



European
Medical Writers
Association

The *Write Stuff*

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Healthcare
communications

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Journal insights

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

Subscriptions

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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).

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Healthcare communications

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■ From the Editor's desk



Healthcare communications: A question of definition

by Mario Nacinovich and Elise Langdon-Neuner



Most EMWA members are employed directly or indirectly by the pharmaceutical industry and their main remit is to produce documents for the regulatory authorities or documents that inform the medical community about drug products, e.g. through papers published in biomedical journals. This issue of *TWS* introduces medical writers who work in industry to healthcare communications. When the words 'health' and 'communication' are associated in a definition, we are to my mind talking about a field that should cross paths with medical writers. But do medical writers work in healthcare communication? To answer this question we need to establish the precise definition of health communications and for this I enlisted Mario Nacinovich's help. Mario is the editor in chief of the *Journal of Communication in Healthcare*, Managing Director of AXON Communications, and adjunct faculty at Boston University and he explores the concept of health communications in the following paragraph.

Ongoing review and appraisal of health communications initiatives have confirmed the value of adopting specific communication strategies to promote health and ultimately facilitate the processes in the prevention and treatment of disease. Effective health communications strategies worldwide unite varied approaches, theories and frameworks from a range of disciplines, including but not limited to communication, public relations, behavioural sciences, social marketing, and health education. The definition and practical aspects of these disciplines can be considered empiric, while the definition of 'health communication' has not been universally accepted nor ingrained in its practitioners. According to the Office of Disease Prevention and Health Promotion in the United States, "Health communication is the study and use of communication strategies to inform and influence individual and community decisions that affect health. It links the fields of communication and health and is increasingly recognised as a necessary element of efforts to improve personal and public health" [1]. Health21, the 'health for all' policy framework by the World Health Organization (WHO) European Region, took this characterisation to another level in 1999 when it stated that it is a "public responsibility to ensure that citizens receive extensive, accurate and timely information on health and health care through various communication channels; information itself exerts a key influence on people's health and how they use health care services" [2]. These attempts to accurately capture and define health communication should be considered key milestones in thought-leadership as just a few years prior, in 1993, the U.S. Centers for Disease Control and Prevention (CDC) acknowledged that it

was "a term used by many, but it lacks a precise definition" [3]. In a somewhat dramatic shift in thinking, Maibach and Holtgrave later espoused that the term included the use of "communication techniques and technologies to (positively) influence individuals, populations, and organizations" [4]. More recently, Ishikawa and Kiuchi helped to simplify our understanding by stating, "Health communication consists of interpersonal or mass communication activities focused on improving the health of individuals and populations" [5]. For many in our emerging field, the following integrated definition has become the new gold-standard definition of health communication—it is a "multifaceted and multidisciplinary approach to reach different audiences and share health-related information with the goal of influencing, engaging, and supporting individuals, communities, health professionals, special groups, policy-makers and the public to champion, introduce, adopt, or sustain a behaviour, practice, or policy that will ultimately improve health outcomes" [6].

Three feature articles in this issue of *TWS* illustrate the gold-standard definition of healthcare communications and highlight its diversity. Catherine Mary's article probes the elements necessary to engender public trust in healthcare messages issued by governmental authorities, healthcare professionals and journalists, by reference to the H1N1 influenza pandemic. Daniele La Barber and colleagues look in their article at how healthcare professionals can communicate more effectively with their patients. The third article, written by Matthew Doherty of Medicines for Malaria Venture, explains the role of Product Development Partnerships in developing drugs that are not profitable for the pharmaceutical industry, and the importance and different aspects of communication for such non-profit organisations.

Healthcare information can be disseminated to the public in different ways, e.g. by interpersonal communication, health journalism, TV and electronic communication. Electronic communication is the mode of communication which Karin Eichele explores in her Webscout column in this issue. She reviews websites that offer information on e-health¹ ranging from a report on the value of e-health

1 The term e-health has been used since 2000 but there is no universally agreed definition of the term. The European Commission defines e-health as "the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers." For a discussion of other definitions see: <http://www.openclinical.org/e-Health.html>

From the Editor's desk

tools for patients and the benefit of recipient participation in the communication process to the use of social media in health communication. The public's appetite for health information is evidenced by the increasing popularity of newspapers and magazines columns written by medical/healthcare/science journalists. It is apt that this issue of TWS introduces a new column on medical journalism edited by Diana Raffelsbauer. In her first article she tackles the hot topic of predictive genetic testing. Only after she had written the article did the German government vote to allow embryos to be tested for severe genetic disorders.

In a quest to discover opportunities for medical writers in healthcare communications, I telephoned Meet Recruitment who had advertised a job for a senior medical writer in healthcare communications. Hannah Donaldson, a director of the agency, told me that their agency handled jobs in healthcare communications. I was on the right track. But the jobs she described were in pharmaceutical companies and centred on communications relating to a particular product. This is exactly the area of engagement of most EMWA members and is an illustration of the loose definition of 'healthcare communications' mentioned by Mario. Asked which sort of agencies she thought would offer jobs within the gold-standard definition I presented, she replied, "Healthcare PR." Matthew Doherty, an author in this issue, is an external relations officer whose job is to coordinate the proposal and reporting processes between Medicines for Malaria Venture. He does not portray himself as a medical writer, but he does write and edit texts that often contain a lot of medical content. The WHO would seem to be an obvious employer of medical writers in healthcare communications; however, they told me they did not employ medical writers as such, but rather public health specialists and technical officers, who mainly write reports. They do hire writers to review and sometimes revise reports written by the technical experts to make them less 'technical', depending on the target audience.

The only area in which the definitions of 'medical writer' and 'healthcare communications' cross paths would appear to be medical journalism—Catherine Mary and Diana Rafflesbauer, for instance, are medical journalists and members of EMWA. But this could change in future. Just as the mountain might come to Mohammed, so might health communications come to the traditional medical writer. Historically pharmaceutical companies have confined their communications to healthcare professionals and regulatory bodies. However, the public has a negative perception of the industry and with the increasing empowerment of the end user, the patient, much work is needed to reverse this perception.

Diageo, a manufacturer of alcoholic drinks, was faced with a similar problem, the public's negative perceptions of the alcohol industry. It undertook a proactive stakeholder and media programme on responsible drinking, thus positioning itself as part of the solution, rather than a contributor to the problem of alcohol abuse. The pharma industry

could perhaps redirect part of its US\$ 16 billion a year spending on marketing to physicians, which encourages over prescription of drugs, to programmes that encourage healthy life styles and discourage overmedicinalisation. If this tack were to be adopted, more medical writers would find themselves working in healthcare communications!

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Journal of Communication in Healthcare

(<http://www.maney.co.uk/index.php/journals/cih/>)



Journal of Communication in Healthcare is a peer-reviewed professional journal analysing pertinent topics and theories, pre-eminent practices, and emerging innovation in communication across the diverse multidisciplinary fields of healthcare. Articles within the journal actively examine and engage in both traditional and new media approaches, from interpersonal patient-provider dialogue and relationships, to mass communications with the public. The scope of the journal includes the latest topics in healthcare social media, mobile health, interpersonal behaviour and communications, health literacy, public relations and public advocacy, community or social mobilisation, professional medical communications and constituency relations and strategic partnerships.

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From the Editor's desk

An alternative editorial: The Swedish issue

On reflection, this issue of *TWS* could have been called the Swedish connection, with an article on how Swedish is being corrupted by English, two articles reflecting on Abba's grammar (and a bit more), a Swede's view of EMWA's Berlin conference in the Freelance section and a short piece about Alfred Nobel. Extending the Scandinavian flavour, Christina Johnsen—from Sweden's neighbour, Denmark—describes how she sprouted from a sedated state in academia into a go-getting medical writer. Julia Boese also gives an account of her route into medical writing, which will be interesting for anyone considering taking the MSc course in medical writing at Innsbruck University.

There's so much more in the issue too, including two new columns. The Medical journalism column, mentioned already, and Phil Leventhal's Manuscript writers' column catering for medical writers who prepare papers for biomedical journals. The Journal watch column will also be of special interest to these medical writers. Regulatory writers will be eager to read about the discussion relating

to European Medicines Agency's transparency and about active comparator trials. The Freelance section includes a debate on hourly rates and tips on writing stories compiled in the wake of a disastrous course on fiction writing. I have always wondered why so little fiction relates to the workplace but perhaps we don't need fiction when we can read about the cloak-and-dagger dramas among Pfizer's higher echelons (<http://features.blogs.fortune.cnn.com/2011/07/28/pfizer-jeff-kindler-shakeup/>). As for broadening your reading experience the Translation section's article on outsourcing tackles general issues in translation as well, and is a recommended read for translators who might not be interested in outsourcing, and likewise for those interested in outsourcing who might not be interested in translators. The article about how a Turkish journal was successful in going bilingual should not to be missed by anyone involved in bilingual journal translation.

Elise Langdon-Neuner

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Announcing the 34th EMWA Conference

14-18 May 2012
Coral Beach Hotel & Resort
Paphos, Cyprus

Cyprus

We are very pleased to announce that the venue for EMWA's 34th Conference will be in Pathos, Cyprus at the Coral Beach Hotel, which is located overlooking the sea and bordering Akamas National Park.

We will be offering an exciting selection of plenary lectures, a keynote speaker, seminars and discussion panels on the theme of **Paediatrics**. In addition, we will have an extensive educational programme with foundation and advanced level workshops to be applied towards the EMWA professional development certificates as well as many new workshops.



Come and take advantage of the opportunities to continue your training as a medical writer whilst networking with other writers from across Europe and the rest of the world.



Congratulations

by Rita Wellens

I am writing this while August is slowly but surely winding down and I hope that you enjoyed a relaxing summer. This *TWS* issue will surely nudge you back to the business-as-usual pace and is packed with the latest information on medical writing topics as well as announcements on upcoming events.

The summer months were exceptionally hectic for the Executive Committee (EC) due to the search for a new EMWA Head Office (HO). It started off with a face-to-face meeting in London with MCI, who were reluctant to continue as EMWA's HO. Constructive discussions centred around the best way for all concerned to schedule a seamless transition process to a new HO.

The space allotted here will not allow for a detailed overview of the procedures followed by your dedicated EC, but suffice to say that a request for proposal was put together and sent out to seven UK-based potential providers. Next came a face-to-face bid defence meeting with the shortlisted candidates. Available EC members who had also attended the MCI transition meeting in June (Gillian Pritchard, Sarah Choudhury, Sunethra Wimalasundera, Jo Whelan and I) gathered again in London on 25 July to evaluate the candidates on their strengths in both association and conference management. Susan Bhatti and Shanida Nataraja tuned in by phone. After in-depth discussions, including hot topics such as state-of-the-art integrated software solutions able to accommodate and grow with EMWA, the EC unanimously decided on Kingston Smith Association Management (KSAM). Their contact details are available on the inside cover of *TWS* and KSAM will take over officially on 19 September 2011. Definitely, there will be more to follow on KSAM later on EMWA's website, but for now, please join me in welcoming them aboard and thanking MCI for their collaboration during the transition period.

In parallel with this HO search, valuable lessons learned over the past years regarding burdensome workshop administration were successfully tackled. In other words, we killed two birds with one stone—sounds a bit ferocious—and took this transition as an opportunity to also implement key administrative changes. These will enable members to have more control over the registration process for workshops/conferences and will ensure that EMWA's HO has less administrative headaches with the workshop/conference programme. A huge thank you to Jo Whelan, our Education Officer, and the tireless members of the Educational Programme Development Committee to make it happen. These efforts are also part of EC's continued strive to make the latest integrated software solutions buzz for the benefit of all and...to keep cutting costs.

Time to highlight some other key achievements!

Still steering along the cost-saving course, the EC requested EMWA's HO to revisit the Cyprus conference venue. Regardless of an in-depth sweep of other enticing venues, it still topped the charts and hence remains the prime choice as to preferential room rates and conference costs. In short—a great deal for you to hone your medical writing skills at a fabulous location is awaiting you next year 14-18 May 2012 in Cyprus (see *TWS* page 142). While I am writing, Sunethra, Conference Director, is masterminding a global selection of speakers for EMWA's flagship conference in Cyprus.

While our key focus this summer was on planning HO transition activities and whipping into shape the London 2011 and Cyprus 2012 conferences, EMWA's membership experienced a steep rise during the past trimester by an unprecedented whopping 25%. A current total of 1,175 EMWA members will hence feast their eyes on this *TWS* issue. Thank you Elise, *TWS* Editor-in-chief, for highlighting this news! Congratulations are due to all of us for making EMWA shine as a prime reference for professional medical writers. Of course, festivities will mark this rounding of the cape of '1000' members and more on fun celebrations to be announced later this year...

EMWA keeps up their great efforts in helping academia forge advanced medical writing courses and I refer to Alistair's contribution in this issue on page 162, which highlights further progress made in EMWA's collaboration with the Medical University of Innsbruck.

Reminder of upcoming not-to-be-missed events

- If you happen to be in London this month 27-30 September, please visit EMWA's stand at the Pharma MedComms World meeting where Jo Whelan will be our representative. Other EMWA colleagues including Alison McIntosh, Andrea Palluch and Adam Jacobs are presenting on effective medical writing from clinical trial investigations.
- Last but not least, the programme for the 33rd EMWA Conference, which will be held in London on 3-4 November 2011, is available on the EMWA website and—in line with the autumn's meeting focus on training—we are delighted to offer a choice of 24 different workshops from the EMWA Professional Development Programme. Go register now!

I wish you all the best and I hope to welcome you in November in London.

Rita Wellens
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Healthcare communications: Figuring out the outside view

by Catherine Mary

In our societies, communication is king. It is sometimes reduced to 'key messages' that are more designed to hide a problem or to sell an idea or product than to leave the audience concerned fully aware of a given situation. This is not the kind of communication I care about.

Originally a scientist and latterly a science journalist and writer, I have wondered for years what good communication should consist of, particularly with regard to complex situations in health or environmental issues.

A health communication campaign is successful when it leaves the people concerned able to take the right decision or to endorse the right behaviour regarding their health. Its purpose is therefore to warn people about a given situation—as complex as this situation is—so that they are in turn able to deal with it. In addition to ensuring the clarity and consistency of the messages, this necessarily also requires a subtle understanding of the outside view—the view of the people concerned—as disturbing as it might be.

It is easy to figure that communication campaigns aimed, for example, at the prevention of HIV infection should carefully take into account the behaviour, beliefs and sensibilities of the populations concerned, regardless of whether they are drug users, prostitutes or homosexuals. However, taking into consideration mindsets that are different from our own may be destabilizing, particularly when those mindsets disturb us and make us uncomfortable.

In this respect, much can be learnt from the H1N1 influenza pandemic. The communication challenge here lay in the fact that the virulence of the pH1N1 virus was unknown at the time it emerged and that its evolution was uncertain. Governments had to strike the balance between the need to call up means to tackle the virus should it evolve into a virulent form and the risk of wasting public money should it turn out that the virus was less virulent than initially feared.

Everyone remembers the hiatus this situation provided and the speed with which conspiracy theories spread when the data coming out from the southern hemisphere started to show that the pandemic was moderate. At that time, scientific arguments were poorly efficient at convincing people to get vaccinated, and in France ultimately only 8% of the population was vaccinated. Some countries like Sweden performed better, but globally the communication campaigns on vaccination against H1N1 came up against several hurdles in the general public and the message concerning the rationale for pH1N1 influenza vaccination did not get across properly.

Misleading information spread in the mass media certainly played a role in the loss of confidence of the general public in those who handled the pandemic. However, the fact that fake allegations covered public health messages is to my opinion, more a consequence than a result of this loss of confidence.

In his recent book entitled *The feeling of risk* [1], Paul Slovic (Department of Psychology, University of Oregon, USA) stressed the importance of the trust in risk communication. "Trust is essential and also fragile" he wrote, referring to various situations of risk communication, including the H1N1 pandemic and nuclear power. He notably emphasised the importance of the affects in the perception of risk that may cloud the understanding of reasoned arguments. So, why was trust weakened that much during the H1N1 pandemic, and why did affects take over?

This is a question that I have puzzled about. There is no obvious answer to it, but it is most likely attributable to the interplay of several factors which vary between countries. In an article in the *New Yorker* entitled *The fear factor* [2], the journalist Michael Specter made an interesting analysis of how the collective unconscious could constitute a fertile ground for anti-vaccines electronic rumours to spread, and therefore makes trust a very touchy issue. He referred to the mass influenza vaccination programme initiated in 1976 by the US government after army recruits at Fort Dix, New Jersey, became infected by a new influenza virus resembling the virus that caused the Spanish flu epidemic of 1918. The virus never took hold, but more than 40 million Americans were vaccinated and a few of them suffered from Guillain-Barré syndrome, a rare adverse event of influenza vaccination. "*The episode helped establish a widespread fear of vaccines that—fuelled by groundless but impassioned claims about a link between autism and the measles vaccine—persists to this day. More than that, it created a false sense, shared by millions, that vaccines were at least as threatening as the diseases they prevent,*" Specter writes. Because at the beginning of the epidemic of pH1N1, the US Centers for Disease Control and Prevention referred to a "swine flu virus" in the *Morbidity and Mortality Weekly Report (MMWR)*, he assumes that Americans associated the term "swine flu" with the public health debacles of 1976.

In France, in addition to anti-vaccines rumours, the lack of involvement of general practitioners during the H1N1 vaccination campaign significantly contributed to weakening

Healthcare communications: Figuring out the outside view

the trust of the general public in health authorities. General practitioners usually have long-term relationships with their patients and play a crucial role in providing them with information related to health topics. They therefore could have acted as firewalls against anti-vaccine rumours. However, the French government neglected this role and a mass vaccination campaign was organised without calling on them. As a result, people did not understand the rationale for H1N1 vaccination and massively rejected it. The legitimacy of the one who conveys the message is thus crucial in communication. It is also noteworthy that health professionals may take advantage of this legitimacy to spread spurious messages. This is what happened in the UK in 1998, when the gastroenterologist Andrew Wakefield raised suspicions regarding the safety of the MMR (mumps, measles, rubella) vaccine, asserting that his data showed the vaccine was responsible for autism. This was the start of one of the biggest anti-vaccine campaigns, leading to a large drop in measles vaccination coverage in the UK and elsewhere, followed by a resurgence of the disease.

Another important factor of distrust in the French context was the inconsistency of the messages spread in the mass media by various opinion leaders of the medical world. While French flu experts emphasised the need to vaccinate the entire population—even after data from the southern hemisphere on the impact of the epidemic in different groups of the population started to be available, other medical experts went against the WHO position, one of them saying, for example, that pH1N1 flu was just a bout of seasonal flu. This inconsistency further fuelled public confusion, while at the same time, suspicions began to be raised by the press as to the role of the pharmaceutical industry regarding pandemic preparedness and response.

More generally, the community of professionals involved in influenza pandemic preparedness and response—whether they are public health professionals, flu scientists or flu medical experts—has not dealt very well with the view of the general public [3]. As the pandemic involved the general public, working methods and concepts familiar to those professionals were all of a sudden viewed from a different angle. The seemingly obvious uncertainty inherent in a flu virus became subject to misunderstanding, the usefulness of vaccination was questioned, and the terms of collaboration between industrialists and specialists became suspect.

Many of those professionals reacted to critics by castigating the general public for not understanding anything at all, instead of being open to the outside view by striking a balance between unfounded and legitimate suspicions. “By failing to acknowledge legitimate reasons for some criticism, WHO may have inadvertently contributed to confusion and suspicion,” pointed out the review of the WHO (World Health Organization) handling of the H1N1 pandemic discussed at the 64th World Health Assembly in Geneva (16–24 May 2011), which otherwise concluded that WHO did very well on other aspects. It also underscored

the lack of clear and accessible information regarding the severity of the pandemic and the lack of transparency regarding the conflicts of interest of experts advising WHO.

Events surrounding the H1N1 pandemic shed light on the pitfalls of communication strategies relying too much on key messages, as key messages do not convey the complexity of a situation such as the uncertainty of the evolution of a new influenza virus. Likewise, each time human relationships are at stake, the crux is to keep the trust of the people affected. This necessarily involves a dialogue based on a respectful approach of the outside view. In communication too, ethics matter.

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Photo: Marlies Neuner

High and dry

A photograph, this one recently taken on the Isle of Eigg, Scotland, can explain a thousand words or even just three: ‘High and dry’ means stranded, without help or hope of recovery. According to The Phrase Finder (<http://www.phrases.org.uk/meanings/high-and-dry.html>) this term “originally referred to ships that were beached. The ‘dry’ implies that, not only were they out of the water, but had been for some time and could be expected to remain so. It was used in a ‘Ship News’ column in The [London] Times, August 1796.”

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Communication and collaboration— Influencing behaviour through effective partnership and information sharing

by Matthew Doherty

Partnering to develop products

At the end of the 1990s, the pipeline for malaria drugs was almost non-existent as the pharmaceutical industry did not view the malaria market as a viable investment in view of costs and risks of development versus a relatively small market opportunity. The antimalarials in use were growing more ineffective and were no longer saving lives due to growing parasite resistance. In these markets, where the profit model was inverted, malaria was not an attractive proposition to the developers of new drugs. It is a disease of poorer populations who, although they offer a huge demand for a high volume of newly-developed products, do not have the purchasing power to ensure pharmaceutical companies a return on their enormous initial investment in research and development (R&D).

Product Development Partnerships (PDPs)¹ were created to address this kind of inequality by focusing on developing new products to respond to health problems prevalent in low and middle income settings. These not-for-profit organisations were formed because commercial incentives had proven insufficient to draw for-profit companies into certain important areas.² Medicines for Malaria Venture (MMV) was part of this movement and was created to address the market failure that existed in drug development for the disease. Now in its twelfth year of operations, MMV has matured over time and carved out an identity of its own, having justified its existence and proven the value of its business model. As is often the case, maturity has resulted in greater responsibility and the organisation's partnership network has grown substantially. These partners are numbered in the hundreds and include universities and research institutions, pharmaceutical and biotech companies, service providers and professional advisors, governments and corporate donors, international and non-governmental organisations (NGOs). Vast information and communication networks exist within and around these collaborations that have a direct impact on MMV's mission. Ideas and information are created and exchanged through contact and partnership, membership and collaboration, debate and discussion—and range in scale from interpersonal or interdepartmental to global forums and international conferences.

¹ 15 PDPs currently exist

² such as drug development for, malaria, tuberculosis (TB), sleeping sickness and visceral leishmaniasis, vaccine development for HIV, TB, malaria, dengue fever, meningococcal meningitis and pneumonia, microbicide development for HIV, and insecticide development for vector-borne diseases

Communicating to influence

MMV's position within the global health architecture means that, although its mission is unique, it shares goals and objectives with a number of other entities, both within and beyond its therapeutic area. As no one country, company or NGO can address global health challenges like malaria, the donor, stakeholder and communications networks overlap with many other organisations and, depending on the specific health priorities we want to advocate, frequently requires a cohesive and coordinated approach with others, often with the aim of creating influence. While MMV's principle mission is the discovery, development and delivery of safe, affordable and effective antimalarials, there are many indirect, subtle and nascent responsibilities that support its main goal. Influencing and, if necessary, changing the behaviour of others is a task that is intricately linked to its collaborative business model and its ability to communicate effectively. Nothing is more important in a cooperative system than communication among participants. When people are able to communicate, they are more collaborative and more trusting, and they can reach solutions more readily. No single factor has as large an effect on levels of cooperation as the ability to communicate [1]. Additionally, the people and organisations that communicate have an influential effect on one another and on entities external to the collaboration.

Organisations involved in global health, as in many other sectors, are working more collaboratively than ever before and global virtual teams are the norm, not the exception. MMV's model is based around collaboration and, as a 'virtual' pharmaceutical company, a primary focus is on product development. This is carried out in conjunction with a vast array of other entities. These relationships are formed and maintained through effective communication, teams and committees being formed and disbanded to ensure that this is optimal and transparent. MMV must be able to produce intangible goods and maintain an emphasis on quality for this kind of knowledge-based product as it does for tangible products, i.e. medicines. This communicative aspect supports the organisation in maintaining its image to the outside world and underpins functions such as fundraising or access to essential medicines in endemic countries. Before anything is communicated externally, a collaborative internal process often takes place to ensure the information is generated and executed correctly. This is both reactive and proactive and involves a number of methods, tools and strategies—the eventual message being dependent on the target audience and the desired outcome.

Communication and collaboration...

Advocating the mission

When the target audience is current and potential donors, the overarching desired outcome is to obtain, maintain and increase funding. MMV's funding comes from government and intergovernmental agencies, private and corporate foundations and individuals. Funding cycles and amounts vary and can depend on a number of factors, including policy and budgetary considerations. The formal process of applying for grants cannot be viewed as a rigid, linear checklist and decisions to fund are never solely based on a set of quantifiable numbers. Conversations exist at various levels of time and space and several years are often invested in relationship-building before significant funds can be raised. Securing and maintaining the interest and commitment of current and potential donors is an on-going, dynamic, increasingly strategised process. Depending on the priorities of specific grantors - drug development, maternal and child health, neglected or tropical diseases, malaria, poverty, the PDP model, global development - MMV may or may not fit with their agenda, something which can change over time. This shift can stem from a number of factors including a change in government, a new business plan, a change in economic climate or a mandated review or report. In order to influence policymakers and behavioural changes amongst grantors, MMV takes part in reviews and committees and holds membership with advocacy and donor groups. Ensuring that we are constantly plugged into the activities of bodies like the Global Health Technologies Coalition (GHTC) the PDP Funders Group or the Roll Back Malaria (RBM) partnership allows us to step into the larger advocacy fray when necessary and relevant, while maintaining our underlying narrative of malaria as a global health priority, the value of the PDP model, the need to invest in R&D, the importance of drugs in the eradication agenda, MMV's stringent financial and portfolio management, and so forth.

As donors become more strategic in their allocation of funds and calls for PDPs to be collectively assessed increase, collaboration and competition often overlap and external relations must be adjusted accordingly. While it is vital to recognise the power of partnerships and that certain objectives can only be achieved through collaboration with diverse organisations, MMV has a responsibility to influence policies and agendas, advocate its own mission and objectives using a number of methods and platforms, and show evidence to stakeholders why financing malaria drug development is a savvy investment. Additionally, while progress in tackling the disease can provide a pretext for current donors to turn their attention away, it is important to show why staying the course is necessary. MMV must be clear and transparent in documenting and communicating its use of funds, associated portfolio and access progress, the ultimate effectiveness of its products through well-researched case studies, contributions to the Millennium Development Goals (MDGs) and lessons learned which might benefit the field more broadly. The goal is to anticipate and meet donors' need for evidence of return on investment.

Communicating with 'the Market'

Most of the PDPs that have launched products have followed the standard pharmaceutical industry practice by picking 'low hanging fruit'. Rather than developing entirely new products, they have tweaked existing ones. Even for such low-cost and effective products, however, uptake remains uncertain. As more products come through the pipelines, there are warnings of insufficient funding both for late-stage clinical trials and barriers including weak health-care systems that make it difficult to administer the product [2]. The global health community is largely aware that, in order for medical innovations to benefit the people who need them, the limited resources on the ground must be recognised. The access and delivery (A&D) of medicines to disease-endemic areas is part of MMV's mandate. With the overall goal of health impact through the uptake of malaria drugs, this incredibly challenging work is structured around three 'pillars': acceptance, expansion and evaluation. The average consumer does not consider it important to know where a drug has come from and how it was developed, so MMV's messages of reliability, quality and efficiency do not resonate at this level and health communications are directed towards professionals and governments.

Although PDPs have been focused primarily on product development, they share a vision of realising the public health impact promised by new products. Introduction and uptake of MMV's products remains the first order of A&D business, playing a unique role in advancing the cause of evidence-based decision-making by health authorities and policy makers. National policy decisions regarding first and second-line treatments are becoming significantly more complex and PDPs are often the organisations most familiar with evidence to support decision making. When a new health product becomes available, countries have a choice to adopt the product into their national health systems or to pursue an alternate strategy to address the public health problem. To arrive at sound policy decisions, countries must engage in science- and evidence-based dialogue with expert resources, such as MMV, who act as objective partners in advising on national treatment policy, however the reach into endemic countries can be limited. Generating data, and bringing the data to the attention of country stakeholders, is an important part of catalysing decision-making [3]. MMV is one contributor to this activity as part of a complex decision-making environment and each of the many stakeholders will bring some perspective, history, and perceived conflict. It is critical to note that PDPs do not have direct profit motives when supporting decision-making. The underlying rationale is to help address a public health problem, for which the intervention can be evaluated for its role as one locally appropriate solution. It is more credible for the PDP to engage local stakeholders on technical grounds, and to provide them with the technical arguments they need so that they (rather than the PDP) can take part in the later, more political parts of the decision-making process. [4] MMV faces such challenges, for example with the availability of Artemisinin Combination Therapies (ACTs). Although the World Health Organisation specifically recommends ACTs as first-line treatment for *Plasmodium falciparum* malaria, the most deadly form >

Communication and collaboration...

