great piece of work. Least: Completing my value added tax (VAT) returns!

L.C.J.: I love the variety and sense of job satisfaction the most; being self-employed I like the lack of security the least!

T.L.: I like the freedom to work when I want and the freedom from office nonsense. I can choose my jobs, which keeps out the riff-raff, so to speak. I can work to my level of competence. I can't think of any downsides, unless I don't have work coming in, in which case I PANIC. One needs to be promotional to a certain extent, which seems to be contrary to the other characteristics required to do the job.

J.W.L.: I find my job both intellectually stimulating and challenging, and my time is reasonably well-paid within the supply/demand system in which I operate. I dislike sometimes having the feeling I have not spent enough time on a particular text, and at times having to defend my work if there is a customer complaint but accept that this is an inevitable part of a busy freelancer's working life.

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

S.H.: Get in with a CRO to gain exposure to as many therapeutic areas as possible. Learn from more experienced writers and take as many training opportunities as are on offer.

L.C.J.: Gain as much experience as possible by writing as many different documents for as many different readers as you can. Try to avoid regulatory writing at the beginning—it's too regimented for the type of style you should aim to develop for journalism, and do some 'shadowing' to give you an idea of what the job is really like.

T.L.: Get psychiatric help. See # 4; if you are unable or unwilling to do or to develop these skills, get into selling insurance or something. Work as an employee long enough to learn the trade and to establish your credentials as a writer/editor. Become professionally visible and credible by publishing, teaching, serving on committees, becoming an officer, and so on in professional associations.

J.W.L.: I would say that significant experience in-house is a valuable way to learn the trade. If this can be combined with some freelance work, this could lead to the opportunity of branching off into full-time freelance work later on.

The editorial board of *TWS* thanks Jason, Lisa, Sam and Tom for answering these questions and sharing their experience with the EMWA members. Lisa recently became a director of Trilogy Writing & Consulting and is opening their UK office.

Diana Raffelsbauer

Freelance medical writer and journalist
PharmaWrite Medical Communications Network
Germany
diana.raffelsbauer@pharmawrite.de

A VAT experience

I translate German texts into English and my Swiss client wanted my work edited from a quality control perspective, which I was really happy about. I found an editor to do this for me, who is actually a German-based certified translator. He did a really good job but on issuing the invoice, he charged my client value added tax (VAT), which my client refused to pay. I have never charged VAT under German law for small enterprises so I have never really been confronted with this issue until now.

According to my Swiss client, they never pay VAT for such deliveries coming from out of the country. The editor formally responded that it was not a 'delivery' but a 'special service' and since the service was carried out in Germany, my client could not be exempt from VAT according to the 2010 changes in the German law, stating §3a Paragraph 1 of the German Value-Added Tax Law (*Umsatzsteuergesetz, UStG*). This paragraph states 'A special service is carried out from where the trader operates his business. If the service is carried out by a permanent establishment, the establishment is considered the place where the service is carried out.' Therefore, my client, a Swiss scientific institute, paid the German VAT of 19%.

It made me wonder and call up the German *Finanzamt* myself.

Firstly, the *Finanzamt* told me that the changes in the VAT law indeed have to do with where the service is performed. If it's done in Germany, German VAT has to be charged. But it seems this paragraph applies in many other different situations.

Secondly, I was informed that under normal conditions like services we usually perform (editing, translation and consultancies), one has to distinguish between entrepreneur and non-entrepreneur clients when invoicing outside Germany. Non-entrepreneurs are private individuals and are liable for German taxes outside Germany but within the EU. Entrepreneur clients cannot be charged VAT under the German law. This is what changed in the law. Before 2010 this distinction was not important. VAT was always charged at the customer's place of establishment and not where the service was done. This is why when issuing invoices outside Germany, we are to acquire our client's VAT Registration Number (Ust-Id-Nr) as an indication of our client's status. Usually, private individuals do not have VAT Registration Numbers. It is recommended that we check for the validity of this number, which can be done online (http://ec.europa.eu/taxation_customs/vies/).

Thirdly, in duty-free ports like Helgoland, Germany and outside the EU such as Switzerland, this VAT issue does not apply at all.

However, VAT can really become complicated if your client is within the EU and is a charitable institution, doing the activity for purposes of profit, or is VAT registered. In such cases, having a financial adviser is the best solution.

Joselita T. Salita

jtsalita@aol.de

For further reading, see: <http://dejure.org/gesetze/UStG/3a.html>,
http://ec.europa.eu/taxation_customs/taxation/vat/how_vat_works/vat_on_services/index_en.htm



Professional indemnity insurance: Should we bother?

by Gregory Morley

From time to time, the freelance business forum at EMWA conferences has addressed whether freelancers or sole trader companies need take out professional indemnity insurance [1] and in an article in last year's *The Write Stuff*, Rosemary Bischoff [2] called for further debate on the subject. For the most part, the consensus has been that any responsibility that a freelancer might have is diluted by the team environment and that as medical writers do not usually sign off on the document, they cannot be held liable for errors or problems in the document [1,2]. By this argument, provided you act with reasonable diligence, then you should be protected against major claims against you.

Throughout my professional life as a freelancer, I have been blissfully (and perhaps naively) unconcerned by the issue of professional indemnity insurance. I am based in Spain and it is my impression that this country is not particularly litigious. Moreover, written contracts seem less common here than in northern Europe or the United States. When contracts are actually drawn up, they usually read more as reminders of the basic terms of the agreement rather than a detailed consideration of actions and penalties in a range of potential but unlikely contingencies. Without nasty reminders of what might happen should something go wrong, the question of liability seemed rather remote. Recently though, I have started to have increasing dealings with clients outside Spain, and I have begun to sign detailed contracts. In one case, a potentially valuable client wanted to include a hefty liability clause. Clearly it was time to think about professional indemnity insurance.

Liability clauses and liability

Medical writers can usually negotiate the removal of liability clauses or indemnity insurance clauses from contracts that they sign [1,2]. Often, the initial draft of the contract will be based on standard contracts used for a range of services. For some of these services, such as those relating to clinical operations or audits, for example, a liability clause would be normal and expected, and the provider of such services would have indemnity insurance. Medical writing is, however, a different type of service, and most clients—who on the whole will be reasonable people—will recognise these inherent differences and alter the contract accordingly. Sometimes though, particularly in the US, CROs insist on liability and indemnity insurance clauses in their contracts with freelancers on the grounds that they have such clauses in their agreements with the

primary client (usually for services that go well beyond medical writing).

Even though it is usually possible to negotiate the removal of liability clauses from contracts, when talking to my father—a retired solicitor—it was clear you can still be held liable for damages arising from the practice of your profession even when there are no explicit penalties in the contract. Likewise, you can also be held accountable for work done outside the framework of a contract. It might be harder, but it is possible. It was also suggested in a discussion I started on the topic on the EMWA LinkedIn site that, if you offer expert services, you can be held to higher liability standards than your average person [3]. Clients can rightly assume that you are an expert and that your work will not be deficient. So if major deficiencies are detected, and these are costly to the client (more costly than the agreed price of the job), legal action could be undertaken to recover costs.

The sign-off argument

As mentioned earlier, many freelance medical writers base their decision not to take out professional indemnity insurance on the fact that they do not sign off on the final document. Documents are usually developed within the context of a team, and the burden of responsibility is shared. This is a strong argument, particularly when drafting regulatory documents, where review cycles and sign-off responsibilities are usually clearly defined. What is more, Rosemary Bischoff [2] argues that Good Clinical Practice clearly assigns responsibilities and that the medical writer should not be legally responsible for the final content of such documents.

As you do not sign off on the documents, you should certainly be protected against claims that you misrepresented or misinterpreted the overall data. The argument does, however, assume that all the process and review rounds went smoothly and cleanly. What happens, for instance, if a couple of reviewers' comments are not fully implemented, perhaps due to demanding timelines or internal conflicts? Would it be the responsibility of the signatory to check that a given comment had been implemented throughout what could be an extensive document before signing off? These may be hypothetical questions, but then the whole concept of insurance deals with protection against hopefully hypothetical situations that could have catastrophic consequences.

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- > Medical writing is not limited to drafting regulatory documents and some writers may take on assignments in which there is no team set-up. In such cases, there is the potential for clearly identified liability. For example, with scientific journalism, responsibility for the content can readily be pinned on the person who wrote the copy and claims for (inadvertent) libel or plagiarism could well apply. For medical writers who assist in the drafting of journal manuscripts, ethical requirements insist that they are acknowledged. This may make it easier for the medical writer to be targeted for legal action. Of course, it is the named authors who should ultimately take responsibility for the content, but can they be held responsible for mistakes that should have been caught by the medical writer, who some would argue is acting in a capacity as a publication consultant? Indeed, whenever medical writers act more in a consultancy capacity, or offer quality control/assurance services, I would argue that the risk of incurring professional liability increases.

The situation with translators

Translators, like medical writers, deal with documents. While the translations of documents such as patient information leaflets will be extensively reviewed and ultimately require sign-off by the sponsor, arguably the role of the translator is more visible and could more readily be singled out in the event that catastrophic mistakes make it through the system. The translation of a scientific article for reprints would also require some sort of OK from the company prior to proceeding to the print run. Once again, a glaring error that might require the print run to be shredded could be attributed to the translator. Given the more visible role of the translators (especially outside an agency setting), it is perhaps not surprising they seem more inclined to take out professional indemnity insurance, and indeed professional translation societies such as the UK-based Institute of Translation and Interpreting encourage their members to take out insurance.

The practicalities of obtaining insurance

According to Gaby Berghammer [3], another reason why translators may be more inclined to take out indemnity insurance is that it is simply easier for them. Most people understand (or think they understand) what translation is. Translators form a large and well defined group. This makes it easier for insurance companies to come up with what they consider an appropriate quote and many national translation associations have negotiated special deals with insurance companies. Medical writers, on the other hand, often form small, heterogeneous and fragmented groups, and mainstream companies just don't know how to assess the risks. For me, it would be easy to take out indemnity insurance with a Spanish company as a translator, but when I approached the Spanish companies about insurance as a medical writer, they were unable to offer me a quote. It was hard even to explain what a medical writer

does (many medical writers will offer a range of services from regulatory writing through to medical communications, making it harder still for the company to understand our business). Often, the word 'medical' is enough to put off many companies. Recently, specialist companies have emerged in the United Kingdom [4] and in Germany that offer appropriate cover. According to my preliminary enquiries, these companies usually only offer cover for freelancers and companies based and registered in their country, and their advice is to contact a local broker. The costs of such professional indemnity insurance will presumably vary widely according to business turnover, type of work, countries where liabilities are covered, and so on, but you can probably expect to pay between €500 and €1500 per year.

The private limited company as a way to limit liability

In the end, in order to be able to sign some of the contracts with clients outside Spain, I was obliged to set up the Spanish equivalent of an Ltd company. Unlike when you are freelance and may have to respond to claims with your house or other personal assets, the company's liability is limited to the size of the (small in my case) initial investment and current assets. I have therefore decided not to pursue the professional indemnity insurance for the time being as my company is something I can walk away from. If and when (hopefully) my company grows in value and reputation, the risk-consequence balance may well change and I will look into indemnity insurance once again.

Other arguments for and against indemnity insurance

One of the attractions of having professional indemnity insurance is that it can provide you with a legal shield. The legal experts at the disposal of insurance companies can be quickly and easily called into action, and can act as a deterrent against clients taking you to court. This may seem all the more important if you work with corporate clients, who themselves will have plenty of legal resources available to intimidate someone without insurance. You would of course be spared the expense of paying up-front legal fees and the effort of having to search for appropriate lawyers to represent you. A counter argument put forward by Rosemary Bischoff [2] is that if a cash-strapped start-up company is aware that a freelancer has indemnity insurance, the prospect of a juicy payment from the insurance company may encourage litigation.

Another argument that I have heard, at least in connection with translators, is that professional indemnity insurance can be used as a selling point, particularly when relatively few other translators have coverage. The idea is that you can paint yourself as business-like, and willing and able to take responsibility for your work. In a sector like translation, which is awash with cheap and relatively inexperienced translators, and where there is often no personal

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contact between client and translator, this argument may hold some weight. Clients who have just pulled a translator's name out of some business directory may well feel more at ease dealing with a translator with indemnity insurance.

The flipside to the above argument is that some clients may wonder why a professional feels the need to take out indemnity insurance in the first place, and may consider this a danger signal. Furthermore, medical writers will usually capture their clients through recommendations or personal contacts. But in an increasingly globalised economy, where it is less likely that there is a personal relationship of trust between client and provider, indemnity insurance may become a stronger selling point. Interestingly, Rosemary Bischoff [2] has voiced concerns that if the industry knows that medical writers can now obtain insurance, they may start insisting on it. However, at the EMWA freelance business forum in London in 2008, only two of the participants said that they had lost work as a result of insisting on removing insurance cover-related text from contracts [3].

Conclusions

It is impossible to make a blanket recommendation about the need for professional indemnity insurance for medical writers. We are not a uniform group and we all have our own particular set of (changing) circumstances. Although I have decided not to take out professional indemnity insurance for now, I still have a nagging feeling I should look into it further. One thing that is clear to me though is that the argument that we, as medical writers, rarely sign off on the documents we write is perhaps overly simplistic and does not fully protect us from potential liabilities.

Acknowledgments

I would like to thank those who posted on the LinkedIn discussion thread and those who replied in private for their much appreciated input. The discussion thread will still be active when this article is published, so please feel free to post any thoughts about issues raised in this article. I would also like to thank Alistair Reeves and Sam Hamilton who both provided valuable critical feedback on the article.

Gregory Morley

Freelance and contract medical writer
Madrid, Spain
greg.morley@docuservicio.com

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3. *Indemnity insurance and liability* discussion in the EMWA LinkedIn group (available at http://www.linkedin.com/groupAnswers?viewQuestionAndAnswers=&discussionID=48326717&gid=2717752&commentID=35066712&trk=view_disc)
4. See for example *The Write Stuff*, 2011;20(1):59

Report on the Freelance Business Forum at Berlin, May 2011

This time the Freelance Business Forum (FBF) was conducted by the new Freelance Support Team. Sam Hamilton, the principal freelance advocate, introduced the new team, which has an international flavour being drawn from different European countries. Thus, this FBF session was co-chaired by Sam (England) and Kathryn White (England), with inputs from Raquel Billiones (Switzerland) and Ingrid Edsman (Sweden), while the proceedings were recorded by Anu Alahari (France).

Thanks to Alistair Reeves

Sam gave warm thanks to Alistair acknowledging his initiative and efforts in setting up and maintaining freelance support over the past eight years. He received a card and an Amazon gift voucher. Alistair explained that he stepped down to allow time for his involvement in the Masters course in Medical Writing at the University of Innsbruck, Austria. He will nevertheless continue to be a supportive and involved freelance member.