- > of the disease, only one in five antimalarial treatments is an ACT, not enough are produced and although many public health services provide them free, the over-the-counter price of a course tends to be a costly \$10. Moreover, most Africans rely not on public health services—which are often poorly resourced and hard to reach—but on the private sector. Within endemic country public sector health systems, where traditional marketing and communication theories cannot necessarily be applied, where life expectancy can be as low as 40 years and health systems are often broken, the impact of products can only be realised after navigating through a myriad of cultural, social, economic and political considerations.

In a few individual countries, there may be more extensive involvement in tracking adoption activities and generating local evidence. This local involvement begins with geographical prioritisation based on disease burden, relationships established during clinical trials, in-country resources, and other factors. Strategies adopted by PDPs to establish a presence in endemic countries vary from the opening of country offices to engagement of part-time consultants or with long-term or ad hoc committees. Once a PDP commits to support country decision making, the approaches vary, but include country consultations, regional meetings, formation of regional, product-specific committees, support of in-country advocates, development of decision-making frameworks, provision of technical assistance to aid therapeutic or diagnostic guideline revision, and conduct of stakeholder and Phase IV studies. To reach large numbers of countries, the formation of partnerships is essential. At this early stage, impact data are limited but PDPs can and do play an important catalytic role in their support of country decision making in a number of target countries [4]. MMV and its drug development partners have also made extensive use of country-level dialogues such as sub-regional meetings (of WHO AFRO and RBM³) and, in select cases, day-long workshops. These provide opportunities to give product-specific briefings and to reinforce recommendations of normative entities (primarily WHO) in terms of best practice for the development and revision of treatment guidelines and for the correct use of new, quality medications in combination with proper diagnosis [4].

Collaborating in the developing world

Activities of MMV within malaria endemic countries include board membership, scientific advisory participation, partnerships for clinical trials, partnerships to launch access projects, and manufacturing issues. MMV is part of several innovative health communication collaborations in the developing world. For example, MMV is scaling up a project in Tanzania—SMS for Life—that allows rural health workers to report the availability of ACTs using their own mobile phones in exchange for a small SMS credit that goes directly to the individual's phone. The principle of the project is very simple: the health facility worker keys in the availability of drugs into a normal sms,

which is then sent to a central database. Reports are then generated, which can be used by the district health managers, the regional health teams and national programme managers for supply management and addressing supply bottlenecks. Other examples of the uses of the data include predicting future stock outs and actively managing order placement, refining national demand forecasts, predicting seasonal or other changes in supply or need. The system can also be expanded to capture information about the total number of cases of malaria, thus mapping supply and demand information, as well as providing a unique tool to report directly on many donor-required malaria indicators. Long-term use of such data would significantly strengthen supply chains beyond the malaria programme.

In early 2011 MMV signed an agreement with the African Leaders Malaria Alliance (ALMA) agreeing to work together to promote the removal of monotherapies, advocate for national scale-up and correct use of ACTs and Rapid Diagnostic Tests (RDTs), and support the dissemination of best practices relating to ACT and RDT use. These issues are completely aligned with MMV's own access work. The creation of ALMA in 2009 is an example of the growing political will and shows that heads of state and governments of endemic countries are taking ownership of activities that require collective action and communication. It also provides a forum for African leaders to keep malaria high on the development agenda. As MMV is constantly striving to engage stakeholders and build relationships with decision makers, being a part of such knowledge-sharing forums creates an advocacy platform in line with MMV's mission. It is also a prime example of how the organisation advocates for behavior change through effective partnering and communication.

Conclusion

As PDPs and their pipelines mature, so will the messaging and advocacy supporting their work. MMV works within systems that are not just built around incentives and rewards but also engagement, communication and a sense of common purpose and identity. While the majority of resources and collaborations are focused on the development of drugs, the communication networks based around the acquisition of funds and the delivery of medicines play a vital role in our mission to help control and eventually eradicate malaria. Within this partnership network, influencing the behaviour of others means ensuring the right information reaches the appropriate audience at the desired time while guaranteeing transparency, consistency and understanding.

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List of medical writing articles written by EMWA members in other journals

The following is a list of articles relevant to medical writing published by EMWA members in journals other than *The Write Stuff*. It is an update of a list published in *The Write Stuff* in September 2010 (*TWS* 2010;19(3):213. Names of EMWA members are printed in bold. The list is also available on the EMWA website (www.emwa.org). Members are requested to send citations to their articles for publication in future issues of *TWS*. These citations will also be added to the list retained on the EMWA website.

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Clinician–patient relationship and adherence to treatment

by Daniele La Barbera, Caterina La Cascia, Alice Mulè, Salvatore Raspanti, Andrea Rossi

From compliance to adherence

Medication nonadherence, defined as a patient's passive failure to follow a prescribed drug regimen, is a pervasive medical problem and a significant concern for healthcare professionals and patients [1] because it may have serious detrimental effects on the patient's health and quality of life, and may lead to further morbidity or mortality. If a patient does not regularly take the medication prescribed, no potential therapeutic gain can be achieved. Several variables contribute to nonadherence and thus negatively affect treatment outcomes, especially in chronic diseases such as diabetes, hypertension and schizophrenia. These barriers to medication adherence are multifactorial and include complex medication regimens, convenience factors (e.g. dosing frequency), behavioural factors, and the clinician–patient relationship [2].

According to Gould [3], the concept of compliance is itself a barrier because it implies the patient's dependence on the physician and does not help the patient to progress towards better clinical goals.

There is a conceptual difference between compliance and adherence. Compliance is the result of a medical model of health care associated with a one-way relationship with a clinician who prescribes the medical regimen with which the patient is expected to comply [4]. Adherence, however, is defined as the extent to which health behaviour reflects a health plan constructed with and agreed to by the patient who shares health decision making with the clinician [5]. Deciding between the terms adherence and compliance is not just a semantic choice; the terms convey different points of view.

An adherence model implies that the physician develops a collaborative patient-centred relationship with the patient, such that the clinician and the patient together choose their goals, activities, and medication regimen. Patients can discuss and negotiate their treatment with their clinician without any concern that they are being judged. A compliance model, however, implies a clinician-centred relationship such that goals, rules, activities, and medication regimes are established by the doctor.

Medication management is one of the main issues in healthcare plans for adults with chronic diseases; the difference between compliance and adherence has therapeutic implications for drug management. When clinicians focus on compliance, they have medication assumption as their first priority, their main objective being to persuade

the patient to follow the prescribed regimen. When clinicians focus on adherence, they must promote and maintain a relationship with the patient based on mutual trust that assists the patient's collaboration and motivation to conform to a plan agreed by both parties. Medication management becomes an important part of the global healthcare plan but is not its only aim [3].

Noncompliance may be seen by the physician as resistance in a 'me-versus-you' scenario. The physician must try to persuade the patient of the medication's safety and efficacy. On the other hand, nonadherence could be seen as a chance to bring new information and communication into the clinician–patient relationship; for example, doctors might ask themselves why some patients adhere to the drug prescription and others do not.

Many factors affect patients' adherence. Bergman-Evans [6] distinguishes between *purposeful* and *unintentional* nonadherence. *Purposeful* nonadherence is related to personal traits, characteristics and values, religious and cultural belief systems, and to patients' choices about the drug prescription (dose, timing, therapeutic and side effects) or the nature of the illness itself. Many other barriers may affect patients' adherence: cognitive, physical, psychological, and economic barriers [3]. Dementia, cognitive impairment, and executive functioning deterioration represent the main cognitive barriers. Specific physical deficits such as being blind or deaf can create difficulties in doing simple tasks such as opening medication containers, reading labels, or understanding the clinician's directions. Furthermore, some patients are compelled to stop treatment because medications are too expensive. Psychological factors may also influence patients' adherence. In specific psychiatric syndromes, as in other chronic diseases, tendencies to deny the chronic nature of the disorder can affect the quality of adherence; the more serious the illness, the higher the risk of patient withdrawal.

The quality of the clinician–patient relationship and patient satisfaction can influence adherence to treatment; both are related to the personal characteristics of both the clinician and the patient, to the severity or the type of illness, and to the clinician's medical and human skills.

The clinician-patient relationship and the role of empathy

Despite the dehumanisation of medical care, there is growing agreement among physicians that the quality of the relationship with the patient is critical in high-quality health care and can influence outcomes. Absence of empathy and compassion in the relationship with the patient

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is acknowledged as a predisposing factor to malpractice [7]. Furthermore, there is a general consensus that there are associations between the clinician’s caring attitude, the appropriateness and effectiveness of treatment, and the patient’s satisfaction [8].

Thus, although the doctor’s knowledge and competences are essential, they alone may not achieve high quality clinical goals and the patient’s wellbeing. The paradox is that while clinicians express their caring by carefully doing what they have learnt—diagnosis, assessment, treatment—patients feel this as uncaring because they need to be heard and emotionally understood [9]. At the end of a visit, even if the physician’s medical input was perfect, if they did not communicate effectively with the patient, the patient is unlikely to fully appreciate their professionalism and, thus, is unlikely to be fully motivated for the next meeting. It seems clear that physicians need to improve their human abilities and communication and relational skills. Is empathy a natural trait or can it be developed? How can a clinician become more empathetic? This is not straightforward.

Empathy can be viewed as an ability to recognise emotions that are present but are not clearly expressed; it allows exploration and awareness of unexpressed feelings so that the patient feels understood [10]; a classical model suggests that this is a complex construct composed of four elements: the first two are emotional and moral components related to the clinician’s intrinsic ability and motivation to pay attention to the emotional experience of others [11]. These are the basic and essential components of empathetic communication. The other two elements, which are cognitive and behavioural components, are even more important in the clinician–patient relationship. The cognitive factor implies an accurate understanding of the patient’s feelings and emotional condition, the behavioural one takes the form of effective communication with the patient about their feelings so that they feel understood and not alone. Feeling understood is intrinsically therapeutic; it bridges the isolation of illness [11], increases the likelihood of deeper relationships and increases adherence to treatment [10]. Empathetic behaviour helps the patient to accept drug prescription; it can extend the therapeutic effects and reduce the side effects of pharmacological therapy; finally, it is absolutely necessary for psychotherapy or rehabilitation programs.

Clinician–patient relationship and the role of communication

The model of relationship-centred care reflects the idea that good treatment aims can be pursued only if doctors do their best to engage in a collaborative relationship with the patient; the relationship with the patient should be the first therapeutic aim. According to Beach’s definition, relationship-centred care is founded on several core principles: 1) relationships in health care ought to include the authenticity of the clinicians; 2) affect and emotion are important components of the relationship; 3) all healthcare relationships occur in the context of reciprocal influence; 4) as in any other relationship, cognitive and emotional processes are present in the relationship with the patient [12].

Emotions, mood and feelings are revealed through non-verbal behaviour, which influences the therapeutic relationship and important outcomes, including satisfaction, adherence and clinical goals [13]. A high quality clinician–patient relationship depends on the emotional context especially nonverbal communication and emotion-related communication skills. Nonverbal communication includes behaviours that are independent of the linguistic content, and includes paralinguistic characteristics (such as speech rate, pauses, loudness, interruptions) and physical behaviours (such as facial expressivity, eye contact, postural position, smiling) [14]. Emotions, feelings and mood are more readily expressed through nonverbal behaviour than by words particularly within the clinician–patient relationship where the patient may be worried that they are being judged by the doctor.

According to Watzlawick [15] “One cannot not communicate” meaning that we communicate even if we do not intend to. Furthermore, we can control our linguistic communication, but we can’t be sure that our bodies are not conveying our thoughts and emotions. In the physician–patient relationship, both the clinician and the patient show their emotions and, consciously or unconsciously, judge each other’s emotions. Doctors may use a patient’s affective cues in the diagnosis or evaluation of their clinical course [16]; on the other hand, the expression of the clinician’s emotions can help the patient in their decision to see their doctor again, and to build a collaborative relationship and a truthful communication rather than to stop the therapeutic relationship.

Clinicians’ skills at communicating their emotions and feelings to patients and at understanding patients’ verbal and nonverbal communication are crucial to positive relationships. Physicians who understand and are aware of their own feelings, and can read and correctly interpret other people’s nonverbal cues, have more satisfied patients who are more likely to attend their next appointment than are those of doctors less skilled in these areas [17]. Some specific nonverbal behaviours of clinicians may affect their relationships and the satisfaction of their patients. Less time spent in reading medical notes, more nodding, more gestures, closer interpersonal distances, more gazing—more smiling, more eye contact, and an expressive tone of voice and face [18,19] may all improve the patient’s trust in the physician and their motivation to adhere to treatment.

Communication can be considered a therapeutic action, and when doctors are aware of this, patients’ satisfaction and adherence to treatment can be improved, regardless of the severity or type of illness. Other elements including age, gender, education, economic and socio-cultural status moderating clinician–patient communication, should always be considered. According to several studies, female patients prefer a more ‘feeling-oriented’ clinician than do males [20]. Clinicians must consider these factors in choosing the most appropriate approach to the patient.

Strategies to improve patients’ adherence

A patient’s adherence to treatment is related to their personal characteristics, their disease, and to the clinician’s >

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- > communication skills and ability to understand the patient's requests [21]. Ley [22] adds a cognitive component to patient adherence: simple and clear communication improves patients' satisfaction by helping them to understand and remember medical information.

With this aim, Ley suggests four strategies:

1. providing simple written instructions;
2. explicit categorization of the material presented;
3. repetition of important material;
4. use of concrete-specific rather than general advice statements.

Bergman-Evans [6] outlines four outcomes for high-quality treatment:

1. reducing inappropriate prescribing;
2. decreasing polypharmacy;
3. avoiding adverse events;
4. maintaining functional status.

To achieve these outcomes, five elements are needed: assessment, individuation, documentation, education and supervision (AIDES Model). Assessment, individuation and documentation are useful to ascertain the patient's disorder, capabilities, and willingness to be treated, and thus to understand the patient and try to develop a collaborative relationship. Education and supervision also help to improve adherence to treatment. Every step of this model requires the continuous participation of the clinician. Besides these conscious elements of clinical practice, clinicians should re-examine their personal aims, qualities, attitudes and their amenability to change; the latter is not easy to improve, but may be more important than any other aspect of the relationship with the patient.

In addition to learning about diagnosis, pharmacology and medical illnesses; physicians should also improve their personal attitude and communication skills. Physicians may use words like *uncooperative* or *untrustworthy* when discussing patients but nowadays, patients may take similar views of their clinicians, which could affect their adherence to treatment and their general satisfaction. Furthermore, in the internet era, patients are more aware of the nature of their illness and treatments, because of the wide diffusion of medical information on the web; many websites are developed by patients for patients, so patients may be much more knowledgeable and empowered in their relationships with clinicians. Furthermore, social networks such as facebook and twitter provide a means of direct communication for patients and physicians.

Conclusion

Patient adherence to treatment is a complex construct related to the doctor's communication abilities and personal skills in building effective relationships. Besides the technical skills, irreplaceable in helping the patient, relational skills are fundamental to high-quality medical care.

The patient's satisfaction is influenced by the clinician's verbal and nonverbal behaviours. The best pharmacological prescription is not enough for the patient and does not lead to acceptance of their disorder. The patient needs to

feel understood, listened to and to be the focus of the treatment and care. It is not easy for a clinician to obtain a patient's trust, willingness and satisfaction. Formulating the correct diagnosis and choosing the best pharmacological treatment is just the beginning of a complex therapeutic relationship that should be characterised by a deep understanding of the patient's needs and by the progressive development of a trusting relationship.

On the other hand, the patient has an increasingly active role in motivating the physician and building a relationship of trust.

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Journal impact factor facts

by Trevor Lane

The journal impact factor (JIF) made its debut about 50 years ago in the *Science Citation Index*, now part of Thomson Reuters' *Web of Science* database. The JIF has become an internationally adopted indicator of the importance, influence, prestige, and quality of academic journals, as well as, controversially, of institutions and researchers [1-3]. This is thus an opportune time to get re-acquainted with the JIF.

The basics

Intended to measure the citation frequency of the 'average' article, the current year's JIF is the ratio of the number of citations received by items published in the previous 2 calendar years to the number of 'source items' in those 2 years [1]. The division of citation counts (the numerator) by counts of 'source items' (the denominator) supposedly accounts for variables such as journal size and frequency [1]. The exclusion of the current year's data supposedly minimises effects of immediately cited items such as letters, editorials, commentaries, and news [2]. The 2-year window was originally chosen to track the dynamic fields of molecular biology and biochemistry [3]. Although a 5-year JIF now exists and the related *Journal Performance Indicators* database allows JIF refinement [2,3], quoted JIFs in annual *Journal Citation Reports* are the crude 2-year scores.

Frequently asked questions

To try to understand more about the JIF, I repeatedly emailed queries to Thomson Reuters between 22 July and 20 August 2011. The dialogue with one technician, previously partially reported to the World Association of Medical Editors [4], is summarised below (note: 'other journals' includes a self-citing journal):

(1) What is counted in the JIF numerator?

"Citations received by all the published content of a journal would be considered for calculating the JIF."

(2) Are journal citations that are contained in reference lists of textbooks, monographs, and government reports included in the numerator, or only citations made by other journals?

"The articles which are indexed in *Web of Science* would only be considered....Please note that textbooks, monographs, and government reports are not considered."

(3) Do conference proceedings contribute to the numerator?

"Journal supplements are treated as important elements of a journal's contribution to the literature....If conference

papers are part of a journal, then the citations they attain are considered in calculating the impact factor. Conference proceedings do not have a separate impact factor....If a conference paper cites another paper in the journal, the citations would be counted for calculating the JIF as well."

(4) What citations are counted: those in reference lists of articles, news stories, editorials, letters, and conference papers, and also those in, say, correction notices?...Can citation refer to any item, including conference abstracts in journal supplements?

"When calculating the impact factor, we consider all the citations that a journal has received.... The numerator of the impact factor considers citations at the level of the whole journal. All citations that clearly identify the journal title and cited year will be included in the *Journal Citation Reports* metrics. This is not dependent on what material was cited."

(5) What is counted in the JIF denominator?

"Please note that the citable items considered for *Journal Citation Reports* calculation comprise [research] articles, reviews, and proceedings papers and not other document types....Supplements and Special Issues that contain scholarly material in the form of articles, reviews, or proceedings papers will be counted as part of the citable items in the denominator of the impact factor. Abstracts-only supplements will usually be indexed as a single item for the purpose of announcing to *Web of Science* subscribers that these materials are available. This one-item announcement is considered an article, and so is included in the denominator of the impact factor calculations."

(6) Does the denominator take into account the fact that some letters are short research articles and some case reports, editorials, commentaries, and educational pieces are also reviews?

"The denominator is composed of...primarily research articles and reviews, but also scholarly commentary, essays, and discussion that add to the literature of the subject."

(7) Some journals may have an online full version of an article and an abridged print version: does that count as one or two articles in the denominator?

"An article is indexed only once in the database (either online or the print) and therefore it is counted once in the denominator."

Journal impact factor facts

> (8) Do any JIF data get corrected if a paper is retracted: that is, citations to and from that paper, and the document count for the journal containing the retraction?

“The impact factor data is not corrected due to retractions.”

(9) If a print journal has not yet assigned final page numbers to an article for printing, but posts an online-early version (epub ahead of print), would citations to that version count towards the journal’s JIF?

“Papers that are not yet officially published, either electronically or in print, but are published in a future issue of the journal appear as online[-early] articles. If a paper is cited while online-early but not yet officially published, the citation will count towards the JIF if: (1) the journal is clearly identified in the cited reference, and (2) the year noted in the cited reference is 1 or 2 years prior to the year when the citing article is published. It is very important to note, however, that whatever year is given in the cited reference is used. We do not verify the cited year.”

(10) If an online-early article in journal A appeared in 2010 and contained some references from other journals from 2008, 2009, and 2010, citations made to that article in 2011 would contribute to journal A’s JIF. In 2010, however, would the 2008 and 2009 citations made by the online-early article contribute to other journals’ JIFs...and does the online-early article get counted in journal A’s JIF denominator?

“Please note that articles are added to *Web of Science* only when they become published items in a journal, and online[-early] articles are *not* added to *Web of Science*. Any reference made by the article would not be available in the database until the article is added....We consider the article only when it is published properly.”

(11) When the online-early article is published properly in journal A, it contributes to JIFs of other journals, although the publication delay may have pushed some references out of the JIF windows: some from the 2-year JIF and some from the 5-year JIF, correct?

“Yes, until the online[-early] article is published, all the references made by this article would not contribute to the impact factor calculation for other journals.”

(12) So, if the print version of the journal A article were published in January 2011, (a) its references from 2008 no longer count towards other journals’ 2-year JIFs but (b) now, any 2010 references do?

“When the article gets published in 2011, its references to 2008 would not be considered, as the definition of the 2-year impact factor would only consider the last 2 years of references made by the article in the current year. Considering this, (b) is valid.”

(13) If the print version of the journal A article were published in 2012, some authors in 2013 might quote the 2010 online version, which wouldn’t add to journal A’s 2-year JIF but would add to its 5-year JIF, correct?

“Yes, the citation would not be considered for the 2-year impact factor; however, it would be considered for the 5-year impact factor.”

(14) And some authors in 2013 might quote the 2012 print version, which would add to journal A’s 2-year and 5-year JIFs. This means that the same paper has a second chance to contribute to its journal’s 2-year JIF...; the article has a ‘second wind’ and its half-life is extended?

“Yes, when authors in 2013 refer to the article of 2012, it would contribute to both the 2-year impact factor and 5-year impact factor.”

All in the name

Given the above information, it is apparent that the JIF is based on counting the number of times an indexed journal is cited, by itself and any other indexed journals, after partial correction for the total quantity of citable items. Included are all citations bearing a journal’s name and target years, regardless of cited source (main issue or supplement), extent of peer review, research maturity, or document type. Online-early items can receive citations but cannot ‘give’ them until final publication in a print or an electronic journal. Importantly, citation accuracy relies on the citing authors.

Unclear definition of the denominator notwithstanding, the JIF is a measure of peer attention or interest. Although the 2-year JIF is widely accepted as a proxy for quality, citation—and the ‘impact’ referred to in the JIF—is insensitive to context and can refer to the good, the bad, and the retracted. The word ‘factor’ in the JIF may also be a misnomer because the JIF is itself a result of many factors, such as index coverage and practices of different (sub) disciplines [5]; publishing procedures, speed, and strategies of authors and journals; document type and reference list length; perceived importance and topicality of research and debate; and dissemination, accessibility, branding, and marketing. However, renaming the JIF the ‘Two-Year Quotient for Journal Citations Among Indexed Journals’ or ‘Two-Year *Ex Post Facto* Journal-Level Self- and Peer-Interest Quotient’ would probably not have quite the same impact.

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How to cope with the transition from being a sedated academic to a proactive but poor medical writer sprout

by Christina Johnsen

After having obtained my degree in health sciences from the University of Copenhagen, Denmark, I got a position as Scientific Assistant, finished my PhD study, and continued my career as a postdoc. For many years I worked on one-year contracts, until eventually I landed a permanent position with SSI, the Danish equivalent of the UK Health Protection Agency. However, in spring 2010, there was a cutback of sixty permanent positions, including mine.

As soon as I had received my dismissal notice, I had a notice period of five months during which time I considered what to do in the future. During my career, I had been collaborating with different research groups, which had resulted in scientific publications in the research areas of oncology, immunology and infectious diseases. Having been employed as a postdoc and lastly as an academic in the public research and science environment for a couple of years, I had gained experience in the field of scientific writing, and I figured that I might use this as a foundation for initiating a medical writing career, either as a freelancer or as a regular employee.

My first challenges in search for medical writing related tasks

During the five months, I enrolled in the EMWA educational programme and attended the educational workshops at the 32th EMWA congress in Berlin. Immediately after my dismissal, I had also started searching for job opportunities but soon discovered that the job market was very competitive. My former career had equipped me with a range of useful competencies, but many of the tasks I had worked with were specific for the institution and would therefore not give me any form of credit on the job market. Every job I applied for had about 100 applicants, so I felt I was looking for a needle in a haystack. Therefore, I contacted a contract research organisation (CRO), and asked if I could work there as a trainee. They agreed to take me on, and I got the opportunity to work with clinical study reporting for two months. During my time at the CRO, which I found very stimulating, I learned about the working culture and the work load in this kind of environment. After my traineeship, I decided to ride on two horses simultaneously searching for jobs and starting on my own.

To begin working on my own, I signed up in a number of translator databases as a non-certified English to Danish translator and proofreader. I was soon contacted by some agencies who needed freelancers for medical text translations and proofreading, and at this time my company,

TransMedEdit, was registered at the Danish Commerce and Companies Agency. The translator jobs were of a varying nature, spanning a wide spectrum: Clinical study protocol amendments, summaries of product characteristics (SmPCs), dossiers and recall letters. One day, I was contacted by a large Danish pharmaceutical company who needed coverage of a scientific meeting. Another medical writer who is listed on the EMWA freelancer site had referred the company to me, and in this way I got my first medical writing assignment. Later, the company hired me for another assignment. I also landed a copywriting task (banner campaign) that offered me a new way of thinking along commercial lines, and most recently an assignment aimed at structuring a PhD thesis. All in all, these first assignments have been of a varied and challenging character.

Some practical tips for pursuing assignments

In Europe, there are a number of non-profit life science cluster organisations presenting all kinds of biotech and life science companies, both small and large. Relevant information about these can be found at http://www.mva.org/content/us/the_region. In the Nordic region, the Medicin Valley Alliance (MVA), which is the Danish-Swedish cluster organisation, represents more than 300 life science companies. Information about the member companies' areas of business can be found on the MVA website. You can apply for a membership, which will give you access to meetings, and networking activities with the companies involved. There are two major advantages in addressing relatively small companies. One is that they may not have the required in-house capacity to take care of their medical writing tasks. Another is that when you contact them, your request may be received directly by the CEO. In my experience, more than half of the companies will respond to your request, and the contact has been established. Most companies will, as a minimum, store your information in their database for later use. This kind of self-marketing requires that your CV is updated so it reflects your ability to meet the company's needs which also requires that you have done some research about the company to which the request is addressed. A suggestion might be to leave a box open on the CV that can be filled in, if possible, with expertise in the areas that the company in question needs. Using this strategy, I have managed to get a meeting set up with people who may be potential customers. >

How to cope with the transition....

- > In February this year, the Pfizer research and development facility in Kent closed down, and about 2,400 people lost their jobs. In an interview, Pfizer Vice President Ruth McKernan, Kent said: “the business closes down because the pharmaceutical model has broken—it has to change. We are going to outsource more functions, and the research will be done in small innovative biotech companies. This may apply for other big pharmaceutical companies as well” [1].

Most of the large pharmaceutical and biotech companies in Denmark have their own in-house people for most medical writing tasks. From the interviews that I have had with medical writing departments in large companies it is obvious that outsourced assignments go to either former employees who have started on their own or to other people with whom they have done business before. Another example is Novo Nordisk outsourcing much of their medical writing assignments to their affiliates in India. So I think that it takes a great deal of luck to land a contract with these companies. The future structure of pharmaceutical companies may open new doors for both freelance and employed medical writers as smaller biotech units will appear with new jobs and maybe also greater responsibilities for medical writers.

Conclusion

Today, the job market for newcomers in the field of medical writing is limited. This feeling is supported by an article

by Jo Whelan [2] who claims that there is a lack of medical communications positions for new writers and graduates while there are plenty of jobs to choose between for more experienced writers. ‘I was headhunted for this exciting position’. This sentence sounds prestigious at first glance, but the fact is that it cannot happen without your own effort. The same must apply when, as an entrepreneur, you are in search of new working challenges. The transition from being a full-time employee to becoming a medical writer sprout with a 360 degree of personal freedom is both challenging but also at times difficult. My hope for my own future career is to get the opportunity of being immersed in new challenging long-term working assignments and in time start to build up a satisfactory work-life balance.

Acknowledgements

I am most grateful to Lisbet Pals Svendsen for critically reading the manuscript.

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Definitions box

Affinity

Affinity is a term used to describe how ‘strongly’¹ a drug molecule binds to its receptor site. The term is another way of expressing the *potency* of a drug (see: Definitions box, *TWS* 2010; 19(1):57). However, all is not as simple as it seems. The full name for *affinity* is *association equilibrium constant*, and it is the reciprocal of the *dissociation equilibrium constant* or K_A . (The K_A is defined as the molar concentration of the drug that causes 50% of the receptors to be occupied at equilibrium, see Definitions box, *TWS* 2010; 19(1):57.) The units of affinity are $L \cdot mol^{-1}$, i.e. it is a dilution, rather than a concentration, the dilution at which the drug occupies 50% of the receptors at equilibrium. Surprisingly, one can still find examples in published papers where the term *affinity* is used in the text although the units are given as a concentration (i.e. $mol \cdot L^{-1}$). These are the units of the dissociation

equilibrium constant (K_A). To avoid confusion (and to avoid irritating purists and pedants like me), it is always best to use the IUPHAR preferred term dissociation equilibrium constant (K_A) and the appropriate units, in this case $mol \cdot L^{-1}$. If you must use ‘affinity’, please ensure that the units agree, $L \cdot mol^{-1}$.

One other little aside: values of affinity, like K_A do not follow a normal or Gaussian distributed. Instead they have a log-normal distribution. Mean values should therefore be calculated as geometric means and their SDs, SEMs and CIs will therefore not be symmetrical about the mean when expressed in arithmetic terms.

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Abbreviations:

IUPHAR = International Union of Basic and Clinical Pharmacology (www.iuphar.org).

SD = Standard deviation

SEM = Standard error of the mean

CI = Confidence interval

¹ For a discussion of the word ‘strong’ see Definitions box in *TWS* 2009; 18(2):131



Prepositions and their role in Abba's downfall

by Neville W Goodman

Grammar is one thing; but idiom is another.

I took the entrance examination for Manchester Grammar School, a class of higher education—the direct grant school—that has disappeared from the British scene, in 1959 aged 11. There was always a question in the English paper requiring candidates to “write a single sentence composed of parts of speech in the order given.” That year, the parts and order were preposition, adjective, common noun, pronoun, verb, proper noun, adverb, and finally adverb. Judging from the other four questions in that section of the paper, about five minutes were allowed to find the eight parts of speech. Magnanimously, the rubric allowed candidates to “Put a dash where you cannot supply a word.”

In Britain, the teaching of grammar was largely abandoned in the 60s and 70s, but has since enjoyed a resurgence. The idea that grammar restricts the imaginative use of language—which I always thought a preposterous and lazy argument—has been successfully rebutted, not to encourage prescription in language, but to enable description. The effect of grammar's former abandonment can be judged from my experience with medical students. Between 1983 and 2007, I taught anaesthetics to 25 students a year in small group teaching (the only teaching that is really worthwhile), giving a series of four tutorials to groups of four or five students. Once having gained their confidence, at some time during the third tutorial I would find an excuse to ask them if they knew what a preposition was. The question was always met by embarrassment. Rightly, because half the students had not a clue. Sometimes, one or two in each group would venture that prepositions were little words (which, ignoring *underneath* and one or two others, and prepositional phrases, is more or less true); or they would know that, in ‘the cat sat on the mat’, *on* was a preposition but without knowing a definition. Fewer than one in ten medical students could tell me that a preposition was a word that related parts of sentences, usually in time and space: at their simplest, as with the cat on the mat, prepositions relate nouns one to another.

So almost all the medical students that I taught would have failed my entrance examination in English at the first word [see note 1 below].

Unfortunately, a knowledge of grammar doesn't help much with knowing which preposition to use, because idiom and usage are more important than grammar. How would you explain to Abba that, “Now we're old and grey

Fernando, since many years I haven't seen a rifle in your hand” (something a native English speaker would never say) is wrong? [And see note 2 below.]

It would be nice to refer to a set of rules that govern prepositions, but there isn't one. Knowing that using an incorrect preposition is a common error when moving between languages, I looked to French, but it's the same there: the grammar book I found said, exclamation mark included, “The use of French prepositions can be particularly idiomatic and is frequently a source of error amongst English speakers as there are so many *faux amis*. The foolproof answer is to learn them individually!”

Bearing these comments in mind, here are some words that cause prepositional difficulty.

DIFFERENT: *to, from* or *than*? The verb *to differ* takes *from* (one differs *from* the other), so *different from* is never wrong. Different *to* is UK usage (30% of the time in writing and 10% in speech [1]), but a good copy editor will change it. Five per cent of the *BMJ*'s *differents* are followed by *to*. Different *than* is USA usage, but predominantly in speech (30%): *different from* is used 90% of the time in USA writing [1]. Different *than* is useful when the sense is *from what*: this is different *than* I wanted.

COMPARE: *with* or *to*? Comparisons are one *with* another. *Compare to* means *liken to*. As Bill Bryson [2] puts it: “‘He compared London to New York’ means that he felt London to be similar to New York. ‘He compared London with New York’ means that he assessed the two cities’ relative merits.” Nonetheless, many people use *compare to* wrongly for *compare with*, and the subtlety of *compare* meaning *liken* may go the way of *disinterested* meaning *impartial*. Five per cent of the *BMJ*'s *compares* are followed by *to*, mostly incorrectly. Compare is often used in the compound preposition *in comparison with*, which is unnecessary.

SIMILAR: *with* or *to*? As it says in WikiAnswers: “In the English language, ‘similar to’ is the customary construction. That's just the way it is.” Bill Bryson agrees (see above). However, while *one drug is similar to another, the results are similar with both drugs*. *Similar as*, apparently an error made by German-speakers, is wrong except when comparing similarities: *They are as similar as we are*.

CONTRAST: *with* or *to*? WikiAnswers advises that “*to* is used when the difference is being emphasized,” while the OED [3] records the meaning “exhibit a striking difference >

Prepositions and their role in Abba's downfall

> on comparison (*with*).” In the *BMJ*, almost all occurrences are *This contrasts with*. The compound preposition exists in both forms, *in contrast* to nearly three times as commonly as *in contrast with*. Both forms can almost always be replaced by *unlike*.

CORRELATES: *with* or *to*? The OED [3] says “*with*, rarely *to*.” If you want an example to provide a logical explanation, a taller person is expected to be heavier: weight goes up *with* height.

CONNECT: *with* or *to*? I have never written connect *with*, but *with* is appropriate if *connect* is used in the sense of *associated*. I suspect this usage is more likely in business than medicine. *In connection with* is unnecessary.

REPLACE: *with* or *by*? **SUBSTITUTE:** *with*, *by* or *for*? You can have hours of fun looking on the internet for answers to all these questions about prepositions. After one such answer, to replace *with* or replace *by*, came the plea, “Still not clear. English being a second language, this is very difficult to understand.” Indeed. *Replace* (take the place of) takes either *with* or *by*: we replaced plaster of Paris *with/by* acrylic. *Substitute* (put in the place of) takes *for*: we substituted acrylic *for* plaster of Paris. The OED [3] records that, more recently, substitute has been used incorrectly for replace, when it could take *with*, but a copy

editor should substitute *replace* for *substitute*. I doubt that our second language speaker would be any the wiser.

When *substituted* appears in the *BMJ*, it is usually followed correctly by *for*; when followed by *by* or *with*, *substituted* should have been *replaced*.

RISK: *of*, *for*, *to* or *over*? The risk is *to* or *for* the individual of the disease *over* a period of time: *the risk to/for women of stroke over ten years*. The choice of *risk to* or *risk for* the individual is possibly a matter of taking the risk or having it imposed: *the risk for me of walking in the hills is less than the risk to Jane of stroke*. I consider that *risk for* the disease (*the risk for stroke*) is wrong, but 7% of *BMJ* writers use it. I could understand a non-English speaker writing *the risk over stroke in women*; I'm sure they would be understood, but it is incorrect.

INFECT: *with* or *by*? People are infected *with* an organism (influenza virus) but *by* a process (not washing your hands).

DIAGNOSE: *with* or *by*? There is a tendency to use *with* for *as having*: *he was diagnosed with hypertension*. I think this is as sloppy as using *like* for *as if*, and my objecting to it is probably just as ineffective. Otherwise, diagnose *with* a device (*hypertension is diagnosed with a sphygmomanometer*) but *by* a process (*hypertension is diagnosed by sphygmomanometry*).

TREAT: *with* or *by*? My preference [4] is to treat *with* a drug and *by* a course of action: *with* penicillin, *by* physiotherapy; and always *by* the doctor or *by* the physiotherapist. Treat can also take *as* (he was treated *as* a fool), and *to* (he was treated *to* an ice cream). We are now getting into the realm of the phrasal verb, one of the wonders of the English language, and the reason that *set* has the longest entry of all words in the dictionary.

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I used <http://wiki.answers.com/> and <http://www.bmj.com/search> freely.

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Notes

Note 1: Readers of *The Write Stuff* might like to attempt to answer the question on parts of speech. Send them to nevwgoodman@mac.com, and I'll report on the most imaginative ones in the next issue.

Note 2: An added complication is that prepositions introduce phrases, not clauses. So while *since* is an incorrect preposition in 'he has not held a rifle since many years', in 'he has not held a rifle since he dropped one', *since* is correct but is a conjunction. What confused me was the role of *since* in 'he has not held a rifle since dropping one'. I thought it was here a correct preposition, and I e-mailed Professor David Crystal. He replied that *since* is a conjunction because *dropping one* is a non-finite clause. Without going into the details of our correspondence, part of his answer admitted that “analyses start to get complicated, as the constructions can be analysed in different ways,” which encouraged me greatly.

Themes of upcoming issues of TWS

The theme of **December's** TWS will be **Management in medical writing**. Phil Laventhal will be guest editing this issue. Submissions of articles on this topic should be submitted to Phil at pleven2@yahoo.com.

The theme of the **March 2012** issue will be **Medical writing in oncology** and the theme of the **June 2012** issue will be **Safety**. Proposals for articles on these topics are very welcome and should be sent to the editor at editor@emwa.org.

As always articles (between 1000 and 2500 words) or short reports (between 100 and 1000 words) on subjects of interest to medical writers which are outside the themes are also welcome. Please send articles, letters to the editor and suggestions for individual articles or future issue themes to the editor at editor@emwa.org.



Since you mention Abba...

by Alistair Reeves

I was interested to see that Neville quoted the incorrect use of *since* used as a preposition in Abba's Fernando ("Since many years ..."). I remember noticing this the first time I heard the song many years ago as a language student and thought: Oh, so the Swedes make that error in English too. I had already come across it when members of other Continental European language groups used *since* this way incorrectly. It is certainly worth taking a closer look at how *since* and a closely related fellow preposition of time—*during*—are used in English.

Since

Since can be used as three different parts of speech. As a preposition of time and an adverb of time, it means *between a defined point in the past and the present* or *during and in the time after* an event, and as a conjunction it means *because*:

- [1] Preposition: *Since* last Thursday, he has been able to feed himself again.
- [2] Adverb: He last consulted me on 26 July 2004 and I haven't seen him *since*.
- [3] Conjunction: *Since* he was confused, he was unable to follow simple instructions.

Unfortunately, as a conjunction, it also means *during or in the time after*:

- [4] Conjunction: What drugs has the patient received *since* she was admitted?

Its use as a conjunction in [4] is perilously close to that of a preposition in [1], isn't it? The main distinguishing feature when used as a conjunction meaning *because* is that it will always introduce a clause, i.e. a part of a sentence with its own verb: in [4], 'was admitted'. A further distinguishing feature between its use in [1] and [4] is that when it is used as a conjunction with the meaning *during or in the time after* it is much less likely to be at the start of the sentence, but may well be.

This is where David Crystal's admission (in Neville's second note) that "sometimes analyses start to get complicated, as the constructions can be analysed in different ways" highlights that we have grey areas in English grammar and sometimes considerable overlap in terminology. For example, every prepositional clause ('Since the injection was given, ...') is also a 'dependent clause' or 'subordinate clause' and an 'adverbial clause', depending on what you want to say. My late cousin, Sylvia Chalker, co-editor of the Oxford Dictionary of English Grammar, also

admitted to me that there are sometimes several different grammatical interpretations of a given phrase, and that now and again she 'just couldn't decide'. The exact nature of *since* may therefore remain unclear, and as Sylvia also said, "Sometimes it doesn't really matter." So let's leave the conjunctive use of *since* there, and just say: if you are using *since* as a conjunction to mean *because*, it is often better to use *because*, in case there is any possibility of confusion with *since* as a preposition of time. What does *Since I have been ill, the stairs are too much for me* mean? *Because* I have been ill, or *After* the time that I became ill? Always look at *since* critically and test whether it might be misunderstood. I have been trying to train myself always to use *because* for years, but that *since* just keeps on slipping in.

What does matter with *since* as a preposition of time, however, is that you cannot say "Since many years" Why not? I always try to find 'non-grammatical' ways of explaining things. Notice that I underlined a *defined point in the past* above. This is the key to understanding the use of *since* as a preposition of time. It cannot be coupled with a *period* in the past—only with a defined point in time in the past—however this point is defined. And sometimes 'a defined point' is longer than an isolated point in time or is only implicit. Here are some examples of correct and incorrect use:

Correct	Incorrect
[5] He has been ill since last Tuesday.	[11] He has been ill since several years.
[6] We have not received any CRFs since the study was discontinued 6 weeks ago.	[12] We have not received any CRFs since 6 weeks.
[7] He has been missing since 4 July 2010.	[13] He has been missing since three days.
[8] I have been ill since my holiday.	[14] Question: How long have you been suffering from migraine? Answer: Since two years.
[9] We have seen a marked decrease since 2 years ago.	
[10] He is the greatest bacteriologist since Robert Koch.	

[5], [6] and [7] refer to a definite point in the past and not to periods defined in absolute numbers with a unit (e.g. years), so *since* is **correct**.

[11], [12] and [13] refer to periods defined in absolute numbers with a unit, so *since* is **incorrect**. Indefinite numeral modifiers (*many, several*) are treated as absolute numbers when combined with *since* (see [11]). This is why 'Since many years ...' does not work in Abba's Fernando. >

Since you mention Abba...

- > So what is correct for these? The answer is for: *He has been ill for several years, We have not received any CRFs for 6 weeks, He has been missing for three days.*

Ah yes, you say, but surely the holiday is also a period and not a defined point in the past. So why is *since* all right in [8]? Even if the holiday lasted 3 months (lucky you!), it is a defined event in the past with an end, and what you are actually saying is: *I have been ill since (I fell ill on) my holiday, or I have been ill since (I came back from) my holiday, or I have been ill since my holiday (ended)*, all of which are implicit defined points in time in the past.

[9] also refers to a period, but by adding *ago* you are saying 'when this period started' so the *since* in this sentence is also referring back to a defined point in time. You are most likely to find *since* and *ago* used in this way when people are speaking rather loosely; *Since we investigated this 2 years ago* would definitely be better for formal writing.

OK, you say, but how can Robert Koch in [10] be regarded as a 'defined point in time'? You are right to question this locution, of course, but it is commonly used in less formal writing and often when speaking. The defined point in the past here is, of course, since Robert Koch (lived), and by skipping the lived, you turn Robert Koch into a grammatical landmark in time enabling the use of *since* together with a name.

Very important: notice that the correct examples in the above table all use the present perfect (except [10], see later). This is because it is **impossible** to use *since* as a preposition of time together with the present tense in English. The verb 'to be' is most frequently involved. This is possible in other language groups and appears to be very difficult to shake off, as I often see and hear similar constructions to the following from even very experienced users of English as a second language: *We are here since yesterday*, which should, of course, be *We have been here since yesterday*, and *We are here since 2 weeks* (or variations on [14]), which should, of course, be: *We have been here for 2 weeks*. The present tense is used in [10] because the verb in the sentence is not modified by the phrase beginning with *since*.

Staying on tense for a moment, in sentences that start with *since*, it is often not clear to the reader whether *since* is being used to mean *in the time after* (preposition; [15], [17] and [19]) or *because* (conjunction; [16], [18] and [20]) until they read the main clause, where the tense of the main clause determines how *since* is being used.

Preposition (during and in the time after)	Conjunction (because)
[15] Since we investigated this 6 months ago, we have not had cause to revisit this issue.	[16] Since we investigated this 6 months ago, we are confident that the results are still valid.
[17] Since we investigated this 6 months ago, we have been confident that the results are still valid.	[18] Since we have investigated this, we are confident that the results are still valid.
[19] Since he was discharged on nifedipine, he has suffered only one attack of angina pectoris.	[20] Since he was discharged on nifedipine, we expect a considerable decrease in angina pectoris attacks.

The present perfect in the main clauses ('we' and 'he' clauses) in [15], [17] and [19] tells the reader that *since* is being used as a preposition. The use of the present tense in the main clauses in [16], [18] and [20] tells the reader that *since* means *because*, and it therefore probably would have been better to start the sentences with the main clause and *because* to make this absolutely clear. If you want to stress the idea of 'because', however, you can certainly start the sentence with the dependent clause. Don't let anyone tell you that you can't start a sentence with 'Because'!

Notice in [18] how the use of the present perfect in the dependent clause ('since' clause) and the omission of the '6 months ago' (see [16]) strengthens the feeling in [18] that the *since* means *because*. But it still would be clearer to use *because*.

During

Let's move on to *during*, where things are simpler because it is used only as a preposition. *During* means *at some time while something else is happening*. This can mean either a single event: *He suffered a stroke during his holiday*; or an extended period, and even repeated periods: *He was confined to bed with malaria for weeks on end during his secondment to the Singapore office*. It is also used to mean *for the duration of*: *The patient must be observed for signs of intolerance during the infusion*. *Throughout* would probably be better here, if that is what is meant, because *during* might be taken to mean that the nurse can 'pop in now and again' to see how the patient is doing.

Like *since* used as a preposition, *during* cannot be coupled with absolute numbers or indefinite numeral modifiers, as in examples [11–14] for *since*. This means that you can say: *During his 4-week stay in hospital, he put on 3 kg*; but you cannot say: *During 4 weeks, he put on 3 kg* [15]. Nor can you say: *The infusion of 5-FU was given during 4 days* [16]. For [15], you have to say *In 4 weeks* or *Over 4 weeks*, and for [16], you have to say *for 4 days* or *over 4 days*. Some claim that you should never use *over* in this way because it might be misunderstood to mean *more than*. As far as I am concerned, this is looking for a problem where there is none.

All of the above brings me on to the various overlapping meanings of *since*, *as*, *during* and *while* ... but I think we'll leave that for a future issue.

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My way to medical writing

by Julia Boese

I love languages. And I love medicine. Thus, medical writing is a logical consequence of combining both for me—a kind of magic key to both my passions. I think we can safely assume that most medical writers share one or both passions with me. What about you? Do you feel the same?

Although I originally qualified as a dentist and had been reading scientific publications for years, I had never given much thought to the whole process of creating them. The first time I began to think about the people behind the papers was during my postgraduate studies. I was studying epidemiological methods and had the task of not only evaluating papers based on studies with different designs on different medical topics, but also analysing datasets using the Statistical Analysis Software ‘SAS’ and presenting the results. Both working with SAS and presenting data were a challenge for me. My relationship with SAS was a kind of one-way love: I needed it and loved its rebellious essence, but SAS did not love me at all, and certainly didn’t need me. C’est la vie. However, one day I proudly held the output of the data set in my own hands.

The next challenge was to present my data appropriately. I browsed through a lot of papers to find inspiration to create my own tables and graphs to convey a clear and concise message to my readers. I found myself admiring those people who were able to do it elegantly—and apparently, effortlessly. Now I know that a huge amount of effort is involved.

Who were these smart, highly-skilled, invisible people mentioned (not always) only in acknowledgements in the papers? I wanted to learn more about them and discovered EMWA. I wanted to be one of them and looked for a conventional way of becoming a medical writer by doing courses of study. I found nothing. I tried to find an internship with the same result. It seemed that becoming a medical writer would mean exercising a great deal of patience and endurance for me, but I was prepared to make the effort. After discovering them, my first step was to start attending EMWA’s training courses at their biannual conferences.

One day in September 2010, I came across some information on my computer about a new postgraduate, extra-vocational Masters Programme in Medical Writing at the Medical University of Innsbruck (MUI) in Austria. I enrolled and I have never looked back—I love it.

We are 15 motivated participants: clinicians, research assistants and medical students. The 2-year programme organised by Professor Michael Nogler, who heads the Department of Experimental Orthopaedics at the MUI, is a combination of blocks of on-site training on Fridays and Saturdays with self-learning in-between on an e-learning basis. The on-site training in Innsbruck consists of intensive interactive sessions with a mix of lectures and exercises. All presentations are recorded and are available as video presentations and PowerPoint slides on ‘ILIAS’, the web-based e-learning management system containing many useful tools for collaboration, communication, evaluation and assessment. ILIAS therefore acts as your virtual classroom for working through any sessions again at your own pace to consolidate knowledge or for the preparation of assignments for assessment. Access and navigation are easy, and downloading files is fast. Each ILIAS user has their own personal desktop—a personal working space where all Selected Items, News, Mails, Notes, and Bookmarks are displayed. This is where you begin your ILIAS session, and continue using it to view or review a block, for instance, or enter a virtual working group. The list of Active Users shows which other group participants are online at the moment.

It is convenient to have your own virtual classroom, especially if you were not able to attend an on-site training session: all on-site sessions missed have to be worked through at home and submitted. This means additional individual work. I understand this feature to be a type of quality control with two effects: it makes students reflect actively on the material and simultaneously trains them to be more disciplined—both essential characteristics of a medical writer. I have already experienced this feature, and this made me decide to do my utmost to be present at entire on-site training sessions in Innsbruck to avoid additional stressful time management at home.

During the first two semesters we concentrated on learning to write a professional grant proposal for a national funding institution and had to have a completed grant proposal ready for submission at the end of the second semester. We were given a thorough grounding in medical English. Then we had separate sessions on data presentation, and editing and proofreading. We sharpened our writing skills and learned to communicate with our readers in plain English. We also learned about observational study design and effective presentation of soft endpoints with various scales >

My way to medical writing

> and questionnaires. The non-medical professionals among us received a comprehensive course in medicine which combined presentations with sessions in the hospital itself. And we were also continuously taught basic statistics in different sessions throughout the year. All these topics were covered in workshops with pre- and postworkshop assignments according to the EMWA format, most with experienced EMWA workshop leaders.

This is not my first experience of such distance-learning programmes. Of course, I can only compare this course with the previous courses I have done. The obvious advantage is learning in small groups combined with the intensive practice in the group, and then afterwards by yourself at your own virtual pace. The programme is well-organised and also well-equipped, both the on-site and e-learning.

As the programme at present primarily focuses on writing skills required for those involved in scientific and hospital research (writing and submission of grant applications and journal manuscripts), it does not cover regulatory writing (see box below about the new course starting in 2012).

I am compensating for this by attending EMWA training courses.

It has been a very exciting year, full of challenges and new experiences. I am looking forward to the second part of the course next year which will be covering manuscript writing in three intensive 5-day workshops, and a great deal of individual study in-between, also making use of distance learning using the ILIAS system.

What did I miss in my first year? I regret having missed the live workshop on data presentation. Of course, I was able to catch up on it using recorded video presentation on ILIAS, but nothing can replace the interactive, live 'performance'.

What my aims are? To learn further from the best lecturers at conferences and at the university—and to be able to proudly put the name of my employer instead of the town where I live on my name badge at a forthcoming EMWA conference!

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New focus for MSc in Medical Writing at the Medical University of Innsbruck

Julia Boese reports (above) on her experiences with distance-learning on the Masters Course in Medical Writing being offered at the Medical University of Innsbruck (MUI) in Austria. This course, with a focus on grant writing and manuscript preparation, was launched by the MUI in Autumn 2010 without EMWA involvement. The present course finishes in July 2012.

Just after launching the course, the course sponsor, Professor Michael Nogler, an orthopaedic surgeon and head of the Centre for Experimental Orthopaedic Surgery in Innsbruck, approached EMWA for help in redesigning the course with regard to content. An EMWA committee has been helping the MUI to redesign the course for the last 6 months, and arrived at a final draft of new course materials in May 2011, just before the EMWA Berlin Conference, where the course was presented at an informational event.

Because medical writing is such a multi-faceted activity, the new course takes a three-track approach, embedded

in general modules which give a thorough grounding in medical writing. Students choose between one of the following tracks which account for half of the material studied in the second year: (1) writing for drug development and regulatory affairs, (2) writing for medical communications, and (3) writing for the academic and hospital environment. Each year has two, 2–3-week autumn and spring onsite training blocks, and otherwise extensive use will be made of the MUI's distance-learning platform, as described by Julia Boese.

The new course has to be approved by the MUI Senate. Because of MUI-internal procedures, approval is not expected until December 2011. Advertising for the course in its new form is also not permitted by the MUI before then, so it will not be possible to publish full details of the course before the December 2011 issue of *TWS*.

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Evaluating the return on attending a conference

by Joselita T. Salita

Faced with many conferences each year companies and individuals often have to deal with decisions regarding conference attendance: which one to attend, or more crucial, is it worth it? Indeed, attending a conference is an investment and coming up with an ROI (Return on Investment) assessment is the best way to justify this decision: $ROI = (\text{Benefits}-\text{Costs})/\text{Costs} \times 100$ [1]. It looks simple but it's not that easy to compute.

Cost factors. The total amount of conference attendance is obviously a deciding factor for many. And it's the easiest part to estimate as one just fills in the obvious: conference registration fees, transportation, food and lodging and other allowances. More elaborate calculations include the employee's time, which can be complicated to compute. Goldfarb states two ways of calculating this: (i) through simply multiplying the employee's salary per day with the time spent in the conference plus overhead cost, and (ii) by estimating the value of the employee to the company, otherwise known as the opportunity cost [2]. The latter, he explains, is the value that the employee could have contributed to the company had he/she not attended the conference. This is difficult to calculate as employees do not generate revenues directly to the company. For the self-employed, however, this may be simpler to estimate.

In order to optimise ROI some cost-cutting measures are suggested such as room-sharing among attendees or attendance at local or one-day conferences instead [3].

Professional advancement. One of the benefits expected from a conference is to gain knowledge and skills. This is quite difficult to assess because of three reasons. Firstly, it depends on how closely linked the goals of the attendee and conference are. No matter what a conference's goals are, each attendee has his/her own unique set of needs and therefore his/her own expectations [4]. Some conference attendees may have direct and practical aims and they can be disappointed if they end up receiving a lot of complex information which has little relevance to their own disciplines. Some companies also send the 'wrong' people to a conference, which can be costly in the end [1]. Secondly, in contrast to costs, which are incurred on a short-term basis, benefits may take a long time to show but may also be long lasting [2]. Those who expect short-term returns are unlikely to get them. Thirdly, the quality of the conference itself matters. Some conference programmes can appear good but their delivery and presentation may be suboptimal. In this case, the message of the conference is not effectively transferred.

A case study used by a group called STMA shows how to monetarily assess ROI based on skills learned from a

conference [5]. It basically involves calculating the savings incurred due to increased productivity or due to time and resource savings. Morell argues that the more important element of knowledge transfer in the form of interactions is undermined in conferences [4]. According to him people sometimes learn more through informal discussions.

Networking opportunity. Many people attend conferences for the sole purpose of networking. Conferences provide the chance to meet people with common interests and thus establish a rapport which can turn into collaboration or business. Networking is more than just getting to know people. It is also getting to be known. It's advertising one's self in a very personal way. Although networking provides a significant benefit from attending a conference, it is also the most difficult to quantify as the connections built in a network are multilateral and may not give immediate returns. Hanson provides ways how to forecast ROI through networking, wherein a metric is defined [1]. For example, if X meetings with Y produced Z sales last year (or based from other data), X meetings at this conference will also bring in Z sales. This can be a metric which, due to many external factors, can be adjusted on a case-to-case basis. After the conference, actual sales are assessed and contributing and confidence factors, which are personally assessed, are multiplied with the assessed sales to come up with actual benefits derived from this activity. (If a person is not the only person responsible for generating sales, but 1 out of two, then his contributing factor is 50%. The confidence factor ranges between 1 and 100% and is an assessment of one's confidence that sales are due to this activity). Hanson also suggests how to optimise networking opportunities after a conference such as doing follow-ups and implementing actions agreed on with key people.