FRC on the EMWA website

Ingrid gave a live demonstration of how to reach the Freelance Resource Center (FRC) webpage from the EMWA website. Currently, the webpage carries articles published in *The Write Stuff* (TWS) of interest to freelancers. She explained that there are 120 articles that appear under eight different categories. She invited suggestions from the members for what they would like to add to the webpage. Claudia Frumento initiated a discussion on putting up a template of a service contract that might be useful to freelancers. This could include clauses to protect the interests of the freelancer, including for example, cancellation fees, a topic that has been discussed on the EMWA LinkedIn group. Helen Kulesza pointed out that templates may have to be country-specific, while Helga Gutz suggested that templates could be based on the nature of the contract. A show of hands indicated that 30 out of the 35 attendees present at this time were in favour of providing a template on the FRC webpage. It was eventually decided that a template would be difficult to provide, but bullet points for inclusion in contracts were feasible. Volunteers were invited to contribute. Andrea Palluch agreed to provide bullet points covering issues to be included in contracts. Helen Genevier volunteered to provide English-French translation of the document. The above members are likely to network and put together a list of points for inclusion in contracts on the FRC webpage.

EMWA LinkedIn group

Sam encouraged freelance members to join the EMWA LinkedIn group and use it to share information, discuss issues or make announcements. Marie-Helene Hayles asked whether the LinkedIn group may be a suitable forum from >

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- > which to launch a discussion on a particular problem with a client in order to obtain suggestions or solutions from other freelancers. Andrea signalled that there are guidelines in place for the content of the postings on LinkedIn. Sam cautioned that one has to be careful to protect one's identity on the web and to be mindful that anything written is widely read and goes on record. EMWA will not get into any individual disputes; however, members are free to seek advice from other members in private.

Welcome to new members

Kathryn welcomed and addressed the new members in the freelance group. She read out a message from Raquel, who could not be present. Raquel coordinates the content of the Out On Our Own (OOOO) section of the *TWS*. She invited members to contribute articles to this section: a full article is 2000-2500 words and a box can be up to 1000 words. She explained that the authors will own the copyright on the articles and can provide a hyperlink to the same on their websites.

OOOO logo competition

The winner of the competition for a logo for the OOOO/FRC was announced. The FRC team (Sam, Raquel, Ingrid and Kathryn) had unanimously selected Claudia Frumento's entry as the best among the 24 entries from 13 members. Claudia's concept of a logo depicting a freelancer juggling his/her time was put on paper by Matjaz Martinec, *TWS*'s graphic artist. Her logo was displayed along with those that had been shortlisted. Claudia received an Amazon gift voucher. More about her in an interview with Kathryn in the accompanying pages.

Miscellaneous questions from members

Alistair objected to a suggestion by the executive committee (EC) that workshop leaders may pay registration fees for conference attendance in the future. Workshop leadership is a voluntary contribution to the EPDP; preparing and delivering a workshop can easily take 50-60 hours, and often leaders run 2-3 workshops per meeting. He reported that he had raised this issue at the annual meeting (AM) and the EC has promised to consider his points.

In regard to the AM, Sam encouraged active participation from all members in this meeting as it is a platform to express concerns or provide a feedback to the governing body of EMWA. To illustrate the point, she asked for a show of hands to find out how many freelancers were completely satisfied with the registration process for the Berlin meeting. Only 12 out of the 39 members present at this time declared complete satisfaction.

Christina Lumpkin had a question about whom to approach for problems regarding the record of the EPDP credits and information on the performance in the workshops. She was asked to check directly with the workshop leader or with Jo Whelan, the education leader or with MCI, the company

administering the workshops. Marie-Helene complained that she was not able to obtain an invoice in the required format (including a VAT number). Claudia wondered if it may be possible for EMWA to obtain a group/institution licence to the AMA style guide and make it available to members. However, it was considered unlikely that EMWA EC would pay for this service.

London conference November 2011

Raquel suggested that for future EMWA conferences, local freelancers may be able to help others by suggesting hotels that may be conveniently located with respect to the conference venue and cheaper than those suggested by the organisers. Sam announced that the FBF at the London meeting has been moved to Thursday, 3rd November, 17.45-18.45 h, as the conference will now only run on the Thursday and Friday, and not the Saturday.

Thanks to all those who attended the FBF and see you again next time!

Anuradha Alahari

accentanu@gmail.com

EMWA OOOO Logo Competition

Interview with OOOO Logo Competition winner, Claudia Frumento

In March 2011 we launched a competition for EMWA members to design a suitable logo for the Out On Our Own (OOOO) section of *The Write Stuff* (*TWS*). The response was fantastic and our thanks go to everyone who entered; the standard was extremely high. We are delighted to announce that the winner is Berlin-based freelance medical writer Claudia Frumento. Her logo depicts a figure toss juggling four rings, which are in fact the letters OOOO! Her neat concept and design were further improved by *TWS*'s graphic designer.

I asked Claudia about her design and participation in the competition.



EMWA OOOO Logo Competition

What inspired your design?

C.F.: I don't really know, actually the idea of a juggler just popped up in my head and the more I thought about it the more I liked it.

Tell us about your design and your thoughts behind it.

C.F.: I think that is the way I feel quite often as a freelance medical writer, having to do everything simultaneously: writing, accounting, acquiring new clients, IT support, travel, etc. There is this constant balancing act between things that are important but not urgent, those that are urgent but not so important, as well as those that are important and urgent! I feel that if I lose control of any, then the business will not be successful, and I like to be successful. Sometimes I really miss the secretarial or IT support I had as an employee. But honestly, I would never want to go back to work for a company and have a boss who gets replaced every two or three years, as was the case in the company for which I worked before. I enjoy being my own boss and the more I practise the better I juggle!

What motivated you to take part in the competition?

C.F.: As soon as I read the e-mail announcing the competition, believe it or not, I got the idea for the logo. Since I had some spare time I started drawing it and there it was.

Describe how you felt when you were told you had won?

I was really happy! I was out in the street walking the dog, so some people turned around when I started screaming... and my dog got scared!

Have you done anything like this before?**Tell us about any previous designs or other art work you have been involved in.**

C.F.: Well, not exactly like this, but similar things, such as logos for gadgets or events or sales meetings of the company for which I used to work. My 'artistic' career started many years ago: I paid my university fees working as a medical illustrator—I loved the job but couldn't earn enough from it. The illustrations I did were for all sorts of materials: anatomy books, posters and publications (graphs, illustrations) and whatever was necessary for other types of written material. At that time everything had to be done by hand, there were no PCs with appropriate software. I remember that my favourite shops were art tool shops. After finishing my engineering studies I got married and moved to Germany where I got my PhD in medical informatics. Then I started working for Eli Lilly (they had a medical technology business at that time). I've always done some writing and art work, just for fun: short stories, furniture design, interior design, even clothes design. I remember once, I woke up in the middle of the night with an idea for a 'self-sustainable' bikini bra that stays in place without any obvious support. I got out of bed and by morning the bikini was ready and I took a splash in the swimming pool that same day! In my job as a product

or training manager for the medical devices companies I worked for, I had to describe the gadgets at our sales meetings. I didn't go out and find a company to do this for me but experimented with illustrations myself and some turned out really cute: flamenco snappers for Parkinson's disease, a logo for the sales meeting in 2000, a layout for special binders for sales/training material, etc.

How was your collaboration with TWS's graphic designer? Did the logo turn out the way you expected?

C.F.: I had sent my idea as a black and white design and the graphic designer did a great job of transforming it into the final logo; but I didn't really work with him directly.