A conference is also the opportunity to cultivate relationships already established. These relationships are as important as new ones in terms of monetary value and the intangible benefits of friendships built from such relationships must not be underestimated. Other networking benefits not convertible to monetary values are getting long-lasting advice from an expert [2] or being 'infected' with the enthusiasm of other attendees, particularly in the case of freelancers [6].

Team building opportunity. Some companies send more than one person to a conference. Such an out-of-office atmosphere may open up opportunities to discuss ideas or share experiences which, in turn, may enhance communication and bonding between or among co-workers.

Evaluating the return on attending a conference

> Although most of us take pleasure in attending a conference, it might help to sit down and do an ROI. Hanson's step-by-step procedures were thought out for people in sales attending trade shows [1] and the STMA model for sports turf managers [5], but with some creativity, they can both be applied to anyone's conference assessment. The only difficult thing is deciding how accurate one wants to be. Marketing professor Sharan Jagpal from Rutgers University has criticised the use of ROI calculations for conferences as having no effective measures for long- and short-term gains [7]. What is important though is to know that an ROI assessment is doable and in times of budget-cutting, it might be the answer to justify your next conference attendance.

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Alfred Nobel: Scientist, writer and a paradoxical character



wikispaces

You probably know who won the Nobel prizes last year and that Konrad Wilhelm Röntgen received the first Nobel Prize for physics for his discovery of X-rays. But what do you know about Alfred Nobel, the man who willed his fortune to annual rewards for those "who shall have conferred the greatest benefit on mankind" in the fields of physics, physiology

or medicine, literature and work to promote peace? One thing you might not know is that he was a prolific writer including poems and drama but mainly of letters, both business and personal. He wrote 20-30 letters a day in 5 different languages (Swedish, Russian, English, French and German), equally fluently. Contact with his factories was primarily by letter.

Nobel secured 355 patents and by the time he died in 1896 he had established 90 factories in 20 countries. His father had been a master builder, manufacturer and inventor but went bankrupt twice and his son's early education was at a school for the poor. Nobel started to experiment with Ascanio Sobrero's invention, the highly volatile liquid nitroglycerine, in 1862. His aim was to find ways of handling it and his first breakthrough was the invention of a detonator. Subsequently he found that nitroglycerine could be stabilised by mixing it with silica, which led to his discovery of what he called dynamite from *dynamis*, the Greek word for power. His initial attempts to manufacture his 'blasting oil' resulted in the factory, a shed, blowing up and killing his brother and 4 other people. The misfortune attracted considerable press coverage and incidentally demonstrated nitroglycerine's superior blasting power to gunpowder. This came just at the time

when an effective method for blasting through rocks was much in demand for building railways, and also at a time of military expansion.

Although he had a passionate interest in weaponry Nobel strongly supported the struggle for peace and disarmament. He is quoted as saying that "It could well be that my factories will put an end to war more quickly than your peace conferences, for when two armies of equal strength can annihilate each other in an instance, then all civilised nations will retreat and disband their troops."

He never married nor had children. Two engineers were chosen in the will to travel the world and sell the shares in his companies to realise the 31 million Swedish Kronor that formed the fund for the Nobel Prize. Family members contested his will. Even Oscar II, King of Sweden and Norway, protested against Nobel's wish that the prize should be international urging that it be confined to Swedish and Norwegian nationals. But it was important to Nobel, who was an internationalist and had lived in a number of countries including Sweden, Russia, Italy, France, and the US, that a person of any nationality could receive the prize.

A likely candidate for the Prize himself, Nobel would have probably refused to attend the ceremony and the banquet as he avoided the limelight and disliked pomp and ceremony. He often wrote of his wish to leave business life and devote himself to his true calling, which he considered to be 'science'. He was rich enough to have done this. What motivated such a shy man of ill health to drive himself to exhaustion by working all hours and travelling constantly between his factories by train only to give away his fortune? He was deeply depressive and Svante Lindqvist, curator of the Royal Swedish Academy of Engineering Sciences, suggests in his booklet about Nobel that he took refuge in hectic activity to distract himself from a dread arising from his insight into the pointlessness of life. Food for thought in today's business milieu.

Source: Lindqvist S. *Alfred Nobel: Inventor, entrepreneur and industrialist*. Stockholm: Royal Swedish Academy of Engineering Science, 2001.



Spotlight on Sweden: How English is changing and replacing Swedish

by Stephen Gilliver

Once, fumbling for words while shyly conversing with a colleague in Swedish, I had a total blank, completely forgetting the Swedish for bring. Guessing that it might be *bringa*, I was kindly reminded that it was in fact *ta med sig*.

Not liking to be wrong, I looked up *bringa* in the hope that it might be a valid alternative and found that the free online Swedish-English dictionary www.ord.se, hosted by leading publisher Norstedts [1], indeed lists *bringa* as a legitimate translation of bring (albeit in a different context to the one in which I used it, with *att bringa klarhet* meaning to bring clarity).

My guess, though incorrect, was based on a certain amount of logic. It is very common for Swedish to take an English verb and simply add the suffix *-a* or *-(e)ra*. Thus, Swedes are known to *starta*, *printa*, *returnera* and *testa* things. It is not entirely unheard of for them to *fucka upp* occasionally.

It is of course routine for languages to borrow from each other: from Swedish, English has adopted *ombudsman* and adapted *smörgåsbord*; France famously celebrates *le weekend*. The difference here is that Swedish is taking words that it doesn't need. It already had words for print (*skriv ut*), start (*börja*), return (*skicka tillbaka*), test (*prova*) and mess up (*göra bort sig*) when it adopted their English equivalents. It is therefore not only acquiring new words and phrases out of necessity (*checka in* and *outsourca*, for example), but also out of preference.

So what are the reasons for this? One obvious explanation is the ability of a large proportion of the Swedish population to speak English. English is a compulsory subject in Swedish primary and secondary schools, while the mass broadcasting of subtitled British and US films and TV programmes means that kids are exposed to English as soon as they are old enough to be plonked in front of the telly. The verb *dissa* (which means to dis) is a clear product of this imported culture. In an EC Eurobarometer survey conducted in 2005 [2], some 89% of Swedes questioned claimed to be able to speak English “well enough in order to be able to have a conversation.”

The changing language situation in Sweden has not escaped the notice of politicians. In December 2005, the Swedish parliament clarified Sweden's language policy, among other things affirming that Swedish is the main language in Sweden [3]. The fact that it felt the need to do so speaks volumes.

On its website [4], the Language Council of Sweden describes the increased use of English as a “threat to

democratic values.” Strong words. Founded in 2006, the Council is a department of Sweden's official language authority and describes itself as “the primary institution for language cultivation in Sweden.” Part of its mandate is to “monitor the development of spoken and written Swedish.” Going one step further, it aims to also “influence the language situation in the country.” The Council's website helpfully provides a link to a list of Swedish alternatives to what it describes as “*Onödiga engelska ord*” (unnecessary English words) [5].

We should perhaps, therefore, not be too surprised that the Council's new word list for 2010 [6] contains only one non-adapted direct English loanword¹: *app*². A report published in 2003 [7] and summarised in the *Nordic Journal of English Studies* in 2004 [8] illustrates the challenge the Council faces in its efforts to limit the spread of English. Report author Mall Stålhammar studied a range of source material, including dictionaries and new-word lists, and found that 3,735 English words entered the Swedish language in some form or other between 1900 and 2000—an average of 37 per year^{3,4}.

The declared aim of a second body, the Swedish Academy [9]—founded in 1786 “to advance the Swedish language and Swedish literature”—is to “work for the purity, vigour and majesty of the Swedish language.” The inclusion in its official word list [10] of a whole raft of English loanwords, including the aforementioned *dissa*, suggests that it hasn't been 100% successful in achieving these grandiose objectives⁵.

As well as keeping it nourished with loanwords, English is influencing Swedish in more subtle ways—for example, giving new meanings to existing words. *Acceptera* has long meant to accept something one perhaps shouldn't be expected to accept; it now also means to accept in the >

1 A word that has been adopted or borrowed from another language

2 Another “new” word that will be familiar to many Europeans is *vuvuzela*, which also entered the Oxford Dictionary of English in 2010. The origins of words such as *Facebookfest* (Facebook party) and *spotifyera* (to use Spotify) are not entirely elusive.

3 These numbers comprise both direct (non-translated) loans and translation loans. Between 1900 and 2000, 64% of new English loanwords were direct loans—adapted (e.g. *detektion*) (21%) and non-adapted (e.g. *animation*, *deadline*) (43%).

4 Between 1950 and 2000, an average of 56 English loanwords were added per year.

5 An 18-person committee whose members are elected (for life) by secret ballot. The Swedish Academy chooses the recipient of the Nobel Prize in Literature each year. The decision to jointly award the 1974 prize to Eyvind Johnson and Harry Martinson was not without controversy: both were members of the Academy at the time.

Swedish replaced by English

- > sense of accepting an invitation [11]. Not even grammar is immune, with the genitive apostrophe (as in His Master's Voice) creeping into written Swedish.

According to the Language Council of Sweden [4], "The fact that Swedish is the majority language in Sweden means, for example, that safety instructions, operating instructions, product information, machine translation systems etc. must be available in Swedish." This rule clearly doesn't cover advertising: at the time of writing, Sony Ericsson was running TV adverts entirely in English. The company's marketing team obviously doesn't feel that providing Swedish subtitles or a Swedish voiceover (as other advertisers do) will win it any more customers. The Council further states that "The language used in the educational system should normally be Swedish." This is certainly not the case in higher education, in which many courses are taught entirely in English⁶. The Swedish parliament has rightly acknowledged that English being the primary language helps Swedish universities to attract overseas students and researchers, and to collaborate with foreign institutions. Likewise, many Swedish businesses operating in international markets perceive English being the working language to be beneficial.

A clear distinction must be made between spoken and written Swedish, the latter of which has been more resistant to the influence of English. The Language Council of Sweden estimates the prevalence of English loanwords in Swedish daily newspapers at between 0.3 and 1% [12]. Walk around Malmö, the wonderful city where I live and work, and you will find very few signs or advertisements printed in English.

What of the future? Several linguists have argued that English is well on the way to becoming Sweden's *de facto* second language [13,14]. It will be interesting to see if it ever acquires official language status. While it is inconceivable that Swedish will be universally replaced by English, the dominance of English in areas of business and education can only be expected to increase. With regard to written Swedish, even if the number of English loanwords used in print were to double or treble over the coming decades, as the Language Council of Sweden anticipates it might, it would still be relatively low. It therefore appears certain that written and spoken Swedish will continue to diverge. I do wonder how much influence the Language Council of Sweden and the Swedish Academy realistically hope to exert. The language they imagine or wish Swedish to be does not exist and cannot be created.

As a final aside, it was with great interest that I noted the recent announcement by Folkpartiet, a party in the ruling centre-right alliance, of its intention to make Chinese a compulsory subject in Swedish secondary schools. Might English itself soon face competition from Asia?



The road ahead for Swedish? (*Farthinder* = bump ahead)

Swedish words that English could use

<i>Dryg</i>	slightly more than
<i>Dygn</i>	a period of 24 hours (the Swedish for day is <i>dag</i>)
<i>Fika</i>	to have a coffee break (in the company of others)
<i>Hinna</i> (<i>göra någonting</i>)	to have the time (to do something)
<i>Lagom</i>	just right (not too little, not too much)
<i>Orka</i> (<i>göra någonting</i>)	to have the energy (to do something)
<i>Solkatt</i>	a reflection caused by sunlight striking, for example, a watch (literal translation: sun cat)
<i>Träningsvärk</i>	aching or stiffness caused by exercise

Relatives

While English words such as granny and granddad can refer to a paternal or maternal grandparent, Swedish has a more precise naming system. One's paternal grandmother is referred to as *farmor* (literally, father mother), maternal grandfather as *morfar* (mother father), paternal uncle as *farbror* (father brother), and so on. However, this system is not without its own problems, with a grandmother, for example, being referred to as *farmor* by her son's children and *mormor* by her daughter's—potentially confusing when there is a big family get-together!

⁶ A government report published in 2002 stated that doctoral theses written in English should be accompanied by a Swedish summary in order to maintain Swedish as a scientific language.

Swedish replaced by English

Swenglish

The word *Swenglish* (pronounced “Swin-GLISH”) means different things to different people. To some, it is the supposed butchering of English by Swedes, typified by (alleged) misuse of the Swedish word *fart*, which means speed (as in “the fart limit in Malmö was 50 km per hour” [15]). This I have rarely encountered since moving to Sweden in February 2010. Standards of English are, in my experience, generally high. Swedes make a few grammatical mistakes, but rarely use words incorrectly. Others use the word to describe spoken Swedish that is littered with English words. For example, *Ska jag take it easy?* (Shall I...?). This is far more common. When on the train, my attention is regularly drawn to some or other fellow passenger suddenly throwing a “whatever” or “that’s none of my business” into the middle of a conversation. The linguistic term for this phenomenon is code-switching. Why are so many Swedes so fond of it? (According to a doctoral study published in 2001, every fifteenth word used both in business meetings at an international shipping company and by a group of youngsters taking part in a docusoap was English [16].) Much like the broadsheet columnist who slips a Latin or French phrase into his article to make me feel ignorant, there may, I suspect, be a little bit of showing off involved.

A problem for immigrants?

The ability and willingness of Swedes to speak English can pose a problem to those wishing to learn Swedish. My own early attempts to speak Swedish in shops and other public places were often curtailed by the person with whom I was talking switching to English, presumably to move things along. My Englishness was no doubt all too obvious. (Nowadays, people tend to spot that I am foreign, but are not necessarily able to place my accent—a big step forward. I am not displeased when asked if I am German or Finnish!) However, every immigrant I have met since moving to Sweden speaks at least some English, so it may be that non-native English-speaking immigrants face the same problem.

A number of people I know insist on speaking English with me because they see it as a good opportunity to practise. (It is not uncommon for me to engage in conversations in which I speak Swedish and the other person, a Swede, speaks English!) My father-in-law, Örjan, is not one of them. His insistence that I speak Swedish at all times helped me pick up the language more quickly than I might otherwise have done. Thanks Örjan.

Yes and nej

You won’t find it in any Swedish word list, but yes seems to have replaced *ja* in the vocabulary of a good number of Swedes. In contrast, I can’t ever recall hearing a Swede use no in place of *nej*. What does yes have that no doesn’t?

Acknowledgements

I would like to thank my wife Anna Nordle Gilliver, a native Swede, for assisting me with the content of this article and for (hopefully) ensuring that it does not contain any

howlers. I would also like to thank Per Condelius for providing some of the source material, and Bertil Kjellberg for his suggestions of illustrative words.

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Splitting the difference

Another recent phenomenon in Sweden is *särskrivning*, which means splitting up words. You can see it on signs and posters, and elsewhere. For example, outside a mechanic’s garage you might see *bil mekaniker*, which should be *bilmekaniker* according to Swedish rules. It can be fatal because many times the meaning will differ, as illustrated by the following examples:

rökfritt = smoke-free

rök fritt = smoke freely

en långhårig man = a long-haired man

en lång hårig man = a tall, hairy man

kycklinglever = chicken liver

kyckling lever = chicken lives

barnunderkläder = children’s underwear

barn under kläder = children under clothes

With thanks to **Mats Haptén** matshapten@hotmail.com for this contribution

Webscout



Health communication and e-health

by Karin Eichele

Health communication, as you will have learnt reading through this issue of *TWS*, is a wide field. In order to promote public health, it is essential that people know how to obtain and understand information on health and health services so as to make their own well-educated decisions. Within the Web 2.0 era, e-health is a hot topic in the context of health communication and health literacy. E-health can refer to healthcare and medicines services using recent information technology for managing electronic records of patient data, which is not further looked at now, but also to health information services provided online with the goal to inform and enable communication.

<http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook>

For those of you who want to go into detail, I recommend this e-book. It is about setting up complete health communication programmes. And even if this is not specifically relevant for you, some of the more general chapters might be of interest as they provide you with background information on the goals of health communication, what it can achieve and what not, and on some methods used in this field like education entertainment or media advocacy. An overview on the stages of the health communication process is also provided.

<http://www.health.gov/communication/ehealth/ehealthTools/default.htm>

This one links you to a comprehensive study report on the utility and value of consumer e-health tools for people experiencing health disparities, provided by the Office of Disease Prevention and Health Promotion (ODPHP) of the US Department of Health and Human Services. You can navigate through the report in html, but I recommend downloading the complete pdf version. According to the report, e-health tools are well-accepted and generally easy to use. Positive changes in knowledge after using e-health tools were registered. E-health tools will have to be more individualised and easier to access, but in general the report suggests effectiveness and utility of these tools.

<http://hpq.sagepub.com/content/8/1/7.full.pdf+html>

An emotional message is more effective than a merely rational one and it has to build a bridge to the person's individual situation. Participation of the recipient in the communication process is beneficial for the message being received and for having a chance of mediating a behavioural change. These principles of effective communication in public health and the role e-health plays are

addressed in 'Rethinking Communication in the E-health Era' by Linda Neuhauser and Gary L. Kreps.

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

Social media offer great possibilities to fulfil the requirements of effective communication. This short video gives an impression of how social media can serve as a rapidly evolving tool in the health sector.

http://www.cdc.gov/healthcommunication/ToolsTemplates/SocialMediaToolkit_BM.pdf

How can social media be integrated into health communication? Have a look at the Social Media Toolkit for health communicators. It is provided by the US Center for Disease Control and Prevention, gives guidance and shares experiences. This toolkit is not only helpful for optimising communication in the health sector but is also a valuable source if you want to learn more about effective social media communication.

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

Karin Eichele

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Tips for marketing your business through Twitter

The following are 3 of the 6 tips for promoting your business given in an Internet posting by Nicola Ziady titled "6 tips to successfully use #Twitter in business"

- arranging for several users to tweet about your business to make the tweets more believable
- using industry hashtags to send out the message beyond your followers (Healthcare specific hashtags include #hscm, #hcmkg, #socialhc and #WebMarketing)
- using URL shorteners such as bit.ly (<https://bitly.com/>)

For the other three tips see: <http://nicolaziady.com/2011/04/6-tips-to-successfully-use-twitter-in-business-2/>

With thanks to **Alison McIntosh** (aagmedicalwriting@btinternet.com) for sending this URL.



Much confusion about what constitutes ghostwriting

by Adam Jacobs

In this issue, we look at 4 papers (3 of them from *PLoS Medicine*) which all discuss ghostwriting, although they don't seem to entirely agree what it is. Our first paper uses a rather idiosyncratic definition of ghostwriting, and therefore comes across as rather confused. It also badly misrepresents EMWA's position on ghostwriting. The second paper, which proposes a novel solution to the ghostwriting problem, uses a more conventional definition of it, although it fails to make the distinction between ghostwriting and ethical medical writing. The third paper is written by someone who admits to having been a ghostwriter, although as it describes the experiences of only one person, it is impossible to know whether those experiences are common. The final paper is thoroughly critical of Evil Big Pharma because of their sneaky tendency to follow authorship guidelines (yes, you read that right).

So, on to our first paper, by Jonathan Leo and colleagues [1]. To Leo et al, a ghostwriter is anyone who contributed to writing a paper and is not listed as a byline author. Their paper is rather confusing to read, as it uses this definition of ghostwriting throughout, and describes many papers that transparently described the role of the medical writer as having been 'ghostwritten'.

As most EMWA members will be aware, the ICMJE criteria for authorship do not allow someone to be an author simply for writing a draft of a manuscript: other criteria need to be fulfilled as well. Leo et al recognise this, and call for the ICMJE criteria to be revised. They strongly believe that it's unacceptable for a medical writer to be credited in an acknowledgements section and not listed in an authorship byline, although their reason for this is hard to follow. It seems to revolve around the assertion that ghostwriting is bad, because it hides the origin of the paper (which is perfectly true), and mentioning a medical writer only in acknowledgements is ghostwriting, and therefore bad. However, that argument only makes sense if one uses the more standard definition of ghostwriting in which a medical writer's role is not described anywhere, and not the definition of ghostwriting that Leo et al use.

Disappointingly, Leo et al substantially misrepresent EMWA's position here. They describe the practice of thanking medical writers in an acknowledgements section for 'editorial assistance', and state that EMWA "sanction this practice." In fact, our guidelines specifically recommend avoiding that phrasing. Perhaps if Leo et al had hired

a professional medical writer to help with their manuscript they could have avoided making such a mistake?

I enjoyed reading the second paper, by Simon Stern and Trudo Lemmens from the Faculty of Law at the University of Toronto [2]. They describe the possibility of using legal action for fraud to combat guest authors of ghostwritten articles. In one sense, this is a nice idea. Everyone knows that ghostwriting and guest authorship are bad, but we also know that it still happens (although we don't know how often). Enforcing current guidelines on those who knowingly flout them is not easy to do, so if those guilty of dishonest authorship practices could be pursued through the courts, it might act as an important deterrent. However, I have my doubts about how practicable this would be. Legal action is expensive and cumbersome, and unlikely to be used in practice in any but the worst cases. Still, if a small number of high profile cases were to act as a deterrent, that would be welcome.

Nonetheless, despite being largely an interesting read, the paper also annoyed me. They mention medical writers only in the context of ghostwriting, and fail to mention the legitimate and valuable role of transparently acknowledged, ethical medical writers. They also focus entirely on industry-sponsored publications. Guest authorship is known to be a problem in academia as well: why isn't that bad too?

I was surprised to read the third paper in a prestigious journal such as *PLoS Medicine*: a personal account of some experiences by Linda Logdberg, who, by her own admission, had been a ghostwriter [3]. It is merely some anecdotes by someone who admits to having written articles in an unethical way. I'm not sure what it teaches us: we already know that some people have done unethical things. One person's anecdotes do not advance that knowledge. Quantitative data about the practices described would be useful, but they are entirely lacking from the article. It is particularly strange given *PLoS Medicine*'s statement in their instructions for authors that they do not publish case reports.

Our fourth and final paper, by Alastair Matheson, is really rather odd. It consists of a scathing attack on Evil Big Pharma for—wait for it—following the ICMJE criteria on authorship [4]. It accuses pharma of using the ICMJE guidelines "for inappropriate attributions of authorship." Inappropriate in whose opinion, one wonders? Pharma medical writers are also accused of "evading the visibility of byline authorship." Or, to put it another way, given that ICMJE criteria generally do not grant byline authorship to >

Journal watch

> medical writers, “complying with widely accepted guidelines.” Matheson appears to take a very similar position here to Leo and colleagues, arguing that medical writers should be listed as byline authors, even if they don’t fulfil currently accepted authorship criteria. Like Leo et al, Matheson also calls for ICMJE criteria to be revised.

It is, I believe, a legitimate matter for debate whether current ICMJE authorship criteria are the best criteria that there are. I cannot think of any compelling reason why medical writers should not be listed as byline authors, although clearly their role would still need to be made clear to readers. Readers who care about authorship (who I suspect are a tiny fraction of all readers) understand that being a byline author generally means (or should mean) fulfilling ICMJE criteria for authorship, so to list a medical writer as an author while ICMJE criteria remain as they are today would be misleading. Nonetheless, if guidelines were changed so that we all understood authorship to be something different, such that medical writers would normally qualify as authors, I cannot see any problem in listing them as authors.

However, I am also not convinced by the arguments that Leo et al and Matheson make that the current situation, where medical writers are acknowledged, is so terrible. Ultimately, this is a debate that journal editors need to tackle and resolve in whatever way they think best. I have no doubt that the medical writing community would be happy to co-operate with whatever system they come up with, should they decide to change the status quo.

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The following box gives more detail and a different view on the article in *PLoS Medicine* by Linda Logdberg mentioned in Journal watch

Ghostwriting: A former ghostwriter outlines her solution

Writing in the August issue of *PLoS Medicine* [1], former medical writer Linda Logdberg proposes a novel solution to the problem of ghostwriting.

In a remarkably candid article, Logdberg first describes some of the reasons why she became a medical writer (“the need for a job”) and remained one for as long as she did (the pay and the perks, among other things). She then goes on to explain her reasons for leaving it all behind: the lack of direct contact with researchers; the ethically dubious assignments (spinning severe, unpredictable vaginal bleeding as a beneficial consequence of using a particular contraceptive, for example). The final straw came when she was tasked with talking up an attention deficient hyperactive disorder (ADHD) drug which her own experiences as a mother of two children with ADHD led her to believe was a dud.

In the final, and most interesting, part of her article, Logdberg suggests a possible way of tackling ghostwriting (which, according to her description and my definition,

accounted for only a small portion of her work): getting research centres that employ so-called ‘guest authors’ to also hire medical writers, thereby enabling them to work together. This, she argues, would spell the end for MedEd companies—a good thing in her eyes. Other benefits she envisages are a reduction in the number of unfounded claims, faster publication of quality-assured articles, and a big boost to the morale of medical writers, who would be only too happy to return to the academic world.

The funding for these medical writers, Logdberg anticipates, would come from pharmaceutical companies. But can we really expect pharma to cede control of manuscript preparation to academia? Do we expect it to be satisfied with Logdberg’s vision of its own role, one limited to “factchecking... and clarifying issues about dosage, adverse events [and] post-marketing developments”?

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Reference:

1. Logdberg L. Being the Ghost in the Machine: A Medical Ghostwriter’s Personal View. *PLoS Med* 2011;8(8):e1001071.

Pleasing the reader (2)

First impressions

Sociologists tell us that the first 4 seconds of a new encounter are those that make a vital impression on the person we are meeting. Or is it the first 0.4 seconds? It matters little, since the impressions and judgments are made before we even realise they are. This person has a nice smile ... but odd clothes; is open; could fit well into our department; is honest; is shifty. We process the information as it reaches us and form a first opinion very quickly.

How many seconds does it take us to pass judgment on a document that falls into our hands? We scan it: key words of the title—authors—our eyes flash up to the header—journal name, year or company logo—we flick through to the last page to see how long it is—shall I read it now? —ever? —then back to the title to read every word this time, gathering impressions as we go. We weigh up needs, interest and time. We all have too many papers, articles and books waiting to be read. How do we decide whether the thing we hold in our hands or scroll through on our screen is going to be worth the effort?

Layout

Subconsciously at first, we will decide whether it is pleasing to the eye. The layout must appeal. When writing a document, use headings and sub-headings to guide your reader and think about paragraphing. Using too many will make your writing look bitty and busy and will give the impression that you have not managed to collect your ideas into any sort of logical ‘story’. Using too few might indicate the same, and will certainly discourage readers before they have started. Reading your text will appear a mammoth task—probably one to be put off several times. Using just the right number of paragraphs and helpfully indicating, by variation of spacing and subheadings, how your thought clusters fit together, will lift readers’ spirits, help them to pace their reading, and look forward to the ‘story’ you are telling.

Make sure that there is less space between a heading and the text following it than there is between that text and the next heading (Figure 1). Make sure that sub-headings clearly ‘belong’ to the heading above and are not new topics, by using a numbering system or appropriately styled bullets or typeface. Again, vary the paragraph spacing in a logical manner, keeping together that which belongs together. Often, medical writers will be using templates that, for better or for worse, will take these decisions from them. But sometimes it will be precisely for our skills in presentation and word processing that someone has engaged our services.

Similarly, the choice of typeface and font will often have been made for us. If it hasn’t, do consider your readers before you use Goudy Stout Italic because you think its quiriness will enhance your writing. The chances are that there are very good reasons why it has made only rare appearances on the world publication stage. There are other ways of standing out from the crowd. Typefaces that are too small, too large, mixed, fancy or loud should be avoided in our line of work.

Pay attention to capitalisation and be consistent! It is acceptable to capitalise only the first word in a title or heading or to capitalise every (large) word (the rules governing the latter convention depend on the style guide you observe). Choose which style you prefer or refer to the style guidelines you need to follow and stick to them. In English, proper nouns are always capitalised. A proper noun is the name of a particular person, place or thing.