I then asked Claudia more about herself.

What is your 'day job'?

C.F.: My 'day job' is writing regulatory and medical communication documentation for medical devices and pharmaceuticals, and training materials. I also taught a course on technical writing in English at the University of Applied Sciences in Gießen until I moved to Berlin with my family this year.

Tell us about your involvement with EMWA.

C.F.: I've been an EMWA member since 2007. It was Stephen de Looze who told me about EMWA and persuaded me to join it. When I decided to become a freelancer, I really wasn't sure that I wanted to become a medical writer, but Stephen convinced me that this was an interesting line of work. I joined EMWA and here I am, a professional freelance medical writer. I love what I do, because it combines a lot of what I like to do: creative writing (as creative as medical writing can be!), designing layouts for brochures and posters, graphics for training manuals and lots more! I think joining EMWA was the best decision I've ever taken as a medical writer.

Tell us about your role as guest editor of this issue of *The Write Stuff*

C.F.: Elise Langdon-Neuner called me some time ago and asked me if I would be willing to guest edit the TWS issue that would be dedicated to medical devices. Since I have specialised in medical devices and understand the difference between the two worlds, medical devices and pharmaceuticals, I thought it would be an interesting role. I have many contacts in the medical device industry and naively thought it was going to be easy to find people to write an interesting article for TWS, but I was wrong. It was not so easy, everybody is too busy! On the other hand during the entire process of preparing the articles I had very interesting discussions with the contributors on the content of the articles and how to balance the messages. I learned a lot from Elise too, as she really has a wealth of experience and gave the authors and myself some extremely valuable feedback.

Kathryn White
kathryn@cathean.co.uk



My first EMWA conference: 31st EMWA Conference, Nice, November 2010

by Kathryn White

Having recently made the leap to become a freelance writer, I was a little hesitant about attending the EMWA conference at first. This was largely because previously my employer paid for my training and now I had to fund myself! I spoke to several friends in my writing network and they all spoke very highly about the EMWA conferences. They persuaded me to make the investment. After all, it would be a good opportunity to network and the training topics were particularly relevant.

My first impression of the EMWA conference was that of professionalism. The opening plenary sessions were exceptional, and highly entertaining. The two presentations, by Helen Baldwin and Alistair Reeves, on the first evening, were both interesting and amusing. I think they helped to get everybody in the mood for the forthcoming days of conference and were a great start to proceedings. These were followed by a drinks reception in the hotel which was an excellent opportunity to mingle and to get to know your fellow trainees. Unlike some scientific conferences I have attended, here everyone was friendly and welcoming. Despite not knowing anyone there, I didn't feel at all inhibited to join in discussions. It was lovely to catch up with people from all over the world and discuss their experiences of medical writing both in companies and as freelancers. I swapped business cards with a variety of people

and ensured that my cards were placed around the coffee areas to maximise my networking potential!

The first day began with an inspirational presentation by life-coach Elaine Bailey—perfect motivation for the day ahead. Overall, I thought there was a good mix of workshops and presentations, punctuated with breaks to enable people to network or enjoy the beautiful surroundings of Nice. In the evening of day one you had an option to go on one of the organised dinners. I didn't attend on this occasion because I wanted to spend time with my partner who came with me to enjoy the sunshine and sights of Nice. However, I thought it was a great addition to the agenda and one I would certainly consider another time. The freelancer's business forum held at the end of the first day was a further opportunity to network and to gain information from more experienced freelancers. It was very well attended and I think is an essential part of the EMWA conference.

I chose to attend three advanced workshops and enrolled in the professional accreditation scheme that EMWA run. This, alongside the fact that I was paying for the training myself, meant that I was determined to get the most out of the course. My mission was made easier by the fact that the training itself was informative, well-presented and very relevant. The pre-workshop assignments were a good way of preparing for the workshops themselves. I learned a lot from each workshop and now feel much more confident about taking on assignments from clients in the areas covered. All too often you come away from training courses with a huge folder full of notes which goes onto a shelf—or under the bed—never to be read again! This was certainly not the case from the EMWA conference. The topics were well-chosen with an appropriate amount of material covered in each; sufficient to adequately cover the subject with time for questions and discussion. The hand-outs were concise and informative. The post-workshop assignments really helped to bring home the key messages and ensured that you read through your notes!

Was it worth the investment of time and finances? Absolutely! Not only was the training value for money, attending the conference made me feel a welcome member of the organisation.

Kathryn White

Cathean Limited Medical Writing Consultancy

UK

Kathryn@cathean.co.uk

Geography lesson

The theme of the 2011 EMWA spring conference was 'Globalisation' so we all know where the countries of the world are situated, especially those that are currently constantly in the news, right? But maybe countries are not where you think they are. You can check your knowledge of geography with the puzzle on the following site: http://www.rethinkingschools.org/just_fun/games/mapgame.html. All you have to do is drag the country's name onto the map. There are no scores or time limits. It's fun and maybe you will learn sometime!

Out of Hours

Kathryn White is the second 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’.

K.W.: I am a keen horse-rider and own two horses, one of whom I compete in dressage and the sport of eventing. The latter is the equivalent of a triathlon for horses. You compete in three disciplines: dressage, showjumping and crosscountry, in one day or over three days. People may be familiar with the famous eventing show, Badminton Horse Trials, which takes place in the UK and is televised worldwide. The sport of eventing is quite unique in that, despite the fact that I am a relative amateur, I’m able to compete alongside Olympians and World Champions, such as Zara Phillips! In my spare time I enjoy writing equestrian articles for publication in magazines such as Eventing and Eventing Worldwide. I also write a monthly blog for a top equestrian retailer, Equilibrium Products. The blog describes my adventures as a horse-owner and competitor. Recently, I was invited to help with the editing of a newsletter for a national equestrian organisation and I am very excited about it.

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

K.W.: I particularly enjoy interviewing riders and celebrities in the sport of eventing; many of whom are my heroes. I will never forget being invited to attend an open day with top rider and Olympian, Pippa Funnell, at her yard in Surrey. I had to stop myself from being too awestruck to ask sensible questions! I have been very fortunate to have had the opportunities to report from premier events such as Badminton Horse Trials and the European Eventing Championships in Fontainebleau.

Describe a recent assignment.

K.W.: I was asked to write an event report for Eventing magazine which was my first assignment for them. I was very nervous as they had a strict remit, word count and tough deadlines! Also, it is a reputed national publication in the world of eventing, read by many of the sport’s celebrities and officials.

What was the topic?

K.W.: The report described a national event which I attended at the Warwickshire College of Agriculture. Several top riders were competing alongside amateurs and at three different levels. The event ran over 2 days.

What did the assignment involve?

K.W.: I attended one day of the event so that I could interview the organisers, report on any mishaps and provide

a detailed description of how the competition went. It was great fun because I spent all day watching the action and interviewing interesting people. I have friends who are riders or officials on the eventing circuit so it was a good excuse to catch up with them. My partner is a commentator for the sport and a good source of back-room gossip! I had to keep track of who was likely to win each section of the competition and then, at each prize-giving, I needed to interview the winner and runner-up.

My remit was to interview the top two riders of each section, but only if they were amateurs i.e. riders who didn’t event professionally. In particular, the magazine wanted to know of any unusual jobs these riders had in order to support their hobby, and any interesting facts about them and their horses. I wrapped up my last interview at 7 pm on Saturday evening and had to submit the finished article first thing Monday morning, having caught up with the rest of the competition via phone and internet on Sunday. It was a long weekend and hard work but I loved every minute of it. I never get over the excitement of walking into a newsagent’s and seeing my work in print!