Titles

Having gathered some first impressions, the reader will more consciously start to read some keywords or small chunks of text (not necessarily in the order in which they come), and will hope to recognise a few names, terms, and subject matter. We look to the title to help us home in on the content. *The Write Stuff* devoted a whole issue [1] to the titles of biomedical journal articles, and in her article there [2] Viviana Soler described titles as “the doors that allow readers to access the content of a text.” In the context of ‘pleasing the reader’, the door metaphor emphasises the importance of a good title, but Soler also recognises that it is difficult to consider all types of reader. A fine balance is needed between using the correct medical terminology, giving the correct impression of the results obtained, and making the title understandable for all potential readers. A title that is too long or that needs to be read several times to be understood is not kind to the reader. Neither is one that is too short or too general. Think about your title, discuss it with your team, and work on it. Come back to it again and again, and make sure that it effectively describes the content of the text you have written. Remember to adapt it as sections of your text get red-penned or new results are included. Test your title on a couple of people, if possible one with medical and one with linguistic expertise. >

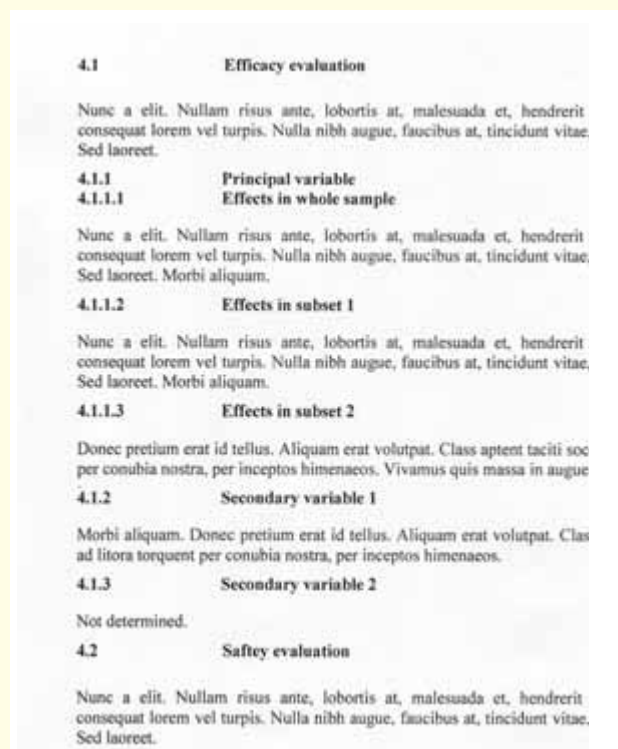


Figure 1: An example of inappropriate spacing between section headings and text, and poor differentiation of headings

Good writing practice

- > People notice different things and are sensitive to different issues. Recently, a study title had been agreed upon by the whole European team in my company, but an American colleague who came on board at the end of the process objected strongly to the use of the word ‘girls’ in a paediatric study. ‘Female adolescents’ was finally chosen as the most appropriate way to describe the study population, ensuring no offence was given.

The title of a clinical study may be set in stone once it has been registered with health authorities, but there is nothing to stop you adding a sub-title that is more understandable to the general public on your patient information leaflet. Similarly, the title of the article in the medical journal publishing the results can be made more specific.

Errors

Avoiding mistakes, no matter how small, has to be the priority of every writer. None of us wants to be shamed in public. Clearly identifiable mistakes or typos (especially on the first page), mistakes in the header or footer, misspellings and inconsistencies also annoy the reader. The danger in working intensively on a document for a long time is that we no longer ‘see’ it properly, even if we think we do [3]. Sometimes, if we’ve got really fed up with it, we don’t even want to ‘look’ any more. That’s when a fresh pair of eyes can be really helpful. If you can get someone to give your document even a perfunctory ‘once over’ with a critical eye, it is to be recommended. In days gone by, I often discovered mistakes in my own or in others’ documents while standing at the photocopier. Just before the document was posted off to a dozen people I would notice the most glaring of mistakes. Nowadays we push the ‘send’ button and often don’t even have the document open on the screen as we do it. Sometimes we might not even have printed it. Beware! We have all produced documents that looked perfect on the screen but then somehow metamorphosed on being squeezed through the rollers of the printer. So, I encourage you to take a last look. It’s such a relief when you discover last year’s date yourself, rather than waiting for the Principal Investigator’s secretary to point it out.

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2. Soler V, Medicine and linguistics: A necessary symbiosis in medical titles. *The Write Stuff*, 2007;16(4):151-152
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Overwriting (1)

Overwriting occurs in two forms: (i) repeating information unnecessarily, and (ii) giving the reader more (and often much more!) information than they actually need to understand your point.

Overwriting does not mean using wordy phrases or polysyllabic words that are supposed to sound impressive, e.g. ‘therapeutic armamentarium’, ‘on a regular basis’ and ‘utilise’ instead of ‘treatments available’, ‘regularly’ and ‘use’. Nor does it refer to conceptual errors that lead to longer and incorrect formulations. More often than not, it is not done to impress, but because authors do not think

about what they are writing or just copy what other authors do—or they write as they speak. When we speak, we can take many more liberties with listeners than with readers when we write. Stamping out verbosity in your texts is not easy and takes much self-discipline.

Overwriting is easier to cure, but authors still have to apply themselves to eradicate it. Freeing yourself from unnecessary repetition is all to do with gaining confidence in yourself as an author. This also applies to giving the reader more information than they require, but there is evidence that the latter type of overwriting is also affected by the author’s culture [1]. The effect of culture on writing practices will be considered in future issues of *TWS*.

Two simple examples illustrate the two types of overwriting and how they differ from verbosity and conceptual errors.

Unnecessary repetition – {-} = conceptual error; [-] = verbosity; (-) = unnecessary repetition:

{The design of} the present study {aimed to compare} women with symptomatic leiomyoma during pregnancy treated with myomectomy and women (with symptomatic leiomyoma during pregnancy) [who underwent conservative treatment] (for leiomyoma) [in order] to determine differences in clinical features on presentation (between the two groups of patients).

The design did not compare anything. The study actually compared the two groups and did not just aim to do so. The phrase ‘who underwent conservative treatment’ could just be ‘treated conservatively’. ‘In order’ is always superfluous. ‘With symptomatic leiomyoma during pregnancy’, ‘for leiomyoma’, and ‘between the two groups of patients’ are unnecessary repetitions. ‘Between the two groups of patients’ does not look like a repetition at a first glance, but it is: we know there are two groups and the study compared them, so we know the study was looking for differences ‘between the two groups of patients’. Leave it out. Repetition does not just mean using exactly the same words, but also repeating the same ideas.

Sometimes overwriting in the form of repetition is necessary—but this is the exception.

Excess information:

5 patients underwent myomectomy: 4 of these patients (80.0%) had preoperative abdominal pain and 1 (20.0%) had premature labor and abdominal pain.

It hardly needs to be pointed out here that the percentages in brackets are examples of excess information and that the addition of 20.0% in brackets after the 1 is almost absurd—or even an insult to the reader.

The only argument that might be valid in similar cases is that it was done for the sake of consistency. But even though consistency is one of the high principles of GWP, we will see in later issues that there are definitely instances where consistency is not necessary—and even not desirable.

We will be looking at other examples of overwriting in the future.

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References:

1. House, J, 1997. Translation quality assessment: a model revisited. Gunter Narr Verlag, Tübingen, Germany

Checklists (1)

Scientific writers are required to maintain high standards when reporting on research results to avoid inaccurate reporting and, in some cases, substantial wastage of money. The Consolidated Standards of Reporting Trials (CONSORT) statement, issued in 2001, was the first example of a comprehensive and structured guideline including practical examples and a clear explanation of how to use it to communicate the results of randomised clinical trials (RCTs). The CONSORT guidelines also included templates to use as checklists when writing certain parts of articles, for example, the abstract. The CONSORT statement was updated in 2010 and now includes 8 official extensions, mostly in the form of checklists and detailed instructions to be used when reporting on the results of 'special' RCTs: non-inferiority studies, cluster RCTs, harms-related RCTs, herbal and non-pharmacological interventions and acupuncture, pragmatic trials, and abstracts for congresses. To date, 20 non-official extensions to CONSORT have also been developed as guidelines for the reporting of results from almost any kind of RCT research.

In addition to these, different guidelines and checklists to use for the results of observational, health-outcome, quality-of-life, mixed-method, and many other types of studies have been published. To complement all of these, pharmaceutical companies have developed Good Publication Practice, individual editors have developed their own guidelines, most journals have their own instructions for authors.

We are fortunate that the EQUATOR (Enhancing the QUALity and Transparency Of health Research) programme (<http://www.equator-network.org>) was financed

by UK National Health Service to collect and provide a comprehensive and updated index of all these standards.

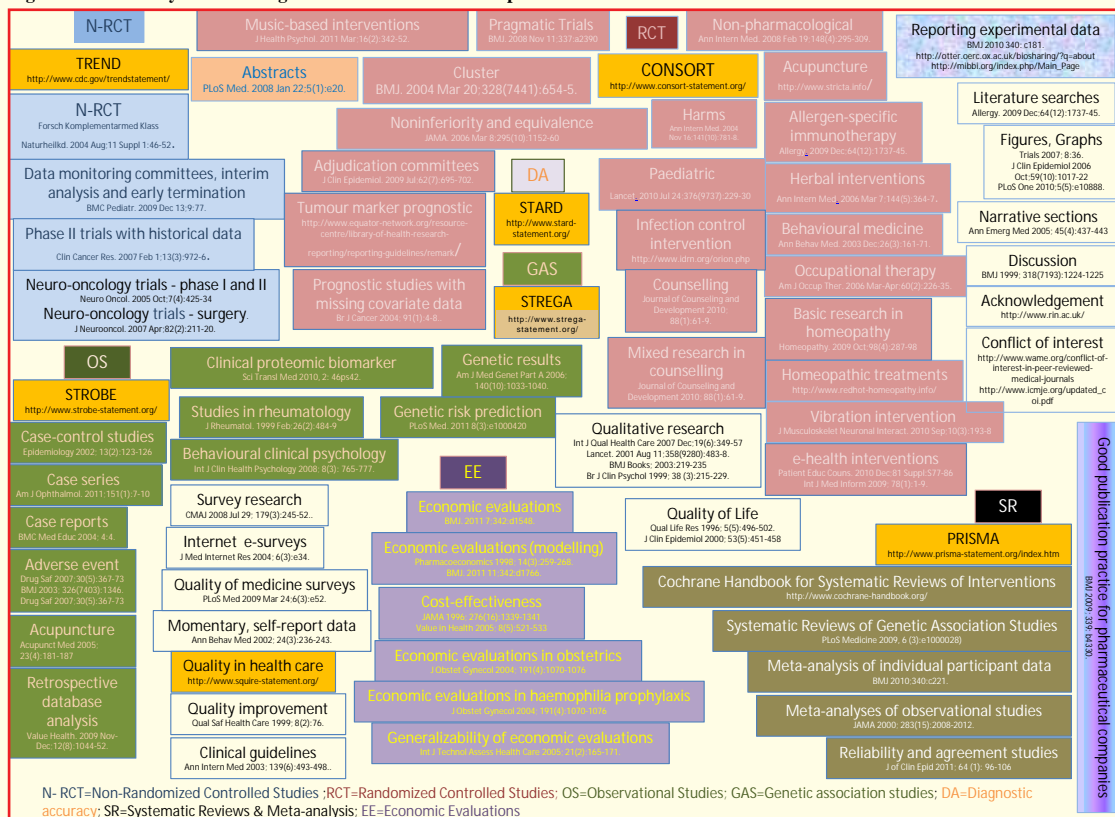
For regulatory purposes, other standards have been developed, the most famous being the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Also for regulatory purposes, most major pharmaceutical companies have developed their own templates based on ICH to produce the documents required.

Most of the guidelines are simple checklists, and others are templates. In some cases they include questions or just headings. A CONSORT-like structure is preferable for all types of guideline, but they should not be allowed to become too long, complex or time-consuming to apply; sometimes you can overdo checklists and forms, and spend more time dealing with these than writing.

Since it is generally recognised that they improve the quality of the scientific literature, their number is going to increase in the future. Figure 1 shows how the large number of checklists and guidelines available have been grouped in EQUATOR to simplify the identification of the most appropriate choice for the text under preparation. Guidelines being developed specifically to standardise terminology in health research reporting and those developed for specific diseases or conditions may not be included. In the near future, a group at EMWA hopes to develop a more comprehensive guideline that will assist the writer in identifying the most appropriate guideline, checklist or template for the information they wish to present.

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Figure 1: Summary of the main guidelines and checklists for publication of scientific data



Out on our own



We hope everybody had a great summer break.

In this issue, we are delighted to have US-based freelancer, Brian Bass, Fellow of the American Medical Writers Association (AMWA) and author of *The Accidental Medical Writer*[®] Series (www.theaccidentalmedicalwriter.com) contribute to OOOO. In the first of a series of

business-based articles, Brian and Sam debate different ways of charging for freelance services.

In our Out of Hours series, Ursula Schoenberg shares with us the delights and challenges of short story writing.

We are lucky to have the EMWA Berlin conference revisited in this issue from the perspective of a non-writer, thanks to Anders Holmqvist.

And finally, we wrap up with the 3rd of Diana's interview series with freelance EMWA members.

In the upcoming issues, OOOO will bring you a series of articles on life-coaching for freelancers.

As discussed at the Freelance Business Forum in Berlin, a checklist of items to be included in a contract/work order would be an invaluable resource for freelancers. We are happy to inform you that we have been working on this document and we hope to present to it you at the meeting in London at the 33rd EMWA Conference (3-4 November 2011). This resource will also be published in TWS's December issue and archived in the Freelance Resource Centre of the EMWA website. No doubt this document will continue to grow and evolve as we receive more input from other freelancers. In other words, we want to hear from you, too. Special thanks to Claudia Frumento and Andrea Palluch for their valuable inputs.

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The Berlin conference— A review from a non-writer

by Anders Holmqvist

My expectations on the trip to Berlin were high—finally the moment had come when I would meet the people in real life with whom up until then I had only had contact with via e-mail or LinkedIn. Unlike the other 32nd EMWA participants, I didn't attend any workshops since I'm not a medical writer. Instead, my mission as a freelance art director, illustrator, photographer and project manager was to make contacts with medical writers. So there I was, in the lobby of Andel's hotel, trying to recognise people from the pictures I had seen in TWS or LinkedIn, rather like a detective!

Over 17 years I have collaborated closely with a medical communications consultant/writer in Sweden. In recent years our main focus was on illustrated reporting from international medical conferences. When my Swedish writer colleague decided to retire two years ago, I started to look for his successor. I contacted several medical writers via the EMWA homepage and have remained in regular contact with them via e-mails, LinkedIn or Skype. Before the Berlin meeting I had already had the pleasure of collaborating with a couple of EMWA members to report on scientific symposia. But as a freelancer you cannot afford to rest on your laurels; when you're not working you have to be active and find opportunities to promote yourself and what you can offer. Otherwise there is a huge risk that, one or two months down the line, you will find yourself existing solely on tinned spaghetti bolognese eight days a week.

I saw a great opportunity in the EMWA spring conference as it took place in rather close proximity to my home and in a city that I'm always pleased to return to. I was eager to catch up with old (Internet-) contacts and hopefully make new ones as well. I made a rough estimate; could I afford this trip? Business hadn't flourished for a while, and my boss (myself!) made it perfectly clear that this business trip had to be on a 'super-tight budget' in every sense. I was lucky to find a cheap return flight (106 €) from Copenhagen, only 33 minutes by train (thanks to the bridge between Sweden and Denmark) from my home town Lund in the southernmost part of Sweden. Furthermore, I found a decent hotel in Uhlandstrasse for 68 € for three nights, breakfast included, albeit with shared WC facilities. The boss grudgingly gave his approval, on the express condition that I restricted myself to live on cheap curry-wurst¹ and Berliner Kindl² for 3 days...

So was this trip worthwhile in terms of time and money? I'm inclined to say "yes." Time—I had plenty of it. Money—my super-tight budget efforts paid off admirably. I had plenty of opportunities to reach a large number of potential collaborators among the 367 attendees, through conversation and by putting my information leaflet on the

¹ curry sausage
² a type of beer

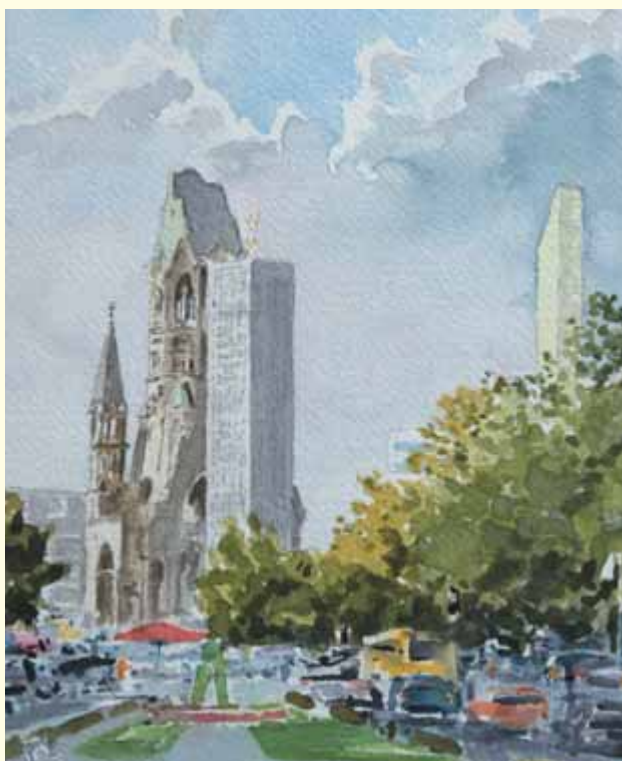
The Berlin conference—A review from a non-writer

registration/ hospitality desk in the lobby. Among the new acquaintances were at least one or two medical writers with whom I plan to bring out a joint information leaflet, in which we will offer clients a ‘complete package’: text, photos, graphs and references in one hit.

As I stood in the hotel lobby, lobbying, there were times when I found it difficult to explain in a simple way my idea of collaboration which could help freelance medical communication projects. On these occasions I felt like a salesman more than anything else, a job category that I myself find very hard to tolerate when on the receiving end of the pitch! I imagine that not just me, but writers too would find a notice board useful where business partner messages or tips on various medical writing-related jobs could be displayed. In fact, there was a notice board in Berlin, but its purpose wasn’t pointed out prominently. Maybe a suggestion for the 33rd EMWA conference?

When a freelancer hits upon hard times, it might be helpful to think ‘outside the box’. In my case this thinking brought me to Berlin. For a freelance medical or scientific writer, this outside-the-box-thinking could mean permitting yourself to consider teaming up with a partner who can assist you with aspects other than text writing.

Being a non-writer, I did not attend any seminars or workshops at the conference, so I’m not aware whether alternative medical writing opportunities have been discussed such as symposia reporting and proceedings, booklets, reporting on international medical conferences, textbook and magazine/newsletter production, monographs, etc. My suggestion for freelance scientific and medical writers who are prepared to think outside the box is to embrace these possibilities. I’m fully aware that issues such



as confidentiality, copyrights, credibility, etc. may arise, which will be important to address when planning seminars and workshops for future conferences.

My time in the Andel’s Hotel lobby was an intense experience. I met lots of friendly and open-minded people from all over Europe—the language centre of my brain almost overheated, switching from Swedish to German, English, French and Danish or a mixture of everything. I was especially pleased to finally meet the very nice crowd of people working with TWS, with whom I have been in contact as part of my commission to contribute illustrations and photos to the journal. The hours passed quickly, and in the afternoon it was refreshing to experience the solitude (and the Berliner Kindl), strolling around and exploring a city that never ceases to fascinate. I used the S-Bahn to travel to and from the conference, which gave me a bunch of ideas on new watercolour motifs (I’m a watercolour artist as well), simply looking out of the window. “*Wenn jemand eine Reise tut, so kann er was erzählen*”³, a German poet wrote, and as I’m rapidly running out of words, I’m delighted to be able to put this obvious phrase into pictures instead. After all, I’m not a writer...

Acknowledgements

Thanks to Maria Dalby for (as always) constructive comments on this article.

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³ Can be translated as “he who travels has a tale to tell.”



Opposing views: Project versus hourly rates

by Brian Bass and Sam Hamilton



One of the greatest challenges facing freelancers is deciding how to charge for their services. The debate rages on about the use of project pricing—that is, a fixed fee based on set project specifications—versus charging by the hour for services rendered. In this article, two experienced freelance medical writers present their views.

Brian:

The Case for project pricing

In my opinion, the age-old debate of hourly based versus project-based fees is no debate at all. There is certainly a time and place for hourly fees; for example, when you're just getting started (for a short while until you gain experience), or when you're working on premises (and the number of hours you are putting in is obvious to the person buying your services). Otherwise, charging an hourly rate punishes the proficient and rewards the inefficient.

The reasons are simple: (1) there is a maximum hourly rate that companies are willing to pay; (2) most people get better and faster the more they work in a chosen field; and (3) the bottom-line cost is what matters most to the company hiring the freelance writer.

Viewed a different way, consider this example:

Hourly rate

A writer starting out may charge €60 an hour and take 50 hours to complete a project, for a total of €3000, which is quite acceptable to the client. As the writer gets better, he or she increases the hourly rate to €70, completes the same project in just 30 hours, and earns only €2100—a €900 (30%) cut for being a better writer. In time, the writer becomes even more proficient, and increases his or her hourly rate to €88. The same project is now completed in just 20 hours, and the writer earns only €1760—41% less than when the writer started out and was charging 32% less per hour.

In this scenario, the better you get at what you do, the more you are financially punished, and the harder you have to work to earn the same pay as when you were a less-proficient writer.

Project rate

A writer starting out charges €3000 for a project, a rate that is quite acceptable to the client. He or she takes 50 hours to complete the project, earning the equivalent of €60 per hour. As the writer becomes more proficient, he or she charges €3000 for the same project, but now completes

the project in 30 hours. He or she has just earned €100 per hour, a 67% rate increase. In time, the writer becomes even more proficient. Charging €3000 again for the same project, he or she now completes it in just 20 hours, earning the equivalent of €150 per hour! That's a 150% increase in earnings over when the writer started out, and does not take into account the increasing value of the project to the client over time, which should enable the writer to increase the project rate and earn even more.

In this scenario, you are rewarded for getting better at what you do, earning a rate I dare say few clients would be willing to pay. You can then choose to either work less for the same income or continue working hard and earn lots more money!

The challenge of project pricing

I believe project pricing is the smartest way to work from a business standpoint, but it's much easier to give your client an hourly rate and let them worry about the budget. In this respect, I use project pricing as a marketing tool. I tell my clients I will stand behind my project estimate no matter how efficient I am, as long as no project conditions change. This instantly erases one of the greatest concerns clients have when hiring freelancers—their budget. As a result, my clients see me as a partner rather than as merely a vendor, or worse yet, as an expense.

Of course, the challenge of project pricing is calculating the estimate. I start by preparing several estimates for the project using different factors including the amount of TIME I expect the project will take, my EXPERIENCE with similar projects and what I charged for those projects, what my COLLEAGUES might charge, and what I consider the VALUE of the deliverable to be to my client. I ask a lot of questions up front to define the scope of the deliverable and identify my client's expectations, and I define the limitations myself if the client doesn't provide all (or any) of the information I need. Everything gets documented in my estimate, so if any part is incorrect the client will let me know, and if the project goes out of scope I can revise my estimate based on the new specifications. My estimate is usually so buttoned down it becomes our contract.

To help you develop project estimates, you can get a free Freelance Estimating Checklist at www.theaccidentalmedicalwriter.com.

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Sam:

The Case for the hourly rate

In my opinion, we need to remain flexible so that we can deliver the products our clients want and in a way that best fits their business model. After all, if we aren't able to conform, then we are out of the running as a potential vendor.

What clients want

Suppose an EU-based pharma company, contract research organisation (CRO) or biotech company sends out a request for a proposal (RFP) for preparation of a regulatory medical writing deliverable. You ask your potential client if they prefer an hourly rate with an upper limit on the number of hours, or a set fee for the entire deliverable. Your client doesn't mind either way, so you propose a set fee. Your detailed proposal, including project-specific assumptions, is well-received and you win the project.

You are now required to fit in with your client's administrative systems and are set up on their timesheet system. You are expected to enter the daily hours worked on the project and submit them on a weekly or monthly basis. This is where your carefully bid, set-fee approach may start to unravel. By the end of the project, it is clear to your client that you are a highly efficient worker, but your hourly rate puts you out of the frame for the next project.

The question you should really have asked at the RFP stage was 'Do you have timesheets that I would be required to complete?' If the answer is 'yes', and in my experience, only the smaller biotechs will say 'no', then you must quote by the hour.

Don't get lost in the detail

It isn't necessary to break the hours down in your RFP any more than to the level of say a draft and a final version deliverable. How you expend the overall number of hours is then up to you. The simpler the breakdown of proposed hours, the easier it is for both you and your client to track. By reviewing past proposals for similar projects and comparing with actual expended hours, it is possible to fine tune proposed hours to place you well amongst potential vendors.

Fair price

Value for money is always appreciated. This does not mean that you need to keep your hourly rate low. Clients are prepared to pay more for those with expertise and experience, so use your knowledge of freelance business rates in Europe [1] and set your hourly rate fairly, whilst keeping your level of expertise, experience and earning requirements in mind. A project delivered on time, and within budget at a fair rate will inevitably cast you in a favourable light when your client has another project to resource.

Repeat business

Repeat business is what it is all about. Imagine a situation where over 90% of your work is for regular clients. You no longer need to seek out business because it comes to you through your pool of regulars. Over the longer term,

Opposing views: Project versus hourly rates

relationships develop that allow more flexibility in your working than if the client doesn't know and trust you. You maintain a steady flow of work over the year, without having to seek out each individual project, which can be unsettling, exhausting, and a distraction from paid work.

Fairness and transparency, flow of work and relationship-building all drive the case for the hourly rate. Now you decide....

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Look what's in store for you in Kensington

We recently gave a training event near Gloucester Road tube station in London. Looking for a restaurant one evening, we chanced upon a pharmacy (not a national chain) with the following to offer:

We couldn't help wondering how the "confidential assessment" is performed. And look at the name of the shop!!

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Barbara Grossman

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Out of Hours: On Chekhov, elephants and writing for pleasure

by Ursula Schoenberg

The Chekhov should have tipped me off. It was one of the short stories on the required reading list I had received after enrolling in the course 'Write a Short Story in a Weekend'. I can't stand Russian writers. As Marvin the paranoid android from the 'Hitchhikers Guide to the Galaxy' says, they make me feel very depressed. None of the other selections appealed to me much either. The Zadie Smith was quite good, but paradoxically rather short for a 'real' short story, and with more non-fictional than fictional overtones. I was taking this course to expand on my non-fiction writing and to break through my 1,000 word barrier! Was the weekend in London going to turn out as I had hoped?

To backtrack: The older I get the more I realise that the only thing that gets me into a reliable state of 'flow' is writing. Professionally, this can get me into some hot water (seen from a cost-benefit perspective) if I go that extra mile for a piece of work that is already good enough, but that I'm so engrossed in that I lose my sense of time. I try

to avoid that. Privately, I also spend a good deal of my time writing. But this 'out of hours' writing isn't destined to pay my rent or save me from a doddering old age filling supermarket shelves. It is 'amateur', done from love of the activity and nothing else.

It started several years ago, when I saw a sign in a local shop announcing a 'Creative Non-Fiction Workshop for Beginners'. That's for me, I thought. I'd hitherto resolutely suppressed the impulse to write other than professionally. Not that a part of me didn't have a niggling suspicion that I was ignoring the elephant in the room. A living room full of books. Countless biographies of women writers on my bookshelves. Genetic predisposition in the form of my mother, who I remember either typing wildly at her desk or perched in the American wilderness with a diary on her knee, scribbling. The pile of lovingly written and illustrated stories I'd compiled in grade school that were hidden in a box in my garage.

Grasping the elephant resolutely by the tusks, I enrolled in the course and got to know Kate Baggott, the Canadian writer offering the workshop. She gently coaxed our group of six (all women) along and encouraged us to tweak and share our stories. The result was several non-fiction pieces that I defiantly put up on a personal blog to give myself the courage to persevere. I sent out several pieces to writing competitions, with limited success. Thanks to the Internet you can spend days of your life researching places to send your work and hope that someone will take notice and nominate you for a short list.