Describe how this type of writing helps you with your technical work?

K.W.: The magazines have word limits for their articles and they work to strict deadlines. This has helped me enormously with writing journal manuscripts and clinical summaries. In both types of writing there is a certain amount of background reading and research to be done before you begin an article. Equestrian journalism has also given me the confidence to talk to people I don’t know very well and obtain information without being phased; so talking to KOLs and journal editors is no longer a challenge! I’m hoping that working on the newsletter will give me greater experience of editing and proof-reading, which are skills I can apply in my role as a medical writer.

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

K.W.: Working in the pharmaceutical industry, in general, has taught me the importance of planning and project managing an assignment. I have also gained organisational skills and a sense of professionalism that are paramount to getting things done efficiently and to a high standard. Some of the equestrian articles I have written have been quite technical or science-based. This is where my clinical background has been a great help.

If you have an ‘out of hours’ story to share, please contact Raquel at medical.writing@billiones.biz

Words, Grammar & Co

Further comments on 'Compilation of QRD decisions on stylistic matters in product information' from the EMA

In the September 2010 issue of *TWS*, I commented on Version 11 of the above document [1]. Diana Taylor of Parexel recently drew my attention to a new version ("rev.14") (<http://www.ema.europa.eu/htms/human/qrd/docs/stylisticmatters.pdf>). Comparison of the two documents shows that it contains little new for us in terms of items that deal with style. Some of the text has been tidied up a little and expressed a little differently, but the basic messages are the same. A third of the issues are still not style issues, i.e. caution with dietary recommendations, inclusion of general health information, use of combined printed package leaflets for different dosage forms and strengths, various issues surrounding the use of trade names (now called invented names) and INNs, and how to express strengths for single- and multi-dose preparations. There have been some, mostly small changes to these items (e.g. expanded information on using English and Latin translations of INNs), but these are not our concern here.

Amongst the remaining issues, linguistic changes have been made to the points on abbreviations and acronyms, consistency, use of foreign terms, gender, imperial measures, strength of normal saline, general format of units, degrees temperature and SI base units, but there are no changes in content, so my previous comments are all still valid.

The following points have changes in content:

Use of 'should'

The previous version stated that 'should' must be avoided because when it is translated into romance languages and Croatian, the translation means 'it is preferred that' and not 'must'. Croatian has been deleted.

Number separators

It is worth reviewing this section as a number of small—but important—changes have been made.

Use of microgram written out and as an abbreviation

The section has been expanded and now gives recommendations for each member state ('member state' is still capitalised, but no longer hyphenated in Version 14!).

My previous comments therefore also still apply for the above three points.

One change that has been made by the editor of the text is that when giving examples, 'e.g.' is now preceded by a semicolon in many instances. Not a practice to emulate, despite the origin of this document, as this is incorrect use of the semicolon. A comma is usual if 'e.g.' plus the example(s) are not put into brackets.

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1. Reeves A. Some comments on the 'Compilation of QRD decisions on stylistic matters in product information' from the EMA. *TWS* 2010;19(3):217

Do 'gross macroscopic findings' exist?

No. Because 'gross' means 'macro' in this context and is therefore superfluous.

This is illustrated perfectly by the following diagram adapted from a fantastic little book by Dale Layman called *Medical Terminology Demystified* (McGraw-Hill Professional; ISBN 978-0071461047):

All organisms	=	Gross (macroscopic) organisms	+	Microscopic organisms
Living bodies with organs		Visible to the naked eye		Not visible to the naked eye

Your overall findings are made up of macroscopic and microscopic findings, and 'macroscopic' needs no further definition with the word 'gross', because you have only two choices: you can see the finding with the naked eye or not.

This may unfortunately be a lost cause, but I'm not prepared to give up on this one yet.

Alistair Reeves

a.reeves@ascribe.de

LOL becomes of age

OMG (Oh My God) and LOL (laughing out loud) have been added to the *Oxford English Dictionary* (OED). No, not everybody is happy about this.

In an article on the BBC website¹, James Morgan discusses the acronym LOL and its rise in popularity since it was first used in the 1980s by computer fanatics. LOL is defined in the OED as an interjection "used chiefly in electronic communications... to draw attention to a joke or humorous statement, or to express amusement." Graeme Diamond, the OED's principal editor for new words, justifying its entry said "The word is common, widespread, and people understand it." It conveys tone in text.

One young internet entrepreneur explained that he uses LOL in almost an ironic sense, "like a slow handclap after a bad joke. 'Lol' [*sic*] means 'yes, I understand that was funny, but I'm not really laughing.'" Another saw the word as not only simple and multipurpose but also subtle as it can mean more than just 'funny', depending on the situation. He gave the example, "If I had my bike stolen, my friend might reply 'LOL'. It helps overcome an awkward moment."

Critics argue that LOL doesn't sound like laughter and you can't physically say it while smiling. Marie Clair of the Plain English Campaign is concerned that adults' language is deteriorating through using such teen-speak slang words

¹ <http://www.bbc.co.uk/news/magazine-12893416>

and ignoring grammar. While Tony Thorne, author of the *Dictionary of Contemporary Slang*, does not think slang words restrict vocabulary, adding that the small amount of research on the issue shows that children who use slang abbreviations are the more articulate ones, a process called code switching.

Sometimes LOL has been mistakenly used to mean 'lots of love'. Apparently one mother wrote: "Your grandmother has just passed away. LOL." With such possibilities for ambiguity its use in scientific reports is probably best avoided for the time being.

Data <http://www.economist.com/blogs/johnson/2011/04/change>

Changes in word meanings and the frequency of data are/is

An article on Slate [1] tackles the question of when changes in the meaning of a word should be forestalled. The opening paragraph states, "Suppose a friend said to you, 'I know you're disinterested, so I want to ask you a question presently.'" Then he didn't say anything. Would you be momentarily nonplussed?" Ben Yagoda, the author, concludes that you probably would be because the paragraph contains 4 words whose primary definitions have either changed or are in the process of doing so: *disinterested* used to mean 'impartial' and is now mostly used to mean 'uninterested', *presently* once meant 'shortly' and is now used for 'currently', *momentarily* originally 'for a moment' has changed to 'in a moment' and *nonplussed* has changed from 'perplexed' to 'unimpressed'. Yagoda points out that sometimes there is no other word that expressed the 'obsolete' meaning, e.g. no exact synonym for the 'impartial' meaning of *disinterested* exists. He has devised a guide to assess how long we should try and hold onto the original meanings, bearing in mind their use could confuse your audience once a change has become generally accepted. The guide gives a score for each word under scrutiny calculated from the percentage of Google hits it yields multiplied by a 'utility value' which Yagoda gives to the old meaning.

The article is discussed in the online language section of *The Economist* [2] which also brings the change in meaning of *literally* to the fore. However, what might be of particular interest to medical writers is that it suggests that the guide could be refined by using Google N-Gram Viewer. The example taken to explain the use of this tool is 'data are' versus 'data is'. Google N-Gram Viewer shows that data as a plural noun is still more common in books but 'data is' comes up more frequently on the Internet as a whole.