From writing short pieces of creative non-fiction I decided to try writing fiction. This, I must admit, was a challenge. Ideas aren't the problem. I've got plenty of those. But finding the right form to tell a story doesn't come easily to me. I decided to start small and concentrate on what is called 'flash fiction', i.e. short pieces of fiction that don't much exceed 1,000 words. These too, I put up on my 'secret' blog, with great personal satisfaction, if not for widespread fame and fortune. In the meantime, I had discovered how simple it is to make your own books with the help of web-based programs. This gave me an idea.

As a child I had always been fascinated by my parents' stories of what had happened to them as children. One of my most cherished possessions is a 'real life' account my mother left me about experiences she had during her teens. Now that I had a host of tools at my fingertips allowing me to write and design my own books, I decided to do the



same for my daughter. Thus were born 'Stories for S.', a small book with about twenty stories, each recounting an episode that had happened to me during childhood. I kept the language simple and put in lots of animals for interesting reading. What I learned in the process: It is easier to write when you can visualise your reader.

And then I decided to enroll in that three-day workshop I mentioned earlier, organised by a renowned British publishing house. It was to be tutored by a famous son of a famous writer, with an even more famous author as a kind of 'spiritus rector'. The weekend was fun, though for all the wrong reasons. As far as my fiction writing goes, it was disastrous. I produced the most fatuous short story with the flattest characters I had ever written, in spite of non-flagging encouragement by the tutor. I freely admit I chickened out of the 'now we're all going to read our stories out loud to the other participants' phase and spent a thoroughly enjoyable day walking around London instead.

What have I learned from my 'out of hours' writing? Several things that can also be applied to my professional writing: to have a vague idea of where you are going when you sit down to write. Whenever possible to let a finished piece of writing lie for at least a day before giving it a final edit. Not to panic when the words won't come, but to draw back and be confident that the creative mind will take over. To read a piece of writing out loud to expose potential flaws. And last but not least: to visualise who you are writing for and then do so with clarity of voice and a sense of structure. All of this makes good writing and has to be worked at. Day after day after day.

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Cheap labour

As we at Dianthus Medical have worked on a number of systematic literature reviews, I know how much work they can be. Imagine my surprise, therefore, when I saw this advert (<http://t.co/Q5jrsq7>) for a writer wanted for a systematic literature review, which specified a budget of \$250-\$750. Worse still, several people have replied, apparently willing to do the work within budget. Either they are working for pennies per hour, or this literature review is not going to be completely systematic. It would be scary to think that it might one day get published.

Adam Jacobs

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Pharma and biotech have the best jobs for working mums

Check this out, fellow travellers in the work-life balance continuum. It seems we are on the right track, after all. Or rather in the right industry in the right era.

According to a review by CareerBliss, an online career community and resource, "the happiest jobs" for working mums are in the pharmaceutical and the biotech industries.

This is based on 60,000 employee reviews by women. Here is what these happy mums have to say about these industries:

1. **Pharmaceutical.** The pharmaceutical industry offers job titles that provide job satisfaction and flexibility for working moms. A post-doctoral scholar, for instance, spends their time developing new medication to improve healthcare. Many real past and present post-doctoral scholars reported to CareerBliss that their employers offer premium childcare needs, annual vacation leave, holiday leave, and limited hours per week. The average salary of a post-doctoral scholar is \$39,944.00.
2. **Biotech.** The biotech industry, particularly consulting for a biotech company, is excellent for working moms because it can be freelance, where schedules can be catered to your needs. As a consultant in the biotechnology field, hours can be negotiated with employers who hire you to consult for them. The average salary for a biotech consultant is \$77,517.00.¹

The other industries among the top 5 choices in descending order are:

3. Administrative/Clerical
4. Accounting
5. Telecommunications

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¹ CareerBliss Team. The Happiest Jobs for Working Moms. Available at <http://www.careerbliss.com/advice/the-happiest-jobs-for-working-moms/>. Accessed 21 June 2011.

Thank you

Alistair Reeves would like to thank Sam, the freelance support group, and all those who kindly gave him a card and an Amazon voucher at the Berlin conference when he stepped down as freelance coordinator. Unfortunately, he won't be able to make it to London this autumn (the first EMWA event he has missed for 15 years) and so will have to wait until Cyprus to see everyone in person again.



Going freelance: The third of a series of interviews

by Diana Raffelsbauer

The third issue of the interview series ‘Going Freelance’ features four freelancers based in Germany. Connie Grogan is a chemist with expertise in writing regulatory documents. Stefan Lang is a biologist specialising in medical communications. Alistair Reeves is a certified life-science editor, and Marion Alzer is a sworn medical translator; both Alistair and Marion are linguists. How did they manage a successful career as medical writers and translators without being physicians or pharmacists? Despite the different academic backgrounds, they have some characteristics in common. For instance, they all love language and enjoy writing. Find out more similarities and differences by reading their answers below.

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

C. G.: I am a freelance medical writer offering expertise in English language scientific communication, in particular the preparation of the clinical dossier for marketing authorisation applications (MAAs). About half of my work is in the preparation of clinical overviews and clinical summaries for the common technical document (CTD), with later support for responses to the agency’s questions and issues. Otherwise, I write the clinical portion of briefing documents, paediatric investigational plans, investigator brochures as well as the occasional clinical study report (CSR) and manuscript. In addition to the actual writing, my role is to help clients to plan and coordinate their scientific documentation with processes that ensure high quality and reliable timelines.

S. L.: I offer scientific and medical writing, editorial services, and training in scientific writing. In 2010, assignments were distributed as follows: writing (60%), editing (5%), and training (35%). I predominantly write scientific papers for peer-reviewed journals, and, occasionally, marketing texts such as brochures or folders. My areas of expertise are molecular and cellular biology, oncology, nephrology, and virology.

A. R.: Author’s editing (mainly publications from industry or physicians in hospitals and office practice): 40%; editing regulatory and some medcomms texts: 25%; training in medical and scientific writing and editing: 25%; translation from German and Spanish into English: 10% (not necessarily scientific or medical).

M. A.: As a sworn medical translator, my working languages are English and German. I prefer to translate into my mother tongue German. My key services include:

translations, certified upon request, and back translations; proof-reading and editing; consecutive interpreting / ad hoc translation, for instance, during FDA inspections, GCP audits, or business meetings; translator training; quality control of CRFs, protocols, clinical study reports. The focus of my work is on translation of documents related to R&D, clinical evaluation and post-registration of medicinal products.

How did you become a medical writer?

C. G.: My interest in scientific writing came early. By the end of my undergraduate training (B.A., Chemistry, Indiana University), I had already completed two semesters of scientific writing courses, and I later left a doctorate program (M.A., Biology, Johns Hopkins University) to start my first job as a technical writer. I spent 6 years with Boehringer Mannheim, Biochemicals Div. (now Roche), where I served as the chief editor and contributor to their marketing newsletter and wrote package inserts and technical manuals. It was natural that my first job as a medical writer was for a biologics company (Immuno in Vienna, now Baxter), where I spent three years writing CSRs and manuscripts among other documents. My longest employment as a medical writer was with Astellas (formerly Fujisawa) in Munich, where the writing of CSRs and manuscripts was equally mixed with MAA submission documentation. There, I began to love the process of drug development and my particular role in it.

S. L.: After finishing my PhD in biology, I worked as a scientist in basic research for a couple of years. Then, I moved from academia to clinical research, becoming a project manager for diagnostics, and moved back to academia. Until then, my writing projects had been research papers, reviews, funding applications, some marketing texts. Importantly, after 10 years of research career, I realised that I have more fun writing research than conducting research. Consequently, I moved into scientific and medical writing. For about one year, I was employed as a scientific writer. Then I decided to freelance because it offers more flexibility.

A. R.: Made the difficult choice to study languages instead of science; joined Hoechst as a medical translator in 1978; gradually moved into medical writing from the mid-1980s onwards, then into document management and publishing at the end of the 1990s; made redundant in 2002. Gradual shift from writing and translation to author’s editing and training over the past 9 years.

The third of a series of interviews

M. A.: Initially, I chose a career in languages and studied medical translation. After my degree in Applied Linguistics (focus on medical translation) from a German university followed by an M.A. in Linguistics (focus on foreign language teaching) from an American university, I began my working life in a language services department for a leading global pharmaceutical company. The next position in a CRO gave me experience in the management and monitoring of clinical trials. After starting a family, this experience was sufficient to become self-employed.

Why did you choose to work as a freelancer?

C. G.: There seems to be two choices for career development as a medical writer: join management or open your own shop. My long-term professional goal was always to have a freelance consultancy. My work as an employee in industry was very rewarding in itself and was necessary to gain the practical experience essential for a freelancer. My former employers also generously supported my professional development through sponsoring of professional training through AMWA, EMWA, EASE, medical conferences and numerous other platforms.

S. L.: Deciding to work as a freelancer was a conscious life-style choice.

A. R.: I was made redundant after 24 years with Big Pharma. I had had enough of management and staff responsibility preventing me from doing hands-on work, I had no mortgage any more, and my children had finished university.

M. A.: I chose to work as a freelancer because it offered flexible working hours at home enabling me to follow my career while looking after my family.

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

C. G.: I am glad that I worked as an employee for some 20 years in industry before going freelance. It took about two years of professional experience to become proficient as a technical writer and another two years to adapt to a regulatory environment; however, the next 10 years were essential to become an expert. In regulatory writing, this means anticipating the viewpoint of members of the submission team and of the health authorities with every document that you write. This saves time, which is essential with the tight timelines faced by submission teams.

S. L.: A good general scientific background and the ability to think logically and to work systematically—both will help you to familiarise yourself with new subject areas in a short time.

A. R.: Apart from skills regarding the language aspects and content of the work (and not in order of importance):

Editing: You have to be a language lover who can remember that the author did not capitalise a word 15 pages before but just did (or similar); you have to be able to give

reasons why you make the changes you do to other people's work; and you have to know how to differentiate between personal preferences in language and changes that have to be made.

Training: Being able to do a good job (after all, it is a performance!) and making sure the students leave satisfied, even when you don't feel like it.

In general:

- A high level of self-discipline. That means being able to work long days at home alone without being distracted.
- Ability to be and work on your own. You might have e-mail and telephone contact all day, but at your idyllic office in the country that you always yearned for 'away from it all', the only real person you might see for several days at a stretch—and then maybe only for a couple of hours in the evening—is your partner (if you have one), also tired from a long day at work.
- Even if you are young, enthusiastic and ambitious, do your utmost not to work at weekends and on public holidays, and take the odd day off, apart from holiday (make sure you block holiday time in the calendar: you really do look forward to it!). If you are constantly tired and stressed, you are not doing yourself any favours, and you are certainly not doing your clients any favours.
- Extremely difficult: Learn to say no—and always make an obvious effort to find a colleague who might be able to help a client you have said no to.
- If a job is going to take longer than you originally estimated, let the client know as soon as possible. You will often find that what originally had a drop-dead deadline actually has a couple of day's leeway. Or put in a couple of weekends, as an exception.

M. A.: Primarily language skills complemented by a scientific background in the pharmaceutical industry, so that I understand both the content and purpose of the material to be translated. An entrepreneurial approach also helps to become successful as a freelancer.

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

C. G.: My biggest challenge is scheduling projects and making sure that no conflicts in scheduling arise. In all my projects as a freelancer so far, I am the only medical writer on the team, so the level of accountability is very high. Good relationships with clients depend on reliability as well as quality.

S. L.: The biggest challenge I have to face in my daily work is to work on various topics at the same time, writing texts in both English and German.

A. R.: 1) Believe it or not: stopping work. If I am enjoying what I am doing, even if I have been at it since 07:30 and planned to stop at 16:30, I might still find myself at the computer at 19:00 postponing the delicious meal I was

The third of a series of interviews

> going to cook until tomorrow. And we might not even get it tomorrow... 2) Keeping up with the latest developments.

M. A.: Acquiring and maintaining the necessary technical know-how and keeping up to date with the rapid development of communication technology and information technology. Working alone from home with the added complication of developing a business network and combining this with having to manage all domestic/family affairs can be a real challenge.

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

C. G.: I most like the actual task of writing; of course I also have to read a lot, but this I consider part of the task of writing. I least like to decline projects from favoured clients, which is sometimes essential to avoid scheduling conflicts.

S. L.: The diversity of both scientific issues and things I need to deal with as a freelancer is invigorating. But most of all, I like my personal freedom. What I like least is that I have to take care of all these administrative and technical details by myself. Tax matters and failing Internet connections top the ranking list.

A. R.: Like most: no boss, no staff, can say no to things I do not want to do. I will never 'have to retire', I can just gradually slow down (I hope). Also, seeing that quite a few clients learn from my work and that the writing they do has improved over the years thanks to my (I hope) help. I have never regretted leaving a salaried position. Like least: looking after my own IT matters, especially when something goes wrong.

M. A.: Dislikes include: tight deadlines, lack of recognition, poor remuneration vs. level of proficiency expected from the customer. These factors can create low self-esteem. Likes include: flexibility, being at home, being my own boss, avoidance of stress and time wasted commuting to work, freedom to choose which meetings or seminars to attend, the challenge and opportunity to meet and deal with new / existing clients. The latter has been a very positive experience as a freelancer.

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

C. G.: I advise professionals new to the field of medical writing to earn an EMWA or AMWA certificate and to take the certification test for Editor of Life Sciences (ELS) offered by the Board of Editors of Life Sciences (BELS). These are the basic building blocks of the trade. For those interested in regulatory writing, the first step is writing CSRs, because the CSR is the building block of the CTD. Afterwards, submission experience should be sought as soon as possible.

S. L.: You need practice but take as many opportunities to improve your writing skills as you can. There are many short and less expensive workshops for writing in different fields such as technical writing, journalism, editing, publishing, public relations, creative writing. Even if you are

never going to work as a journalist, technical writer, or novelist, any input will help you to advance much further in the field of scientific and medical writing.

A. R.: It is definitely more difficult to 'go freelance' when you are young than when you are 50, as I was. I think you probably have to have about 10 years of relevant experience before you can even think of making such a great step if you want to be credible to clients. You have to decide whether you want to work on your own or still in teams—you can still coordinate teams, even as a freelancer. Short-term, in-house contracts are being offered a lot by headhunters at present. These may sound attractive, but the danger is that you are suddenly working full-time again for six months, say, and on top of that you are still taking on other jobs in your spare time as you don't want to lose clients. It is easy to bite off more than you can chew.

M. A.: Anyone wishing to begin a career in medical writing or translation would be well placed to work in industry or in a service for a few years before taking the decision to become freelance. This provides a valuable insight into the background of the work, how and why contracts are created between different parties, the value created from high-quality translations, and hopefully the chance to develop a working network able to support a freelance business. Having taken the step to become a freelancer, it is important to establish connections with the relevant professional organisations or individuals and participate actively in regular meetings. Presentations and publications at any level are usually very positive for personal and business development. Finally, there are few freelancers who are able to manage every task in the daily routine. Employing tax consultants, computer specialists and other experts might appear expensive but in the long run you save valuable time to concentrate on what you are really good at.

The editorial board of *TWS* thanks Alistair, Connie, Marion and Stefan for answering these questions and sharing their experiences with the EMWA members.

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People think I make these up!

Yet another example (which I have not invented) of the best way for authors to deter people from reading their texts:

At treatment initiation, the majority of patients (61.8%, 379 patients) received 50 mg of RLAI with 19.9%, 8.6%, 4.7%, 4.2%, 0.3%, 0.2%, and 0.2% of patients on 37.5 mg, 25 mg, 75 mg, 100 mg, 150 mg, 62.5 mg, and 200 mg respectively. At 24 months the percentages corresponding to the same RLAI doses were 57.8%, 14.1%, 4%, 14.5%, 8.1%, 1% and 0%, there was also 1 patient (0.2%) receiving 62.5 mg and another (0.2%) receiving 67.5mg.

So, not only does the author subject the reader to a totally disrespectful respectively at the end of the first—very long—sentence; they further subject the reader to a bunch of % values that jump up and down, expecting the reader to remember the order in the first sentence.

How can authors seriously do this? At least the following would have been better, but still far from ideal:

379 (61.8%) patients started treatment on 50 mg, and most of these (57.8%) were still receiving 50 mg after 24 months. The distribution of the remaining dosage levels was as follows (starting dose/dose after 24 months): 25 mg – 8.6%/4.0%; 37.5 mg – 19.9%/14.1%; 75 mg – 4.7%/14.5%; 100 mg – 4.2%/8.1%; etc.

However, had the author done the best thing and made a table, I hope they would then have noticed that there is something wrong here*; it is no wonder they didn't, as they were not doing themselves a favour with this text either!

* If you count up according to the respectively, the 0% for the 24-month dose corresponds to 62.5 mg and it should correspond to 200 mg, and the text then goes on to give 0.2% for 62.5 mg. This is immediately obvious if you do a table.

Think simple

This needs little explanation. Why make the reader work with a sentence like this:

Compared to studies from the USA and South Africa, where most penetrating injuries are gunshot wounds [27–29], more than 70% of penetrating trauma in our sample of European patients resulted from stabbing.

When it could be like this:

Most penetrating injuries in the USA and South Africa are gunshot wounds [27–29], while 74% of those in our European patients were stab wounds.

Withstanding the mess

Georgios Athanasiadis of the Hospital de la Santa Creu i Sant Pau in Barcelona asks:

Can you help me put some order into this messy sentence: *Notwithstanding, it is important to note that this observation does not rule out the existence of other variants with such a small effect on PC or PS plasma levels that renders them impossible for our study to detect.*

Authors do get themselves into a mess sometimes, don't they? And I do too. But I do try to help myself by not starting sentences with 'Notwithstanding, ...' in the first place. In fact, if I have my choice, I never use *notwithstanding*,

as you can always find a simpler solution with a bit of thought. And when I see *notwithstanding*, the alarm bells ring, because it is an overworked linking word, but still somehow manages to weave linguistic charm and is supposed to sound 'good'.

In my usual (sometimes over-) radical manner, I reduced the sentence to: *Variants below the detection level of our assay may nevertheless exist* (or be present, occur, have arisen etc., depending on the sense) and said that depending on the context, it may be appropriate to add 'Importantly, ...', or 'Notably, ...' or another introductory adverb. I also asked Georgios for the context, as some of the ideas in the apparently superfluous wordy phrases in the original may have been important to incorporate.

The text that preceded 'Notwithstanding, ...' dealt with an apparent disagreement between linkage results and genome-wide association scan results, and discussed whether these were important, what the reasons might be, and what implications this might have. The sentence starting with 'Notwithstanding, ...' was intended to add important concluding, cautionary, but speculative information that there may be a further reason. It therefore deserved a little more substance to it than the radical version I sent back, which was probably more suited to the conclusions of an abstract.

A linking word is obviously needed, but *notwithstanding* is not appropriate. As a concluding sentence, the idea of the importance of the conclusion should be reflected. *Study* was the wrong choice of word: the author was talking about an assay. As a concluding sentence, it was also appropriate to mention the target variables of the assay again (PC or PS plasma levels). And the wordy *levels that render them impossible for our study to detect* just means *below the limit of detection*. Georgios was quick off the mark and returned the following much more acceptable sentence before I had the chance to make any further suggestions:

Finally, it is also important to note that variants with a small effect on PC or PS plasma levels – below the detection limit of our assay—may nevertheless exist.

An appropriate, neutral linking word to start with, followed by the other important ideas, with the information on the limit of detection set off nicely with dashes. The idea conveyed by 'nevertheless' is now much further down the sentence; here, it works more as a 'supporting' linking word, so that the reader is not confronted with this idea as the first—and determining—idea in the sentence.

Getting away from *notwithstanding*, the reader also has to grapple with the following phrase in the initial sentence '*other variants with such a small effect on PC or PS plasma levels that renders them impossible ...*'. *Variants* appears to be the word influencing the number of the verb *render* but it is actually the word *effect* that the *that* refers back to, hence the author's choice of the singular. This is further complicated by *them*, which refers back to the *PC or PS plasma levels* and not the *variants*. In short, even though this may all be strictly grammatically correct, the result is a baffling concatenation of plural nouns, a singular noun unnecessarily modified by 'such', a verb that appears to have the wrong number, and a confusing relative pronoun and pronoun, which only clicks into place when you have read it three times. A real mess—but it can happen easily to any of us.

Words, Grammar & Co

Slow process of adjustment

The following is a good example of a sentence where too much is going on between the subject of the sentence and its verb:

In view of these risks, a variety of new treatment modalities, such as laser therapy, high intensity focused ultrasound (HIFU), transurethral microwave therapy (TUMT) and electrovaporization, have been introduced with the aim of reducing complications during and after surgery.

This happens very easily when you are giving examples. Here we have four examples interposed between the subject and its verb, further complicated by the addition of abbreviations because this is the first time the terms were mentioned in the text, all introduced by a prepositional phrase. I thought I would minimise stress on the reader with the following:

In view of these risks, (a variety of) new treatments have been introduced, aiming to reduce complications during and after surgery. These include laser therapy, high intensity focused ultrasound (HIFU), transurethral microwave therapy (TUMT)(,) and electrovaporization.

I am not a keen user of *a variety of*, so I decided to delete it, and eventually put in a comma before the *and* in the second sentence. What's wrong with *a variety of*? Maybe it's just me, but I feel it's just too casual for formal writing.

During my third read-through, I realised that the *new treatments* are also superfluous, because if these 'modalities' have been introduced, then they are new for this disorder (adenoma of the prostate) and they are the real subjects of this sentence. So my final sentence was as follows:

In view of these risks, laser therapy, high intensity focused ultrasound (HIFU), transurethral microwave therapy (TUMT) and electrovaporization, amongst other treatments, have been introduced, aiming to reduce complications during and after surgery.

Had there been only two examples in the sentence and *a variety of* had not been used, e.g.:

In view of these risks, new treatment modalities, such as laser therapy and high intensity focused ultrasound (HIFU), have been introduced, aiming to reduce complications during and after surgery.

I would have left the original basic structure because the subject and its verb are much closer together, but I would still have got rid of *modalities* and just said *new treatments* (the author wanted the idea of 'new' there).

The whole text then came back for a further round of editing after peer review, and I realised that *In view of these risks* and *aiming to* were also superfluous, because the risks had just been mentioned in the sentence before, so *a therefore* was quite adequate; and why else would you try out the new treatments if not to reduce the risks?

So our final sentence was as follows: *Laser therapy, high intensity focused ultrasound (HIFU), transurethral microwave therapy (TUMT) and electrovaporization, amongst other treatments, have therefore been introduced to reduce complications during and after surgery.*

Which do you prefer?

I was recently sent the following four sentences and asked to say which I felt was best for the reader, and why:

- [1] The 100 patients in the monopolar resection group were between 52 and 83 years old (mean 69.1, SD±7.2), and the 108 patients in the bipolar resection group were between 51 and 87 years old (mean 69.5, SD±7.9).
- [2] The 100 patients in the monopolar resection group had a mean (±SD) age of 69.1 (7.2) years (range 52–83), and the 108 patients in the bipolar resection group a mean (±SD) age of 69.5 (7.9) years (range 51–87).
- [3] The mean (±SD) age in the 100 patients in the monopolar resection group was 69.1 (7.2) years (range 52–83) and was 69.5 (7.9) years (range 51–87) in the 108 patients in the bipolar resection group.
- [4] The mean (±SD) ages in the 100 patients in the monopolar resection group and the 108 patients in the bipolar resection group were 69.1 (7.2) years (range 52–83) and 69.5 (7.9) years (range 51–87) respectively.

Even though [4] starts with the real subject of this sentence (the age and not the patients), I discounted it immediately because using the plural for the subject in this way is unusual, and there are too many numbers and brackets all piled up at the end with an unhelpful *respectively*.

In [1], we have two parallel clauses with different subjects (100 patients and 108 patients). This is a complication we do not need in a sentence which actually should have a different subject. What is the sentence about? It is about age, and so that should be the subject. Also, it is unusual to quote the range first and then give the mean ± SD. This might set the reader wondering why the author did this, so [1] is not my first choice either for these two reasons.

This leaves us with [2] and [3]. [2] has the same problem as [1] with the subject. In [2], the author also dispensed with the verb ('had') in the clause about the bipolar group because both clauses have the same structure and content. If this is the case, you can often skip the verb in the second clause if the clauses are short. We often do this when speaking. But here the clauses are too long to be able to do this comfortably for the reader. So [2] is not my choice either.

[3] starts with the appropriate subject for this sentence (mean age) and then skips the subject in the second clause about the bipolar resection group. We often do this with clauses with the same subject in a sentence when the clauses are linked by 'and', again especially when speaking. The verb 'was' is repeated, as it would be too much to skip that as well (although you might well do this too when speaking). Also, the author ignored parallelism and pulled forward 'was 69.5 (7.9) years (range 51–87)', otherwise it would have been too far away from the subject for reading comfort. So if I had to choose one of these sentences, it would be [3], as the best for the reader. I would probably go one step further and remove some brackets:

- [5] The mean \pm SD age in the 100 patients in the monopolar resection group was 69.1 ± 7.2 years (range 52–83) and was 69.5 ± 7.9 years (range 51–87) in the 108 patients in the bipolar resection group.

However, regardless of subjects and verbs, all these sentences have the problem that they simply contain too many numbers for reading comfort. Why try to pack the information about the size of the groups and their ages into one sentence? A solution with two sentences probably would be better. And can't we get rid of some [6] or all [7] of the brackets and pare down the long names of these groups (since the article is about bipolar and monopolar resection of the prostate, it would be a very bad-willed reader who understood the word 'bipolar' here in its psychiatric sense):

- [6] The monopolar resection group contained 100 patients and the bipolar resection group 108 patients. The mean age in the monopolar group was 69.1 ± 7.2 years (range 51–83) and in the bipolar group was 69.5 ± 7.9 years (range 51–87).
- [7] The monopolar resection group contained 100 patients and the bipolar resection group 108 patients. The mean age in the monopolar group was 69.1 ± 7.2 years, range 51–83, and in the bipolar group was 69.5 ± 7.9 years, range 51–87.

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Communicating outside the box and innuendos

Why do we use innuendos in communication? Why not just call a spade a spade rather than inviting a young lady to come to your room to view your etchings? This question is answered in a brilliantly illustrated talk by Steven Pinker titled 'Language as a window into human nature', which can be viewed on the RSA website (<http://www.youtube.com/watch?v=3-son3EJTrU&feature=relmfu>). The RSA states on its website that it is "committed to strengthening public debate and to providing free public platforms for debate, discussion and for sharing the best new thinking across a range of disciplines." It does not actually say what RSA stands for (but Wikipedia does, search RSA). Therefore the site could not have been written by a medical writer as we all know that abbreviations should be written out when first mentioned in a document. However, another clip on the site titled 'Changing education paradigms' does refer to medicine, in fact, the over medication for ADHD (attention deficit hyperactivity disorder) and is also well worth viewing for a novel perception of what is wrong with education today (<http://www.youtube.com/watch?v=zDZFcdGpL4U&feature=share>).

Use of metaphors in politics and science

The Free online dictionary defines a metaphor as "A figure of speech in which a word or phrase that ordinarily designates one thing is used to designate another, thus making an implicit comparison" [1]. Metaphors are used in non-fiction writing to help the reader understand complex ideas by comparing them with well-understood concepts. But they can also be used as a tool to influence people. For instance, Democrats' in the US are promoting a Democratic metaphor of society-as-family with a 'nurturing parent' model of leadership [2]. Psychology researchers Lera Boroditsky and Paul Thibodeau recently showed that presented with a criminal depicted as a 'beast' 75% of students recommended harsh law-and-order solutions but when the metaphor 'virus' or 'plague' was used for the criminal 44% suggested social reforms and only 56% favoured a harsher solution [3].