1. Yagoda B. The "Nonplussed" Problem. Available at: <http://www.slate.com/id/2290536/>
2. Is it literally too late to stop the drift? <http://www.economist.com/blogs/johnson/2011/04/change&fsrc=nwl>

Forget large and bold text— it's not so easy to remember

Putting text in large or bold font is irritating for a reader but writers usually adopt such ploys in the hope that the text will be better remembered by the readers. This turns out not to be the case. Benedict Carey writing in *The New York Times* reviews the research. He refers to a study shortly to be published by Nate Kornell, a psychologist at Williams College in the US, in which participants were asked to assess how well they thought they would remember a list of words printed in fonts of different sizes. Most thought they would remember large text better but in a subsequent test the font size of the list of words made no difference to how well they remembered them. It only made the participants feel confident that they *would* remember the text. Another study published in *Cognition* found that participants who read about aliens in 16-point Arial font did not do as well in a subsequent exam about the aliens as those who had studied the same text printed in 12-point Comic Sans MS or 12-point Bodoni MT, which are less familiar and harder for the brain to process (the first group achieved average marks of 72.8% and the second of 85.5%). The explanation given by the researchers is that if text is written in a hard-to-read font you can't skim it and are forced to read it more carefully—in terms of memory what comes in easily also goes out easily.

Source: Carey B. Come on, I Thought I Knew That! April 2011. Available at: http://www.nytimes.com/2011/04/19/health/19mind.html?_r=1&emc=eta1

Elise Langdon-Neuner
editor@emwa.org

"Most thought they would remember

large

text better but in a subsequent test the font size of the list of words made

no

difference to how well they remembered them"

■ For regulatory writers

Fit for purpose

In everyday life, we constantly make decisions about how much effort we are going to put into a task, activity or chore to produce an acceptable result. For example, I am usually a scruffy dresser and don't expend much energy or money on my appearance. Dressing smartly just doesn't seem necessary for going to the supermarket and other activities of daily living (though my wife may sometimes disagree). However, when I have an interview, wedding, funeral, or some such more formal event, a voice in my head will usually nag me into making an effort to look clean cut and ironed.

Management types would call this "fit for purpose" (or "fit for function") [1]. The bottom line is, I suppose, that we only have a finite amount of time, energy and resources that we can spend on a given task. If we concentrate too much on one task in search of taking something that is acceptably good a little closer to perfect, we are taking away time from other professional (or leisure) activities. As pointed out in a recent blog, in a pharmaceutical corporate environment, this can lead to interminable and wasteful discussions in meetings about whether, for example, "very critical" is grammatically correct (because "very" qualifies an absolute property) even though the phrase itself is perfectly comprehensible [2].

There are of course situations where an attitude of "that's good enough" is clearly not appropriate, and can set you on a slippery slope towards mediocrity. For the sake of posterity, it is just as well that Michelangelo didn't take a look at the roof of the Sistine Chapel and say, "Well, it'll always be fairly dimly lit in here, and the aged cardinals will be a bit short-sighted anyway, no need to overexert myself...."

Regulatory documents, on the other hand, are clearly not works of art. They usually have a specific purpose and are produced to fairly well-defined specifications and target a very specific audience (usually reviewers at the health authorities) whose job it is to read and understand these documents, however tedious. It is therefore rather pointless to waste time arguing about minor points of grammar when these will not detract from the reviewer's understanding of the document.

Although the quest for grammatical and stylistic perfection is usually inappropriate in the context of regulatory documents, it is important to ensure that the numbers and facts themselves are correct, that they are correctly placed where the reviewer would expect to find them, and that the sources are duly cross-referenced [3]. Presentation, however, will be more important in some cases. For example, stylistic sloppiness in an investigator's brochure, which is intended to be read by investigators hard pressed for time, could ultimately decrease readability and prevent potentially important information from being transmitted. In this case, a little more attention to language and style may be justified. In certain discussion sections of high-level

documents, nuances can be important, but it has been argued that problems with grammar or certain formatting issues are unlikely to change the meaning. It is therefore important to have a feel for how good is good enough, and this implies a good understanding of what the intended purpose of the document is and who will be reading it.

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2. Gregory Cuppan blog "Writing in the life sciences." *Not knowing when good is good enough in writing regulatory documentation has a huge cost*. 22 December 2010. Available from <http://mcculley-cuppan.blogspot.com/2010/12/not-knowing-when-good-is-good-enough-in.html> (Accessed 10 April 2010).
3. Gregory Cuppan blog "Writing in the life sciences." *Importance of language and writing style in a clinical study report*. 04 January 2011. Available from <http://mcculley-cuppan.blogspot.com/2011/01/how-important-is-language-and-writing.html> (Accessed 10 April 2010).

Revolving doors at the EMA

At the end of last year, Thomas Lonngren stepped down as the executive director of the European Medicines Agency (EMA) after completing the maximum 10-year term allowed in the post. His many achievements, besides helping bring together some many different national competent authorities with different agendas under one roof, include encouraging communication with other regulatory agencies such as the FDA and the commitment to greater transparency. In the latter case, there is still some way to go, but as testament to the increasing openness of the agency, the European Union Drug Regulating Authorities Clinical Trials (EudRACT) database finally went live in March after many broken promises to make the database available to the public. The regulatory community, it would seem, has much to be grateful to him for.

His time since stepping down has, however, been somewhat controversial [1]. Briefly, the chain of events is thus. At the end of December 2010, he informed the management board of his intention to work as a private consultant to the pharmaceutical industry, essentially saying that, scout's honour, he would do no work that would generate a conflict of interest. The management board took his word at face value, and didn't feel the need to ask any further questions.

While not openly questioning the integrity of Thomas Lonngren, some felt that due procedure had not been followed for a person with such intimate knowledge of sprawling workings of the EMA. In February, a number of consumer organisations and organisations for greater transparency sent a joint letter to John Dalli, the European Commissioner for Health and Consumer Policy, expressing concern about the potential abuse of insider knowledge [2].

The EMA management board, now under pressure from within the European Union and from general public opinion, issued a statement that they were satisfied that Thomas Lonngren's activities "as communicated" to them by him in February did not generate any conflict of interest. The board then went on to belatedly impose restrictions

For regulatory writers

on his activities, in particular forbidding him to provide any specific product-related guidance to pharmaceutical or other companies.

What I think is surprising about the whole affair is that Thomas Lonngren got caught up in this controversy in the first place. Surely a person experienced in the inner workings of the regulatory world, with consummate diplomatic skills, and who has campaigned for greater transparency in the regulatory processes, must have been aware that some would view any cosy relationship with the pharmaceutical industry with considerable suspicion? Of course, hindsight is a wonderful thing and perhaps he just never gave it a second thought, immersed as he would have been in clearing his desk before leaving. Whatever the reasons, it is a

shame because it represents a blemish on what was otherwise an impressive mandate.

Gregory Morley

Freelance and contract medical writer
Madrid, Spain
greg.morley@docuservicio.com

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1. See for example Ben Goldacre's "Bad Science" column in the Guardian newspaper, 5 March 2011. Available from <http://www.guardian.co.uk/commentis-free/2011/mar/05/bad-science-drug-trial-secrecy?INTCMP=SRCH> (Accessed, 10 April 2011).
2. *EMA puts curbs on new work by ex-chief Lonngren* in PharmaTimes Online, 22 March 2011. Available from http://www.pharmatimes.com/article/11-03-22/EMA_puts_curbs_on_new_work_by_ex-chief_Lonngren.aspx (Access, 10 April 2011).

French-English *faux-amis* for medical writers

In France and other French-speaking countries, few medical writers are native speakers of English. Medical writing in English is complicated for French speakers by *faux-amis* (false cognates), which are words with the same or similar spelling in the two languages but that have different meanings.

Using the wrong word in English can sometimes be funny. For example, *préservatif* in French is condom in English, not preservative! Most often, though, such mistakes lead to confusion or annoyance.