Jamie Cunliffe, an immunologist, writes on his *morphostasis* website that "There has been a great trend to condemn metaphor... 'out of hand', as unscientific: so much so in biomedicine that the literature generated in scientific journals has become increasingly sterile and unadventurous" [4]. Then he proceeds to show that metaphors are indeed used prolifically in science writing giving immunology as an example and listing words like self/nonsell discrimination, tolerance, trigger, architecture, migrate, generate, recruit, kill and activate. These words with 'day to day' meaning are used analogously, he points out, to enhance our understanding of the immune system. Very commendable as most of us need all the help we can get to understand immunology, however, Cunliffe is not jumping for joy. He's concerned about something that I have also noticed. Have you ever told an author that his or her use of a word is incorrect only to receive a sharp retort that those people in the know in the field all use the word in that sense? Cunliffe describes a phenomenon of metaphors stealthily appearing in scientific writing and then taking on a life of their own. They attract potent advocates and protectors and become millstones when used with a religious fervour by writers who adopt them as literal truths rather than useful analogies, "Although their meanings have often shifted subtly, their authority become unchallengeable without first committing an act of heresy. Metaphors should always remain malleable and their validity should be frequently reviewed; and they must be acknowledged so that we can stay on our guard."

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Words, Grammar & Co

A surfeit of parameters

In a letter to the *BMJ* in 1965, DM Sinclair [1] asked “how much weight to accord to observations on an enumerable finding where no distinction appears to be made between a simple measurable quantity and a parameter.”

In 1966, the *BMJ* published a leading article [2] titled, “Pause at the parameter.” It didn’t cite Sinclair’s letter of the previous year, which makes me feel slightly less guilty that I overlooked the leading article when I wrote “Paradigm, parameter, paralysis of mind” [3] for the Xmas *BMJ* nearly 30 years later.

The leading article started, “Those hardy students whose reading of original papers extends beyond their titles will have noticed of late a technical term that has come into fashion... Incidentally it gives the impression that what the writer of it is doing is science.” It finished, “That ‘parameter’ is a useful term is evident from the frequency with which it appears in the literature today. But many readers would find it more useful still if they could understand it. Those writers therefore who feel an obligation to communicate their thoughts to potentially interested readers, and not merely to record them for the assistance of staffing committees, would help many a lame duck to reach the pool of learning if they pause before putting a parameter in his way.”

This is a fascinating piece of writing. It is only 45 years old, but feels slightly archaic in a way that is difficult to define; it shows that skip-reading is not a new phenomenon driven by the expanding knowledge base; and we see that publication for promotion of self rather than of knowledge is not new either. It also has a clever title - *parameter* is sometimes misused for *perimeter*; and note “putting a parameter in *his* way.”

There were eight letters published in response. Philip Jacobs wrote, “At best, one would say that the word is imprecise and is used to give an aura of innate science.... You, Sir, have done a service by your exposé of the woolly term ‘parameter’.” [4]

The intervening years have made *parameter* even more woolly. In the wider world, it means just about anything that can be measured, literally or metaphorically. So:

...but will it come within the parameter [scope] of the review?

In the second innings, the ball turned less, and Warne was able to operate within smaller parameters [limits], with the line no longer such a give-away.

No ratings on waterproofness were given—one of the most important parameters [properties]...

Ten years after Bolero sealed Olympic gold at Sarajevo, they were again pushing the parameters [bounds] of the sport...

Moral parameters [guidelines], including ... restrictions against sexual involvement with patients and drug abuse, exist to maintain the integrity of the physician-patient relationship.

Or, *parameter* is used as padding in redundant phrases:

Thirty-years-ago, motherhood ... would have been restricted to those in couples, and those within the parameters of normal fertility.

Conceptually, it is so difficult to accept. Yet it’s going to change the parameters of science.

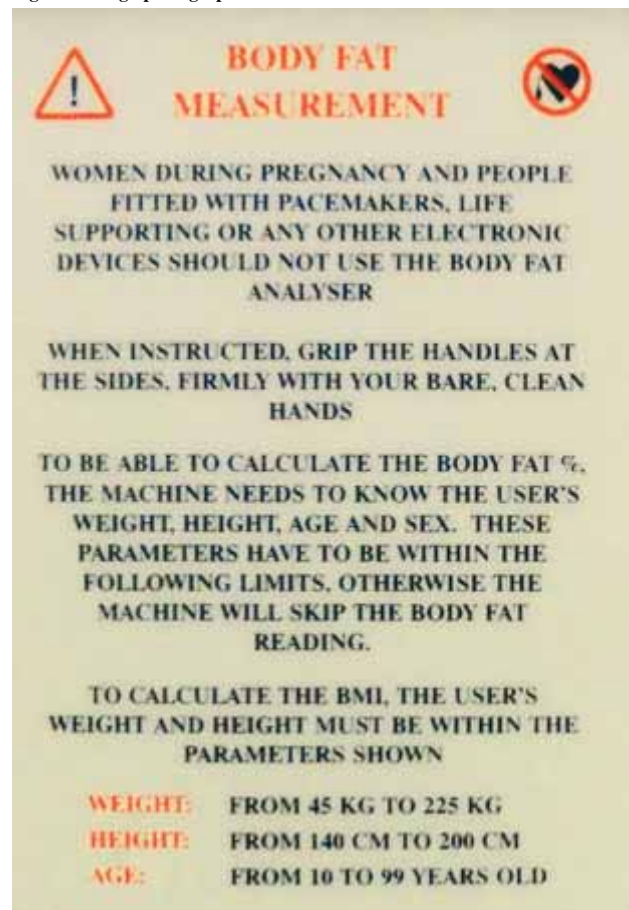
Where this cannot be avoided, they will be advised to think of England at all times, and, even then, only within the parameters of current Government thinking.

... current generations of adults cannot easily escape the parameters of their gender socialisation.

Medical writers no longer write *parameter* to impress; it is no longer a term that has “come into fashion.” Medical writers now write *parameter* because they think it is the correct word. It rarely is. Things that can be measured directly—with rulers, spectrometers, by noting their occurrence, or whatever—are variables. Heights, weights, ages, blood pressures, number of fractures, five-year survival, all are variables.

The distinction between *variable* and *parameter* is less clear when more complex measurements are made—for example, from the electroencephalogram. In statistics, the meaning is clear: the *mean* and the *standard deviation* of the variable are the parameters of the normal (Gaussian) distribution. (Other distributions have other parameters.)

Figure 1: Sign photographed in Boots



Knowing the parameters gives the shape of the distribution; so we can estimate, for example, without having to measure the whole population, how many people weigh more than 100 kg. But you don't measure parameters so that you can calculate their parameters; you measure variables so that you can calculate parameters.

On the other hand, in Boots, you have to make sure that the parameters are within the parameters shown (see Figure 1). Context is all.

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A growing demand for a more precise terminology of biosimilar medicinal products

Nowadays healthcare providers in the EU encourage the use of biosimilar medicines due to their lower costs [1]. For example, biosimilar epoietins are around 25-30% less costly than the originators' products in the EU [1]. Their production process can be different from that of the original drug. All manufactures use their own cell lines applying their own expression systems, fermentation and purification techniques. Several biosimilar drugs are traded under different brand names by a few different companies. Physicians (and pharmacists) should be aware of their clinical applicability since both reference product and

biosimilar exhibit several isoforms that differ in the glycosylation patterns ('microheterogeneity') and, hence, biological activity [1]. In addition, all biological medicines are potentially immunogenic.

In the latest (August) issue of *Nature Biotechnology*, the members of the Biosimilar Medicinal Products Working Party (BMWP) at the European Medicines Agency (EMA; London), highlighted the problems arising from imprecise usage of the term biosimilar in the literature and the potential for unjustified concerns about the efficacy and safety of biosimilars [2].

They proposed a more precise terminology to make differences among terms of biosimilar, me-too biologicals/biologics, noninnovator biologicals/biologics, second generation (next generation) biologicals/biologics and biobetters (see Table 1 in [2]). "A biosimilar is a copy version of an already authorised biological medicinal product with demonstrated similarity in physicochemical characteristics, efficacy and safety, based on a comprehensive comparability exercise."

New EU guidelines for biosimilars define the nonclinical and clinical studies that need to be carried out to show that the biosimilar medicine is similar and as safe and effective as the reference medicine [3]. Clinical trial design may be different from that for a novel molecular entity and should use different (clinical or pharmacodynamic), more sensitive endpoints in order to detect potential differences between the biosimilar and the reference product [2].

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Table 1 Proposal for a more precise terminology.

Term(s)	Definition	Implications
Biosimilar ^a	Copy version of an already authorized biological medicinal product with demonstrated similarity in physicochemical characteristics, efficacy and safety, based on a comprehensive comparability exercise.	Only very small differences between biosimilar and reference with reassurance that these are of no clinical relevance. Extrapolation of clinical indications acceptable if scientifically justified.
Me-too biological/biologic	Biological medicinal product developed on its own and not directly compared and analyzed against a licensed reference biological. May or may not have been compared clinically.	Unknown whether and which physicochemical differences exist compared to other biologicals of the same product class.
Noninnovator biological/biologic		Clinical comparison alone usually not sensitive enough to pick up differences of potential relevance. Therefore, extrapolation of clinical indications problematic.
Second-generation (next-generation) biological/biologic	Biological that has been structurally and/or functionally altered to achieve an improved or different clinical performance.	Usually stand-alone developments with a full development program.
Biobetter		Clear (and intended) differences in the structure of the active substance, and most probably different clinical behavior due to, for example, different potency or immunogenicity. From a regulatory perspective, a claim for 'better' would have to be substantiated by data showing a clinically relevant advantage over a first- or previous-generation product.

^aComparable terms defined by the same/similar scientific principles include the WHO's 'similar biotherapeutic products' and Health Canada's (Toronto) 'subsequent-entry biologicals'.

■ For regulatory writers

Transparency at the European Medicines Agency, could do better?

The debate about whether the European Medicines Agency (EMA) is sufficiently transparent was revived recently when two Danish academics published their woes when trying to obtain the clinical study reports for placebo-controlled trials of the anti-obesity drugs rimonabant and orlistat [1]. They wished to explore the data on these drugs further, and explained to the EMA that the results available in the public domain might be incomplete (the [in]famous publication bias). They further argued that weight-loss pills are controversial, and perhaps not always harmless, so any reassessment of the results would be for the greater public good. Arguments that you might have thought would have carried sufficient weight for the information to be made available. The EMA, however, repeatedly stonewalled the request, alleging that the administrative burden associated with redacting sensitive commercial information was too onerous. This was clearly unacceptable and by using such arguments, the EMA was opening itself up to allegations of putting commercial interests before potential health issues.

But is it really as bad as it looks? In Spain, I am well accustomed to dealing with soul-crushing bureaucracy, which is often inexplicably inefficient and slow. I don't believe, though, that my frustrations with Spanish civil servants have anything to do with a hidden agenda, for example to make life difficult for foreigners (my Spanish wife has also had her run-ins with the bureaucrats). By analogy, I am not convinced that the problems these academics encountered were due to a sinister plot to protect the commercial interests of companies. I suppose if you are keen on conspiracy theories, you could also argue that the EMA was worried that a reanalysis of the data might uncover incompetence on their part. But the most likely explanation in my mind is simply the bureaucracy involved. I don't work at the EMA, but I should imagine that if no official channel or procedure had been set up for dealing with these requests, they would have been bouncing around eternally within the system, while hollow-sounding excuses were offered to the outside world.

On a positive note, my recent dealings with the Spanish bureaucratic machinery have been much more expedient. In fact, last month, I managed to get two things done in the offices of the Madrid town hall in less than five minutes, a new personal record. Although I am sure there will be future encounters that are less smooth, this was evidence nonetheless that even the most entrenched bureaucracies can lighten up (partly in response to public discontent). The EMA, for their part, now seem to have set up the necessary procedures, as yet untested, to deal with such requests for information. In the face of public and political pressure for change, the agency is being dragged kicking and screaming towards fuller transparency.

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Active comparator trials before drug approval

Currently, in Europe, active comparator trials are encouraged during drug development in cases in which there is already an active treatment available [1]. Ostensibly, the insistence on active comparator trials is to help better define the risk-benefit assessment in the context of existing standards of care by showing that the newcomer is at least as good as what is already available.

In the United States, the FDA does not mandate active comparator trials, but in practice, the number of pivotal trials with active comparator data is similar to Europe [2,3]. This is perhaps not surprising given the considerable overlap in the clinical programmes supporting filings in the two areas. However, on the behest of consumer groups and payers such as insurers, upcoming legislation on the funding of the FDA may also include the requirement for the FDA to mandate active comparator trials.

As it stands, when a new drug comes to market in a blaze of publicity, there is often only limited head-to-head data on whether it is actually better than older, cheaper, tried-and-tested alternatives. The slick pharmaceutical marketing machines can quickly create a demand and, with no hard evidence available, physicians (and patients, especially in the US where the sense of patient empowerment is greater) may not be able to resist the idea that new is better. In time, companies and independent bodies may conduct randomised head-to-head studies, and observational studies will also provide real-world data. But there remains a period after approval when such data will be lacking, hence the idea to force the pharmaceutical companies to do these trials up front.

Another suggestion is to insist that the label clearly indicates that the new product has not been shown to be any better than (or even comparable to) existing products when no comparative data are available [4]. The thinking behind having such statements is, I suppose, that it would make it easier for physicians to resist the pressure to prescribe the new drug, and ultimately force companies to conduct head-to-head studies if they want their drug prescribed.

The hint of extra regulation has got certain pro-free-market groups, if not apoplectic at the thought, at least worried (see this paper from a free-market think tank [5]). A major criticism is that while head-to-head trials may show non-inferiority (equivalence) of the test drug, if a trial design is flawed (whether intentionally or not, for example, with inappropriately low comparator doses), it cannot distinguish between two effective drugs and two ineffective drugs. The free marketers therefore argue that the data generated are unlikely to be of much use for clinical decisions. If permissible on ethical grounds, a placebo arm could also be included in a three-arm study design to help generate more reliable data on the absolute efficacy and safety of

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the test drug. Indeed, this is the preference of the EMA [1], but it also adds to the complexity of the trial.

Another argument put forward by many in the industry against comparative trials is that, in addition to being costly and cumbersome (more patients are required to achieve sufficient power), they are time-consuming. The subsequent delay in approval would eat into time in which the company enjoys patent exclusivity. A creative approach here might be to extend patent protection, as is already done for certain paediatric and orphan indications.

Even if an FDA mandate for comparative trials were in place, it is not clear whether it would increase the number of comparative trials. After all, as mentioned earlier, a similar percentage of approvals in Europe include comparative trials, despite a clearer favourable regulatory position on such trials. In my opinion, we should be wary about imposing too great a regulatory burden. It is often useful to have several drugs available for a given condition because patients might not tolerate one particular class, or

that class might not be effective in a certain type of patient or situation. But I also believe that comparative data can be very useful for making informed choices. As in many things in life, it is a question of finding the right balance.

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■ Biomedical publishing shorts

Responsible research publication

Two position statements (one for authors, the other for editors) were developed at the 2nd World Conference on Research Integrity (WCRI) which took place in Singapore in 2010. Do we really need yet more guidelines when we've already got ones from ICMJE [1], COPE [2], EASE [3], individual journals and, of course, EMWA [4]? I think we do because, although most journals' instructions go into great detail about what your manuscript should look like (e.g. it must be in Times New Roman, 12 point, double spaced with 1 inch margins and Vancouver-style references), they ignore important ethical issues such as authorship and originality [5]. The WCRI also provided a great opportunity to discuss these issues with researchers from all over the world and from a wide range of disciplines. We circulated drafts before the meeting, discussed them in often lively debates during the meeting, and at a special post-conference workshop, and then circulated more drafts afterwards. We received input from researchers and editors from Africa, Asia, Australasia, Europe, the Middle East and North America, and from disciplines as diverse as medicine, mathematics, philosophy and political science. Agreeing content and wording acceptable to everybody was an interesting challenge. Mathematicians, understandably, aren't generally bothered about the protection of research subjects while philosophers struggled with the notion of accuracy in research reports. However, despite some spirited exchanges, there was remarkable consensus about most of the main issues especially after we created a special section on human and animal research to meet the needs of life scientists without boring the others with irrelevant detail.

We realise that journals will still want to instruct authors on how to prepare manuscripts in their preferred style but hope these new guidelines can be incorporated or cited to provide helpful instruction about responsible research publication. The author guidelines cover: research soundness and reliability, honesty, balance, originality, transparency, authorship and acknowledgement, accountability, and adherence to peer review and publication conventions. There is a separate section on the responsible reporting of research involving humans or animals. Medical writers are mentioned in the transparency section (which states that support such as writing assistance should be disclosed) and in the authorship section (which does not attempt to define authorship criteria but calls on editors to promote accepted criteria appropriate to their field which, ideally should be agreed, published and consistently applied within that field).

The process of developing the statements was coordinated by Liz Wager and Sabine Kleinert (Chair and Vice-Chair of COPE). We hope organisations such as EMWA will endorse and promote the position statements and perhaps use them as the basis for training. The guidelines are being published in the WCRI conference proceedings under a

creative commons licence so they can be posted on websites and adapted by individual journals. They will therefore soon be available at www.publicationethics.org (the COPE website).

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Obama's party asks medical journal editors for advice as the FDA comes under the microscope

It is not often that scientific editors find themselves hauled out of their offices to appear before a government committee in Washington, but that is exactly what happened in July this year.

Stung by two published reports which criticised how the FDA approves medical devices ("unpredictable and characterised by disruptions and delays"), Democrats invited editors from the *New England Journal of Medicine*, the *Archives of Internal Medicine* and the *Journal of the American Medical Association* to review these studies to see if they could be used to "form an appropriate basis for policymaking."

Reporting back to the House Subcommittee on Oversight and Investigations, the panel answered in the negative. They noted that the studies in question would not survive peer review at a major journal, highlighting low response rates, design flaws and potential conflicts of interest (both studies were sponsored by the medical device industry).

What were the allegations thrown at the FDA (and often heard muttered by industry representatives)? Among the topics were increasing FDA review times, a lack of consistency in review and data requirements and patient access to innovative products. The FDA went on the defensive by blaming industry for the long review times, saying that 83% of initial submissions and 82% of the follow-up submissions have "at least one deficiency related to quality."

Interestingly, one week later the long-awaited report by the Institute of Medicine (IOM) on the FDA's 510(k) medical device approval process was released. (In a nutshell, the 510(k) programme is an accelerated way of getting medical devices to market by piggybacking on the results of equivalent devices already available to the public).

This critique went much further than anyone expected, even suggesting that the current programme should be

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mothballed. This stark recommendation came on the back of one of the IOM's main findings—the 510(k)'s substantial equivalence requirement does not prove safety and efficacy and should be replaced by a system that does.

The industry wagons are already circling, even to the extent that the report was heavily criticised before it was published. Their nervousness is understandable, after all, what company wants to lose a fast-track programme to get their products on shelves? But their rearguard action may prove to be unnecessary as the IOM report is not binding and the FDA has already stated it does not want to abandon the 510(k) programme completely.

All of the stakeholders in the medical device world are continuing to follow these developments with interest.

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Time delay in retractions can harm patients

The number of articles research journals have retracted after publication has risen by 44% since 2001 [1]. There were 22 retraction notices in 2001 and 339 in 2010. 210 papers had been retracted up to the end of July 2011. Most of the retractions were in the medical discipline. A study of 742 biomedical papers withdrawn between 2000 and 2010 found that 73.5% were retracted for error and 26.6% for fraud. Suggested reasons for the increase are 1. Journals have improved their ability to detect errors, e.g. by using software to detect plagiarism. 2. Research has become more competitive as illustrated by the comment from the editor of the *Lancet*, Richard Horton "A single paper in *The Lancet* and you get your chair and you get your money. It's your passport to success."

Regina Kunz is one of the Swiss doctors whose letter to the editor published in *Lancet* led to the ultimate retraction of the COOPERATE trial (on the combination treatment of angiotensin-II receptor blocker and angiotensin-converting-enzyme inhibitor in non-diabetic renal disease) paper. She said that peer reviewers should have picked up that the effect claimed in the paper was too perfect for such a small sample size. In the meantime the drug combination therapy, the small benefits of which had been outweighed by the side effects, had been prescribed to over 100,000 patients. This is alarming enough but the time it takes to

retract a paper when patients might be receiving medication that is harming rather than helping them is even more alarming. The paper was published in January 2003. It was the second most cited article in *The Lancet* for that month. The letter was published in *The Lancet* in December 2006 and the paper was retracted in October 2009 [2]. Andrew Wakefield's paper on the link between autism and the measles-mumps-rubella vaccine was retracted last year, 12 years after its publication.

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Yet another guideline

In her preface to "Authors' Submission Toolkit: A practical guide to getting your research published" [1], Trisha Groves, deputy editor of the *BMJ*, writes "There are already plenty of guidelines for authors on writing good manuscripts." She justifies yet another one by stating that it tackles practical questions about the manuscript preparation and the submission process that are incompletely addressed in existing guidance documents—however I did not read any information in this article that I had not read elsewhere. Neither are the many good articles that have been written on manuscript writing and publication ethics cited. Only a selected few, together with many guidelines, are listed under 'Resources'. Their selection criteria are not elucidated. Perhaps this is not surprising as it seems that 'articles' are no longer good enough. You need to write a guideline to get yourself noticed, albeit that the rubric for this one is 'Commentary'. It's long. The parts in my view that might be useful for anyone who is not abreast of discussions and articles on ethics in writing biomedical articles are those headed 'Prior presentation and publication policies' and 'Pre-submission inquiries'. When giving workshops on dealing with biomedical journals, I have often been surprised to find that authors and medical writers are reticent to telephone an editorial office to ask even simple questions. The section on 'Understanding the publication plan' is curious for its absence of the word 'marketing'.

A template is provided in the guideline for a submission letter but the reader is not warned that not all editors read submission letters (even at the *BMJ*!). One recommendation is that details of prior submissions are given in the letter. Some journals require this information, e.g. *The Lancet*, which I find unfair. Where a journal's instructions to authors are silent I for one would not voluntarily provide these details. Later in the article the authors say that it is important to disclose any prior rejections and suggest that

¹ See *TWS* vol 19(3) page 185: the editor quoted as saying "there would not be much to be gained from the author's point of view to include a cover letter" was from the *BMJ*.

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> a copy of the previous manuscript is provided with the new submission. The argument for this seems to be that the new manuscript might be reviewed by the reviewer who previously recommended rejection and that “this reinforces the need to demonstrate that the initial feedback from all reviewers has been valued and considered.” No mention is made of the view held by many that reviewers have an ethical duty to refuse to review manuscripts that they have reviewed for another journal and rejected. Although the advice to revise a manuscript in accordance with the rejecting reviewers’ comments before submitting it to a new journal is broadly sound, the quality and bias of some reviewers calls into question a blanket recommendation to do so.

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Scientific (?) spine publications severely criticised by a US Senate committee and the publishing journal

The Spine Journal, one of the most important American orthopaedic journals, has dedicated an entire issue to a controversy regarding the safety profile of a bone growth product: recombinant human bone morphogenetic protein-2 (rhBMP-2) embedded in a collagen matrix. This bone growth product has been approved by the FDA for a set of indications based on a series of industry sponsored studies, but apparently, the publications that resulted from these studies underestimated the adverse side effects and complications related to the product. Even worse, some of the authors of these publications had considerable financial associations with the manufacturer and could have been intentionally under-reporting possible adverse effects. The editors of the June issue state: “The current systematic review found that rhBMP-2-related complications and adverse events as documented in the original FDA reports and subsequent publications are perhaps 10 to 50 times the original estimates calculated from industry sponsored studies” [1] and reference 7 articles that report **not a single** adverse event or complication related to the product in a total of 780 protocol patients. Four of these articles were published by *The Spine Journal* (!), two in the *Journal of Neurosurgery* and one in *The Journal of Bone and Joint Surgery* (American volume). Even *The New York Times* dedicated space in its mid-June issue to a 1,300-word article on this controversy, which has reached the senate: “...two members of the Senate Finance Committee,(...) a Democrat from Montana, and (...) a Republican from Iowa, sent a letter to the manufacturer requesting records involving payments and communications with researchers on the product’s studies.”

What is really going on here? I do not want to sound cynic, but here are my answers to some of the questions that spontaneously arise:

- Is a big corporation associated with physicians that publish articles under-reporting the adverse effects that have been presented to the FDA? Apparently, yes.
- Have researchers declared that they had no conflicts of interest and in the meantime their bank accounts grew together with the revenues generated by the product? Would not surprise me!
- Has the FDA approved products that are not as safe as all of us would like them to be? Most probably.
- Do peer-reviewed journals publish articles that are not really being scrutinised in depth? Would this surprise you?
- And who is to blame? Most probably all of these instances and groups.

In the world we live today, making money and revenue growth are morally accepted and a legitimate objectives of the industry and ‘industrialised’ medical practice. In particular, in the world of medical devices a close cooperation during the product development and testing phase between manufacturer and future user is sometimes key to patient safety, as is the case of endoscopes or heart valves. Although this should not endanger patients, there are some legal loopholes such as the ‘off-label’ use of products and the unofficial promotion of this type of use. Manufacturer and users could be tempted to tap this extra source of income.

From the FDA perspective, it is not only legitimate but almost unavoidable to approve medical products that might not be as safe as expected in the long term. Long-term side effects are sometimes unpredictable and post market surveillance and pharmacovigilance are a valid mechanism to reduce these as much as possible.

Thus we could choose to forgive all of the instances involved, but there is one missing: what about the journal editors and peer reviewers?

Scientific journals claim that their primary objective is to publish objective, peer-reviewed scientific articles that enable the medical community to offer the best possible medical care to the patients. In this context, what *The Spine Journal* has done, dedicating a whole issue to the controversy it has contributed to create, feels like a ‘must’ to control further damage.

“It harms patients to have biased and corrupted research published...It harms patients when poor publication practices become business as usual. Yet harm has been done.”

The promise of *The Spine Journal* to introduce changes to the editorial-, procedural-, and disclosure processes to improve the critical manuscript review and overall publication quality is an important step, but it is only the first one of many that should be implemented by the industry, the medical community and the medical authorities.

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Gender matters in football—A report from a medical writer and fan

It was another summer full of football for me and that comes from being the only female in a family of four and being born in the month of June. I am outnumbered by male family members young and old who are also die-hard football fans and who find it just too convenient to get me World Cup tickets as a birthday present.

To be honest, I am not really an unwilling spectator. There is more to football than just 22 players and one round ball. In fact, there is room for medical/scientific research (and hence for medical writing) in football—and vice versa. And this year's big event—the Women's World Cup—provided a great opportunity for researchers in the field of sports medicine to study the gender differences in the world's most popular sport. Here are some of their findings.

Behavioural patterns

Sports researchers from the Technical University of Munich report that on average, men's matches last longer than women's. This is due to longer interruptions in men's matches, whether to celebrate a goal (male players cheer twice as long), recover from minor injuries (the 'stronger sex' spend +30 sec longer on the ground), or substitution (+10 sec) [1]. Experts speculate that male players have perfected the art of stalling and theatrics. The ladies still have to learn to use time tactically, extremely important in a team sport wherein the final outcome may be decided on the last few seconds of 'injury time'.

Adverse events

It's the same sport, yet the adverse events can be gender-dependent, according to a researcher at the University of Saarland (Germany) [2]. On average, there are fewer injuries in women's football. However, the risk for severe injuries among female players, especially to ankle joint and cruciate ligament, tends to be higher. Concussions and contusions are more common in men's matches. What is surprising was the report that female referees are at higher risk of officiating-related injuries and/or musculoskeletal problems than their male counterparts [3].

And what about adverse events among the spectators? Scientists reported an abnormal spike in acute cardiovascular (CV) events among German men during the 2006 men's world championships—but only on those days when the German team was playing [4]. I speculate that a similar spike in CV events was not observed this year

as the male population of this world still has to come to grips with the fact that women can kick. But I can well imagine—from firsthand experience—an increase in urinary tract problems among the female fans. Unfortunately, football stadiums were not designed to cater to women spectators and their biological needs.

Chronobiology

Researchers believe that chronobiology plays a much bigger role in women's football than in men's. We know the female cycle can play tricks with the results of clinical trials. It's the same in football. Researchers at the Ruhr University of Bochum report that performance in sports is best during the first half of a woman's monthly cycle when estrogen level—that muscle-strengthening hormone—is highest [5]. In other words, women players don't have to dope but just have to use their biorhythm.

Gender-specific medical care

Professional athletes receive the best medical care money can buy, especially the million-dollar earning male football stars. The General Medical Officer [6] of this year's championships assured that the same quality care will be afforded to the not-so-expensive female players. But in addition, the ladies also received specialised care in gynaecology.