To help French authors who are writing medical texts in English, we have compiled a list of words in French that are frequently mistranslated.

Phil Leventhal

pleventhal@4clinics.com

Julie Harriague

jharriague@4clinics.com

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French	English	French	English
Actuel	Current	Instruction	Education
Actuellement	Currently	Juste	Exact, fair
Approprié	Relevant	Large	Wide
Conférence	Lecture	Lecture	Reading
Conservateur	Preservative	Médecin	Physician
Consistant	Thick, substantial	Médicament	Drug
Constant	Consistent	Nature (adj)	Plain, natural (adj)
Crise	Attack	Nature (nom)	Nature (noun)
Délai	Deadline	Perfusion	Infusion
Demander	Ask, request	Physicien	Physicist
Démarrage	Initiation	Préservatif	Condom
Drogue	Illegal drug	Professeur	Professor, trainer, instructor
Eclatement	Rupture	Publicité	Advertising
En fait	Actually	Qualifier	Describe
Enfin	Finally	Réalisation	Fulfillment, achievement, completion
Éventuellement	Possibly	Réaliser	Fulfill (a dream or aspiration)
Évidence	Obviousness	Relevant	Raising (verb), depending on (adj)
Évolution	Development, progression	Renseignements	Information
Exceptionnel	Unique	Responsable	Person in charge, manager
Expérience	Experiment	Responsable (adj)	Responsible
Expérimenté	Experienced	Retard	Delay
Fabriquer	Manufacture	Scientifique (adj)	Scientific
Facilité	Ease	Scientifique (nom)	Scientist
Finalelement	Eventually	Sensible	Sensitive
Formation	Training	Société	Company (work) or society
Grand	Large	Témoignage	Evidence
Important	Big, large, considerable	Tissu	Fabric
Informations	Information	Unique	Only, one of a kind
Initiation	Admission, introduction		

■ Gained in translation

Science at the multilingual crossroads

“The single biggest problem in communication is the illusion that it has taken place,” George Bernard Shaw once said. Because we all see the world differently, barriers to communication may be of a perceptual kind. Then there’s emotions, gender differences, or different languages and the cultural or even ideological diversity they reflect.

“We will bury you”—nuclear threat or ideological tidbit?

Think of the legendary remark by the then Soviet premier Nikita Khrushchev at a Polish embassy reception in Moscow in 1956 when addressing a group of Western ambassadors: “About the capitalist states, it doesn’t depend on you whether or not we exist. If you don’t like us, don’t accept our invitations, and don’t invite us to come to see you. Whether you like it or not, history is on our side. We will bury you!” [1]. America interpreted—or, one might say, misinterpreted—this phrase as a call to nuclear war.

In a 1963 speech, Khrushchev expounded on his 1956 words: “Of course we will not bury you with a shovel. Your own working class will bury you.” This belief has its roots in the ‘Manifesto of the Communist Party,’ which concludes its first chapter with these words: “What the bourgeoisie therefore produces, above all, are its own grave-diggers. Its fall and the victory of the proletariat are equally inevitable” [2]. What has long fascinated me is not only the specific terminology Marxism has brought forth, but the fact that even common-language socialist and communist phrases are replete with ideological turns of thought, many of which date back some 100 or more years. Understanding—and, by extension, translating—these concepts requires a profound knowledge of communist thinking.

Turning to modern-day multilingual Europe, anyone whose daily life involves more than one language may become a victim of carry-over effects between one’s native and one’s working language.

Translation—a potential cause of rheumatism?

In 2008, reports that the index-to-ring finger length ratio is associated with the risk of *Arthritis* made it through the German press. The reports were based on a British study showing that the risk of ‘osteoarthritis’ was higher in individuals whose index finger was shorter than their ring finger [3].

Some German-speaking journalists appear to have skipped their homework here. The German equivalent of the English term ‘osteoarthritis’ is *Arthrose* and refers to a degenerative joint disease. By contrast, the term used in initial German newspaper reports, i.e., *Arthritis*, is the term specifically reserved for inflammatory joint diseases, which was not what the British study had looked at.

In a press release, the German Society for Rheumatology stated that, while the organisation was continuously and emphatically attempting to inform the public about the fundamental difference between degenerative and inflammatory joint diseases, inaccurate reports such as the ones snowballing through the media in early 2008 did little to support the Society’s educational efforts [4].

Thus, the need for bicultural awareness is pervasive—not only among translators, but for anyone switching back and

forth between different working languages and processing knowledge from each.

Catholic church to allow use of artificial contraception?

In early 2011, distribution of the Italian edition of a new youth catechism *YouCat*, a supplement to the Catechism of the Catholic Church, was temporarily stopped because of a translation error in the church’s teaching on contraception [5]. Originally written in German and supervised by Austrian Cardinal Christoph Schönborn of Vienna, the book is based on questions and answers explaining the teachings of the Catholic church.

YouCat will ultimately be available in 25 languages. In the Italian edition, the section dealing with contraception erroneously implied that a married couple can use methods of artificial contraception. Thus, in Italian, the question read: “Can a Christian couple turn to contraceptive methods?” The answer says: “Yes, a Christian couple can and must be responsible about their capacity of being able to give life.” The section goes on to explain that the church does not accept artificial means of contraception but does allow regulation of fertility by natural methods.

Obviously, the error was not present in the original German text of *YouCat*, and it was not found in the English edition. Mark Brumley, president of Ignatius Press, publisher of the English translation of the youth catechism, summarised the actual stance of the Catholic church: “The German text upon which we based our translation does not endorse contraception but clearly affirms the Church’s teaching that contraception is evil” [6]. That’s how a seemingly slight translation error, wrapped up in only two words, could have seriously distorted the Catholic doctrine on contraception.

The Italian publisher had already printed 45,000 copies of the 300-page book and sold 15,000. The book has been removed from the market and will be returned with a correction.

Translators have been working hard to put quality standards in place that help prevent such lapses. One is translation standard EN 15038. In her article on translating a Global Value Dossier, Marion Alzer provides insight into what to watch out for in projects that are too large to be handled by a single translator. European standard EN 15038, while remaining silent about how to assess the quality of the end product of translation, provides useful guidance on how to set up a translation process that works. Whether Cardinal Schönborn and his fellow church dignitaries were aware of EN 15038 is anybody’s guess. Yet, particularly with large-sized translation projects, failing to adhere to its principles can come at a price.

Gabriele Berghammer

gabi@the-text-clinic.com

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Global Value Dossier translation—A team approach

by Marion Alzer

Successfully constructing scientific and clinical documents in the pharmaceutical and allied health industries requires a multidisciplinary effort, because different skill sets and areas of expertise are critical to the final content. Translation of such documents is no different, and the quality of the product depends on the mix of the experience, skills and tools that the translator has at his or her disposal. In cases such as specialised translations or large documents covering many different disciplines, an individual translator is unlikely to be fully competent across all areas of a given text.

After qualifying as a medical translator, I was fortunate to work in clinical trials and quality assurance for approximately 10 years and as a translator for an additional 10 years. Despite this experience, I am sometimes asked to translate documents which either are too large or contain unfamiliar text which I am unable to manage alone.

The present article addresses some of the challenges that may arise to complete translation of a Global Value Dossier (GVD). A GVD is a document summarising all available information on a medical therapy which provides an index of the therapeutic and market value. The size of the GVD can easily reach over 100 pages (>50,000 words) and consist of six or more sections. Within my present scope of services, clients usually request translation from English into German. In this particular case, a GVD was received from a large pharmaceutical company. The therapeutic areas dealt with in GVDs can be quite diverse, and this case was an example of a chronic neurological disorder. A GVD typically describes the disease mechanism, epidemiology, management, clinical assessment of treatment, quality of life, and pharmacoeconomic aspects of the disease. Translation of a GVD by a freelance translator might easily take many weeks or even months, especially if other commitments have to be fulfilled in parallel. So, how can the freelancer respond if a potential client requires a translation of a large document to be completed within just four weeks?

The sections that follow outline how a team approach can be adopted to meet both the challenges of the translator and requirements of the client. This approach may be of interest to freelancers, in-house translators or indeed any other language service provider (LSP) asked to translate a large document. Some of the principles described may also be of relevance to medical writers.

Initial job assessment

The first question for any job is whether the translation can be managed alone? By simply reading through the text one is usually able to assess the nature and scope of a translation. However, for documents reaching the scale of a GVD, a sampling and scanning assessment of the document can be adopted. Two to three hours are required to make a rapid evaluation of the translation requirements of the job versus one's capacity to perform them before replying 'yes' or 'no' to the client. The following criteria are important to consider:

- Volume of text
- Structure and potential complexities of content
- Time available
- Formatting and editing requirements
- Having sufficient knowledge of the therapeutic area
- Mathematical and pharmacoeconomic concepts
- Access to client-specific wording and terminology
- Having the necessary technical equipment, e.g. computer-aided translation (CAT) system

Let us assume the text is challenging, there is insufficient time to complete the job as specified, and some sections present many questions and unknowns. To fulfil the requirements and be able to accept the job, collaboration is needed.

With increasing experience, most translators will develop a working network of trusted colleagues to cooperate on a common task. A team provides sufficient experience and capacity to deliver the job to the specifications of the client which would not be possible for any individual alone. Typically, a team may consist of two or more freelancers, but another important option is to include a translator who works in the client's in-house Translation Service Department. Regardless of one's employment status, it is imperative that the partner be dependable, adequately equipped, and is able to meet the challenges identified in the initial assessment.

Working approach

Working together requires agreement on a coordinated approach. Looking at the sections of a GVD, one partner's experience might be better suited to deal with the quality of life and pharmacoeconomic sections while another partner may be more experienced in translating the scientific and clinical sections. Breaking the job down into working

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> elements allows each team member to translate in parallel, thereby winning time. Complimentary skills also provide a total solution. Focusing on specific sections enables each partner to more clearly determine which additional source documents might be required from the client and which translation tools best serve the team's needs. The following steps have been very useful:

- Discuss the document as a whole, working complementarily to reach the final goal
- Take ownership of specific sections best served by each translator's background
- Analyse which additional information and tools are required
- Request client to provide additional source documents (e.g. lists of references and abbreviations)
- Exchange terminology lists and/or translation memory, if both partners are working with a CAT system
- Define, review and update a working list of terminology and definitions
- Set realistic timelines, allowing for translation, proof-reading and finalisation
- Specify uniform spelling, grammatical and other linguistic conventions.

The importance of some steps should not be underestimated for facilitating the overall working process—use of the translation memory, creating and harmonising a terminology list, and proofreading in accordance with the cross-check principle.

Quality management throughout the working process

The tools and activities described in the following sections are considered to be integral in assuring the overall quality management of the translation.

Translation memory

Before translating a large document such as a GVD, translation memory (TM) exchange should be initiated by importing a TM from the client. A TM is a database that stores text segments, such as sentences, headings and smaller units that have been previously translated. These text segments are stored as language pairs of source text and its corresponding translation. Moreover, using a TM ensures consistency with the terminology in accordance with the client's specifications and therapeutic area in question. The team used the CAT system SDL Trados, which recognises matching text and also offers a concordance search function for individual terms. SDL Trados is efficient in capturing the translator's attention to each text segment, and it increases consistency and productivity. On completion of the translation, the TM can be exported and sent to the client together with the translation of the GVD.

Terminology

A GVD contains a lot of specific terminology that may not yet be included in the TM database and that the individual translator may be unfamiliar with. To guarantee terminological consistency throughout the whole document, a working terminology list can be created. As new terminology has to be translated, it is added to the list and the corresponding target term is amended. If provided by the client, terminology and company-specific wording can also be integrated. For some source-language terms, there may be more than one equivalent in the target language. There is also a trend to retain English terminology even though perfect equivalents exist in the target language and the question arises whether one should follow this trend or use the German equivalent, e.g. 'disability score' in the translated text as *Disability Score* rather than *Behinderungsgrad*, 'quality of life' as *Quality of Life* rather than *Lebensqualität* and 'budget impact' as *Budget Impact*



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rather than *Einfluss auf das Budget*? Another common challenge is to determine which gender should be assigned to non-German terms or abbreviations. For example, does 'EDSS' (Extended Disability Status Scale) take the feminine or masculine gender in German: *der EDSS* or rather *die EDSS*? Once the team has agreed on the preferred solution, this is recorded ensuring that it is used consistently throughout the text.

The terminology list can be updated daily with additional terms and appropriate translations as agreed between partners by exchanging e-mails and discussing difficult terms over the telephone. This approach ensures that each translator is able to access and use the same terminology throughout the GVD. In its final format, a list may easily contain 500 or more terms, which can be provided to the client with the final translation.

Revision by another translator in accordance with the cross-check principle

According to EN 15038:2006, the European quality standard for translation service providers, the translation process comprises the translation proper, checking, revision, and review [1]. The translator is responsible for all of these steps except revision and review. Thus, the reviser is a person other than the translator, e.g., another bilingual language expert, who carries out what is sometimes referred to as a quality-control function [2]. This step in the translation process ensures that the target text truly reflects the source text using consistent terminology and that the translation is suitable for the intended purpose. The reviser examines the finished translation for completeness, accuracy, content and adequacy of style. In case the project specifications also include a review, a reviewer will carry out a monolingual examination, e.g., check the translation for register [1]. Ideally, partners working together are able to exchange their completed sections and examine each other's translations to maintain uniformity of the translation in consideration of the translation conventions agreed earlier in the project. If this is not possible, a third qualified translator may take over this role. This part of the translation process can take up to 30% of the total job time and should not be underestimated when planning the resource allocation.

Practical hints

Although the team approach described brings a number of advantages, there are some inherent pitfalls. Before actually starting to translate specific sections, it is important to clarify the contractual and payment conditions between



the members of the team. This should reflect the relative workloads. Choosing a suitable partner can also be a challenge, but previous experience working together or knowledge that the partner has worked on joint projects in the past are good pointers. Choosing a partner also assumes he or she is equipped to communicate effectively. Information resources on the Internet today provide access to a wealth of contacts and valuable tools. The translator should not be shy to exploit these possibilities. In addition to www.emwa.org, which provides a number of useful resources, www.iol.org.uk (Chartered Institute of Linguists, UK) offers a wide choice of language specialists, and www.bdue.de (Federal Association of Interpreters and Translators, Germany) has a useful search function for locating translators with specialist area experience who might be able to provide the required background knowledge.

Closing comments

Translating large documents using a team approach has proved to be very successful in overcoming the challenges and meeting the specifications of the client within tight time frames. However, this might not always be the preferred or possible approach open to individual translators. Whether you undertake translation of a GVD or other text genres, the experience presented here may provide useful guidance for other challenges you meet within your working profession.

Marion Alzer

Freelance Medical Translator (sworn and certified)
Erding, Germany
info@marion-alzer.de

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