Armed with all this scientific knowledge, I went to see the Women's World Cup finals at the Frankfurt stadium last July, determined to be objective, neutral (I am neither American nor Japanese) and critical. And I ended up hoarse and teary-eyed—as always. I don't care if it's women or men who are playing. I just love football.

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■ Medical journalism

Introducing the medical journalism column

The purpose of this new column that I will be writing is to provide *TWS* readers with a new facet of medical writing: medical journalism. Medical journalists have to keep up-to-date with recent developments in biomedical science, to observe how society as a whole reacts to them, to make use of good judgment based on scientific knowledge, and to merge it with a healthy portion of criticism.

In my choice of launching the column with an article on predictive genetic testing, I was inspired by my work in the field of Huntington's disease. It often led me to think of how I would behave and what decisions I would choose if I were at risk of this fatal disease. The topic also seemed appropriate because of the debate on preimplantation genetic diagnosis at the German Parliament (*Bundestag*) earlier this year and the 10th anniversary of the first human genome project publication.



Predictive genetic testing: To know or not to know?

by Diana Raffelsbauer

I am particularly interested in ethics in clinical research, in how people's interests may be different from those of for-profit companies and, most importantly, in whether people are aware of this. In the context of predictive genetic testing, it is legitimate to ask whether we should make use of all resources that current technology enables, although their potential to improve health-related quality of life is unquestionably welcome. At some point, we have to critically consider the advantages and disadvantages of the options and make the decision whether or not to use them. However, people (especially those without a medical background) are often left alone with answers that they might not be able to understand properly, or they are faced with an action for which they might not be psychologically prepared. So far, the impact of predictive genetic testing on mental health has been poorly investigated.

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If you knew you were at a high risk of developing a fatal, late-onset genetic disease, would you undergo predictive genetic testing while you are healthy to find out whether or not you have inherited the gene that will later cause the disease? If your answer is no, would you change your mind if you knew that a cure for that disease had been found, or if you could prevent the disease or delay its onset by changing your lifestyle or diet? Would you be willing to accept the impact this test may have on your family members? This article aims to discuss some of the issues in predictive genetic testing in view of the recent advancements in human genetics.

The Human Genome Project

Launched in 1990, the Human Genome Project was a huge scientific endeavour aiming to determine the sequence of the 3 billion base pairs that make up the human genome and to identify all the approximately 25,000 human genes [1]. Although the project was finished in 2003, annotation of all genes and understanding their function and regulation are far from being complete. Analyses of the data will continue for many years, requiring the development and improvement of a whole range of bioinformatics methods and tools. The Human Genome Project was also committed to the transfer of technology to the private sector, opening new opportunities to pharmaceutical and biotechnology companies for the development of new medicinal products.

Ten years ago, Francis Collins (the leader of the Human Genome Project) anticipated that "genetic prediction of individual risks of disease and responsiveness to drugs will reach the medical mainstream in the next decade" and that "the development of designer drugs, based on a genomic approach to targeting molecular pathways that are disrupted in disease, will follow soon after" [2]. The next decade has arrived.

The era of 'personalised genome sequencing' began in 2007 with the sequencing of the diploid genome of Craig Venter [3]. In 2008, sequencing of James Watson's DNA was accomplished within only two months [4]. Today's technology is able to sequence the human genome within a few days at costs that are rapidly falling, making genotyping accessible for everyone. In May 2011, the price for sequencing whole human genomes through the Illumina Genome Network was US\$ 4,000. Over the last decade, the price has dropped faster than our understanding of human genetics has increased.

An estimated 30,000 genomes will have been sequenced by the end of 2011 [5]. While the 1000 Genomes Project is ongoing and aims to provide a comprehensive resource of human genetic variation, new projects arise, like the 1000 Mendelian Disorders Project launched by BGI in May 2010. Pharmacogenomics, transcriptomics, proteomics, metabolomics, pharmacometabonomics and epigenetics studies on an individual basis are off the ground, thus paving the way to personalised medicine.

Linking genomes to diseases

Now that we have the code, what's next? In fact, only 1.1% to 1.4% of the genome's sequence codes for proteins; the rest is non-coding DNA, which was formerly called 'junk DNA'. Erroneously, because many types of non-coding DNA sequences do have known biological functions, including transcriptional and translational regulation of protein-coding sequences. Linkage mapping often identifies chromosomal regions associated with a disease that have no evidence of functional coding genes within the region, suggesting that disease-causing genetic variants also lie in the non-coding DNA [6].

Searching for genetic roots of diseases inevitably leads to the search for differences between individuals. While human DNA sequences are 99.9% identical to each other, the 0.1% of variation is expected to provide many of the clues to the genetic risk for common illnesses [7]. Genetic variation gives rise to polymorphisms, such as single nucleotide polymorphisms (SNPs). A SNP is a DNA sequence variation occurring when a single nucleotide in the genome differs between individuals. In a companion volume to the 'Book of Life' (the human genome sequence), scientists have created a catalogue of 1.4 million SNPs and specified their exact locations in the human genome [8].

Following the Human Genome Project, research has focused on studying genetic variants that may be associated with increased risks for common diseases like cancer, diabetes or neurodegenerative disorders. The International HapMap Project initiated in 2002 aimed to determine common patterns of genetic variation in the human genome [9]. Such variations may not only affect general health and disease predisposition, but also mechanisms of responses to drugs and environmental factors. Haplotype maps were released in 2005 [10] and 2007 [11], revealing more than 3.1 million common SNPs in the human genome.

Together, the Human Genome Project and other open-access projects like the HapMap Project have opened new avenues for understanding the complex relationships between genomes and diseases. Medicine has benefited from data sharing among large consortia, which has enabled the rapid and precise localisation of many disease-associated regions. To date, over 800 common SNPs have been strongly linked to 150 traits and diseases via genome-wide association studies [12]. For instance, three new genes (*CLU*, *PICALM* and *CRI*) were reported in 2009 to be significantly associated with an increased risk of developing late-onset Alzheimer's disease [13,14]. A quick PubMed search indicates that roughly one in every six papers published on schizophrenia, bipolar disorder or autism refers to genetics [15]. As of the end of 2010, there were more than 40 confirmed genetic loci associated with type 2 diabetes [16]. The Cancer Genome Atlas in the USA [17] and the Cancer Genome Project in the UK [18] are underway aiming to improve our ability to diagnose, treat and prevent cancer through a better understanding of the

molecular basis of the disease using high-throughput genome analysis techniques. Genome-wide association studies in cancer have already identified over 150 regions associated with two dozen specific cancers [19]. As of June 2011, a search at PubMed using the terms 'genome-wide association studies' and 'cancer' yielded 100 articles published in 2011 alone. Since the 1990s, more than 15 breast cancer susceptibility genes have been identified, the most important being *BRCA1* [20] and *BRCA2* [21], and genetic testing for mutations in these genes in high-risk families is now well established [22]. However, less than 30% of familial risk of breast cancer is due to known genes [23].

Although the impressive advancements in genomics have improved some of our basic understanding of the molecular biology and pathogenesis of different diseases, it would be naive to believe that genes are the sole determinants of our health, and bad SNPs are dictators of diseases. The scenario might be simpler in monogenic diseases, but becomes far more complex when many genes are involved, each harbouring a variant that confers a modest degree of increased risk. These variants interact with each other and the environment in complex ways, rendering their identification exponentially more difficult than for single-gene defects [2]. The modest effect of many of the common genetic variants identified so far, as well as the fact that they account for a small portion of the total heritability of inherited disease variation, have led to the re-examination of the contribution of environment, gene-gene and gene-environment interactions, and rare genetic variants in complex diseases [24]. Copy number variations are very frequent in the human genome [25], and they may have impact on disease predisposition as well, especially in psychiatric disorders [15].

Predictive genetic testing

When the genetic factors associated with a particular disease are known, predictive genetic testing offers at-risk individuals the opportunity to learn their predisposition. Knowledge of the gene status may enable people with positive test results to take preventive measures to reduce the risk, impact and severity of the disease in the future. Such measures include medical surveillance (e.g. breast cancer screening), lifestyle modifications (e.g. physical activity), diet, and drug or gene therapy. As of mid-2008, there were more than 1,200 clinically applicable genetic tests available, with an additional 300 available on a research basis only [26]. And this number was predicted to increase by 25% annually.

There are two distinct categories of predictive genetic testing: 1) *Presymptomatic genetic testing*, which is genetic testing in apparently healthy adults who are at risk for a single-gene disorder. This type implies testing for genetic disorders which are rare, but have a high risk of transmission to offspring; they are caused by mutations which have a very high correlation with an abnormal phenotype >

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- > (a high predictive value) and usually have poor treatment options. Apart from a few exceptions, these disorders are fully penetrant, i.e. they occur with virtually 100% certainty in people who have inherited a specific gene mutation in one allele (in the case of dominant inherited diseases, e.g. Huntington's disease), or in both alleles (in the case of recessive genetic diseases, e.g. cystic fibrosis); and 2) *Susceptibility (predispositional) genetic testing*, which is genetic testing in apparently healthy adults to determine whether they are at increased risk, relative to the general population, for a specific future disease (e.g. breast cancer). This type tests for common disorders which have a low risk of being transmitted to offspring, are caused by a mixture of environmental and genetic factors (the latter having, at least so far, a very poor predictive value), and can be usually prevented through treatments or lifestyle changes. In this case, a positive test result (finding a mutation) does not necessarily mean that a person will develop a future disease. Disease onset may depend on other factors, e.g. other susceptibility genes or environmental factors.

Predictive genetic testing can detect single-gene mutations as disease cause, as well as genetic variants associated with increased risks and predisposition to a variety of diseases. Depending on our current knowledge of the pathogenesis of the disease in question, the test can tell us the disease risk with 100% certainty (in the case of presymptomatic genetic testing) or only a risk estimate (in the case of susceptibility genetic testing). However, as research continues to improve our understanding of disease mechanisms and their interactions with genomic and environmental factors, we may in future reach a point where we can provide accurate risk estimations for any disease. Hence, at least for some genetic diseases, it may be a question of time before susceptibility genetic testing becomes presymptomatic genetic testing.

Because of the dramatic impacts that presymptomatic genetic testing may have on one's life, it also raises many psychological, social, ethical, legal and financial issues. People considering whether to undergo the test must weigh the 'pros' and 'cons' in view of the decision of continuing to live with all the uncertainty caused by the unknown gene status or disclosing it. Therefore, genetic counselling by a multidisciplinary team is recommended in many European countries, both pre- and post-testing. Guidelines for genetic testing for some diseases have been published to advise clinicians and geneticists on counselling individuals and administering the test.

Ideally, genetic testing should meet specific ethical and professional criteria. However, an increasing number of companies are offering direct-to-consumer (DTC) genetic tests, in which individuals can collect their samples at home and send them directly to laboratories without genetic counselling. According to a report in *The Lancet*, an undercover study of 15 DTC genetic tests by the US

Government Accountability Office found "egregious examples of deceptive marketing, in addition to poor or non-existent advice from supposed consultation experts" [27]. Another ethical concern is that some risk predictions offered by DTC genetics firms are associated with conditions for which consumers might not be able to take any action, says Erynn Gordon, the director of genetic counselling at the Coriell Personalized Medicine Collaborative. This raises the question of whether taking some tests "can cause more harm than good." Another risk that DTC genetic testing cannot exclude is surreptitious testing, since some companies are willing to analyse DNA left on discarded items such as chewing gums, used Q-tips, cigarette butts or strands of hair. Currently, the USA has no strong federal regulation moderating the DTC market.

An article on the risks of presymptomatic DTC genetic testing alerted to the fact that most genetic tests currently are not conform with the principles of population screening: "a suitable and acceptable test addressing an important health problem that has a recognizable latent or early symptomatic state, a well-understood natural history, and an accepted and available treatment or intervention" [28]. Moreover, DTC genetic screening may place a substantial burden on the healthcare system without providing demonstrable benefit.

Living with a positive predictive test result

Does early detection of disease risks improve health in presymptomatic individuals? The benefit of prediction or early detection is closely related to the ability to interfere with the natural course of the disease in a positive way. It also depends on the nature of the diagnostic and treatment procedures (if available), and the risks they may bear for affected or at-risk individuals. Last, it also depends on the degree to which each individual will be affected. Those expected to be most severely or least severely affected are likely to benefit less from early detection than those with intermediate severity [29].

Today's technology is able to decode our genome, but are we ready to understand the answer it may give us and cope with its consequences? Is society as a whole equipped enough to make reasonable choices based on the information offered by this technology? Indeed, for most diseases, the impact of predictive genetic testing on psychological well-being has not yet been adequately studied, neither in the short nor long term. A study in a small cohort (N = 119) of individuals at risk for Huntington's disease who had undergone predictive testing identified depression as a very frequent symptom post-testing [30]. Surprisingly, 27% of non-carriers of the mutant gene did not cope well with a favourable result, and 24% of them were depressed (versus 58% of the mutation carriers). The study also reported three suicide attempts in the non-carrier group (versus one attempt in the carrier group). These findings reiterate the

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importance of post-test counselling independently from the test outcomes. Another study in Huntington's disease patients published recently found that a small sub-set of patients (N = 45) without family history had a disease onset nearly 10 years later than would have been expected based on their mutation [31]. This means that not being aware of the disease and not knowing the gene status was an advantage that allowed people to have more disease-free years in their life. Despite intensive efforts in research on Huntington's disease in the last decade, no genetic or environmental factor has been identified so far that could delay the onset of this incurable disease by 10 years. These findings demonstrate that the benefits of presymptomatic genetic testing are not only linked to the disease burden and to chances of treatment, but also to a psychological dimension.

Editor's comment

Readers may be curious to know why in Gargiulo et al's study [30] a quarter of the people suffered from depression after receiving a negative predictive testing prognosis for Huntington's disease. I asked Diana if the authors gave any suggestions as to why the people who should have been pleased with the outcome responded badly.

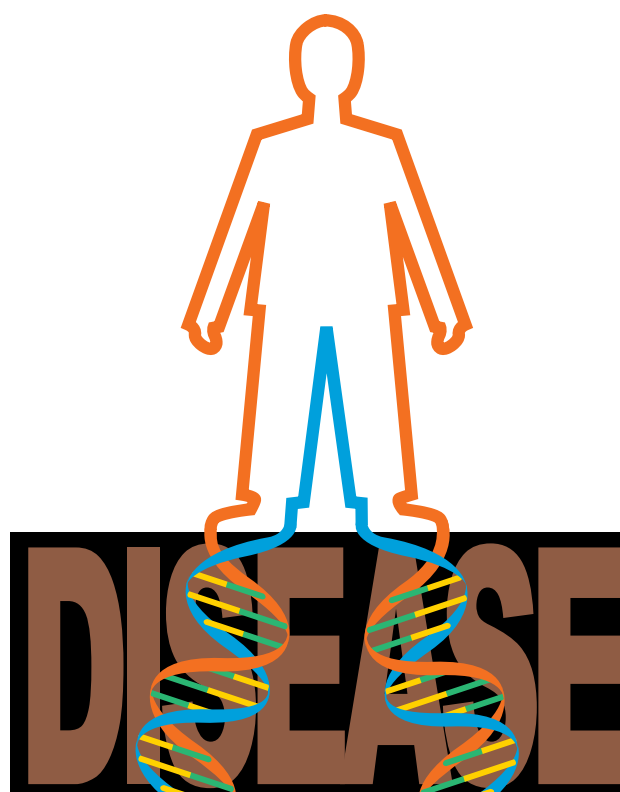
She replied that the authors speculated that "One reason for negative reactions of confirmed non-carriers might be an important change in personal identity of someone who had lived with the idea that he had a serious disease. In any case, non-carriers need time to recover from being 'at risk'. Even after a long delay, the person who is no longer at risk may have difficulty living with the favourable result. We could hypothesise: a) guilt about surviving without the 'bad' gene; b) regret for life decisions made in the past as a function of the risk; c) inability to leave behind the at risk status; d) inability to believe the result and e) reactions of familial environment."

The authors found an association between being depressed before the test and after the test for both carrier and non-carrier groups. They said "The high rate of depression after testing in non-carriers might, therefore, be related to their personal history, and is reflected in the frequency of suicide attempts and hospitalization in psychiatric departments reported by noncarriers and carriers. These results indicate that an unfavourable outcome is related more to a prior history of depression rather than to a 'good' or 'bad' test result."

TWS readers are reminded that there is a facility for making comments on the online version of TWS (www.emwa.org) if they have any questions to the author or comments they would like to make on an article published in the journal.

A positive presymptomatic test result has far-reaching impact on different aspects of life and many decision-making processes, for example, when deciding how many years to invest in education, what profession to choose, and whether to have children or not. It may also lead to stigmatisation and discrimination both in social relationships and in the working environment, even in countries where laws exist protecting against genetic discrimination. And it may make arrangements of health, disability and life insurances or mortgages difficult.

Depending on the severity of the disease, those individuals with positive predictive test results who want to have children face the challenges of deciding for natural conception (and subsequent prenatal testing and whether to abort or not) or, alternatively, preimplantation genetic diagnosis (PGD) in countries where these procedures are permitted and available. They may find themselves in the very difficult situation of deciding what is worth living and what is not. This 'playing God' situation sounds familiar to pregnant women aged over 35 who are offered prenatal testing for the Down syndrome, a routine practice in many countries. In the case of late-onset diseases, prospective parents have to make this decision decades before their offspring develop the symptoms, not knowing what treatment options might be available in the future. Another polemic issue is that, in some countries, prenatal testing and abortion are allowed, whereas PGD, an *in vitro* fertilisation procedure that prevents passing on a genetic disease to the next generation, is prohibited. People who have been tested positive after the birth of their children have to choose whether and when to tell the offspring about their genetic risks. They have to balance the fear and panic this >



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> information may cause against the advantages that any preventive measure or treatment may offer, whilst taking the age of the children into account. As a rule, predictive testing for late-onset diseases is not allowed in minors.

In a recent issue of *Science* commemorating the 10th anniversary of the first human genome sequence publication, Tom Hudson (president of the Ontario Institute for Cancer Research) said that what amazes him in retrospect is the fact that genomic information and technologies grew more than a million-fold in the following decade and, in a way, leapfrog other critical initiatives in health research [32]. “Now,” he said, “clinicians are more and more concerned by over-detection, overdiagnosis, and overtreatment of diseases, as a result of sensitive tests. Whether the disease involves cancer, metabolism, inflammation, or neurodegeneration, it becomes apparent that we have a limited knowledge of disease processes over time and, consequently, limited knowledge of when to intervene and to what degree. In some patients, this leads to unnecessary complications, whereas in others, the failure to act early is irreparable.”

For predictable diseases, accurate information on disease risks might be available out there, but do we really want to know it? For the time being, predictive testing is only

beneficial if medicine is able to provide effective preventive measures or treatments for the disease in question. The problem is that curative medicine does not hold the current pace of disease diagnostics, and preventive medicine strives to close the gaps between both, often with un-specific, common-sense health recommendations. Hence, the most important factor in deciding whether or not to undergo predictive genetic testing is probably choosing the right time to do it.

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Shooting the cover

The photo shooting for the cover of this issue of *TWS* was accompanied by much hilarity. To achieve the nose-to-nose alignment the models had to stand stomach-on-stomach with the lady balancing on a brick. Finally, after many photos that might have conveyed something other than healthcare communications, our photographer Nadja Meister was able to take one that struck the right note.

Introducing the Manuscript writers' column

Welcome to the first instalment of the Manuscript writers' column. In this column, I will answer questions and discuss recent developments related to writing peer-reviewed manuscripts.

Admittedly, manuscript writing represents a small fraction of the area we know as medical writing. However, it is an essential aspect of what we do, and doing it well and efficiently demands high standards. Thus, at least in my opinion, manuscript writing deserves a dedicated column.

Peer-reviewed articles are an essential part of scientific communication. As described by Stretton et al. in a previous issue of *The Write Stuff*, they are "the foundation of medical knowledge"; through them, researchers inform about advances in medicine [1]. Peer-reviewed articles also serve as a source of information for policy makers, and because they are highly regarded by doctors, they directly influence clinical practice and prescribing [1]. For pharmaceutical and medical device companies, therefore, peer-reviewed articles are a key part of a communication plan [2]. Finally, other than the Summary of Product Characteristics, in many countries, peer-reviewed publications

are the only source of information that can be cited in marketing materials.

To make it through peer review and be published, a manuscript should be well organised, well written and of high scientific quality [3]. Manuscripts need to capture and hold the interest of the reader and convince them of the conclusions made. As professional medical writers, we have a lot to offer: we can help improve the quality of manuscripts and the writing in them; we can reduce the amount of time, costs and aggravation needed to deliver manuscripts; and our participation can help reduce the risks and costs of unethical publication practices [1].

If you have questions that you would like answered or interesting information to share, please send an e-mail to pleventhal@4clinics.com.

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How much time does it take to write and publish a manuscript based on a clinical study?

by Phil Leventhal

The answer to "How much time does it take to write and publish a manuscript based on a clinical study?" is a bit like asking "How long is a piece of string?" The time needed to write an article includes the actual time to write a draft that will be submitted and the time to get through the review process, whereas the time to actually *complete* the whole manuscript writing project is far hazier.

I was unable to find any answers to this question on the Internet, so I base my answers on my own personal experience along with informal discussions with other medical writers as well as an ongoing discussion on EMWA's LinkedIn page [1].

Time needed to prepare a final draft Writing time

The 'final draft' refers to the version that will be submitted to the journal and not the version that will show up in print. Generally plan on 80 to 120 hours to complete the final draft for an article based on a clinical study (Table 1). When asked for a single 'ballpark' number, 100 hours is a reasonable estimate. These estimates include the time to prepare an outline, two intermediate drafts and a final draft, as well as time for meetings, phone calls, and e-mail. It does not include time for travel or extras like translations or making figures.

Staying within this time limit requires a writer to be organised and efficient, but it also requires receiving all of the information needed (study reports, detailed technical methods, protocols, appendices, translations, abstracts, posters, and figures) as well as a reasonably well-defined review process that does not result in an excessive number of drafts and review cycles. Also important for sticking to this time line are early decisions about the target journal, authorship, and the key messages. Discussing all of these issues during the kickoff meeting and during the outline review process rather than later on will save a lot of time.

In reality, two drafts plus a final draft is an ideal situation. More often, the number of drafts is higher. Delays are often caused by a disorganised internal review process, inaccessibility of contributors, incomplete or badly written source materials, conflicts between contributors, the need for additional analysis or data, and major changes to the manuscript late in the writing process by other stakeholders. For example, I have had marketing, administrators, and patent lawyers may put a whole new spin on articles, adding extra unanticipated layers of work. There are ways to avoid or reduce these time overruns, for example, by being well organised, keeping in close communication with contributors, and getting input from all stakeholders >

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- > early in the process, but it can be difficult to make others be organised and efficient.

Turn-around times

For the outline, plan 1 week after the kickoff meeting and receipt of all necessary materials. For the first draft, plan 2 weeks from receipt of all comments on the outline. Making fixed deadlines for the remainder of the process is difficult because they are heavily influenced by things that a writer cannot control, such as the availability of contributors and additional analysis or data. In the *best* cases, completion of the final draft typically requires between 4 and 6 months, but be careful to not be held to that because of the influence of forces that are not under your control.

Time needed to submit an article

If asked to submit an article on behalf of the corresponding author, plan 4 to 8 hours over 1 to 2 days. This sounds like a lot, but often, several essential pieces of information will be missing. Information needed for submission may include detailed contact information, highest degrees of coauthors, key words, names of requested and excluded editors and reviewers, figures in correct electronic formats, copyright transfer agreements, and conflict of interest forms. Some time can be saved by collecting this information early in the writing process, but in practice, some of it becomes available only when the writing process is nearly finished. Finally, if asked to write a cover letter, plan 1 to 2 hours of work over 1 day.

Time to get from submission to publishing an article

Peer reviews generally take 2 to 3 months. (Any more than that and you should contact the editorial office to see what has gone wrong.) In addition, many articles are rejected by the editor without being sent out for review because of

page limitations or priority (i.e. lack of sufficient interest or importance for the journal) or because an incorrect journal was targeted. Usually, the journal will send a notice of rejection without review within a month.

For articles provisionally accepted or possibly acceptable following a rewrite, plan 2 to 3 days of writing time over 1 to 2 weeks to rewrite the article and to prepare a rebuttal document in which you respond to the referee's comments. Several weeks will be needed for reviews by coauthors and other contributors and receipt of any additional information, so the total time from receipt of reviewers' comments to resubmission will be 1 to 2 months. At the same time, the journal will usually give a deadline of 1 to 2 months for resubmission, so time lines for completing the resubmission will be tight. Once the resubmission has been sent to the journal, expect about 1 month for a response.

Rewriting is also highly recommended for articles rejected following review, even though they will be going to a new journal. Wherever possible, changes should be made to the article according to the referees comments as if it were a request for resubmission. Of course, it will not be necessary to prepare a rebuttal document in this case. Therefore, plan 1 to 3 days of writing time over 1 to 2 weeks.

Even articles rejected without review and resubmitted to new journals with no major revisions will require some work to make sure that they are reformatted according to the instructions for authors. In this case, plan 2 to 4 hours of work over 1 day.

Combined, if an article is approved by the reviewers with a normal amount of revisions (one), 6 to 9 months are generally needed to progress from the beginning of writing to acceptance by the journal. Additional time will be needed for the article to appear in print, usually between 3 to 6 months, although with online journals, times are shorter. Accordingly, a typical article will take about a year from the start of writing to appearance in print, but do not be surprised if it takes longer than that; most projects suffer from a variety of delays.

Conclusion

For a typical article, expect 80 to 120 hours of writing and meetings, 6 to 9 months from the beginning of the project to acceptance, and 1 year or more from the beginning of the project to publication in the journal. Writers should not be surprised if more time is needed, but they should be organised and efficient to stay within estimates and keep time and costs down.

* If you would like to comment or disagree, please feel free to write me at plevanthal@4clinics.com.

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References:

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Table 1. Estimated working time and calendar time to write and publish an peer-reviewed article based on a clinical study

Step	Working time	Calendar time
Preparation of a final draft		
Outline + kickoff meeting	10-15 h	1 week
First draft	40-50 h	2 weeks
Second draft (and minor corrections)	20-30 h	?
Final draft	10-25 h	?
Total from start to final draft	80-120 h	4 to 6 months (?)
Submission		
Cover letter	1-2 h	1 day
Online submission	4-8 h	1-2 days
Total for submission	5-10 h	1-2 days
Revision (each round)		
Rewriting	8-16 h	1 week
Rebuttal document	8-16 h	1 week
Total for revision	16-32 h	2 weeks
Time to acceptance	-	6 to 9 months
Time to appearance in print	-	≥1 year

Gained in translation ■

Science at the multilingual crossroads

This issue's translation section combines two texts ideally complementing each other. One discusses the challenges national biomedical journals previously published only in the country's vernacular language are facing when going bilingual. The other provides an as brief as possible account of how to plan and prepare for going multilingual.

Science writing never is a simple process. Neither is science translation. At its best, translation may even be an additional quality-assurance step during finalisation of source-language documents. Both writing and translating are most successful when bringing together medical and linguistic expertise in a team effort. Combine the two—and you are well poised to arrive at supreme-quality results.



Outsourcing translations: The hows and whys of it

by Gabriele Berghammer

According to Merriam-Webster's Unabridged Dictionary [1], 'outsourcing' is procuring services under contract with an outside supplier. 'Insourcing,' as we learn from its Oxford counterpart [2], is the reallocation of work previously done by an outside supplier to in-house staff (insourcing has not yet made it into Webster's). Then there's multi-sourcing—not yet covered by either of the two dictionaries—i.e., the disciplined blending of services from both internal and external providers [3].

With translation services, too, that's the three options you have. A distinct benefit of insourcing is to have an internal team of translators who are familiar not only with their company's products, placement strategies, and corporate philosophy, but also with company style and terminology, workflows, development backgrounds, and the competitor situation—all aspects that are important to be able to produce high-quality translations for diverse markets. Whenever workload peaks, an in-house translation division will also be able to seamlessly outsource relevant services to external partners. However, not every company—particularly when small- or medium-sized—, will be able to afford the luxury of an in-house translation team. For people not dealing with translation every day, buying one from external providers can be challenging at best. How to outsource for optimal success?

According to the proverb, "He who fails to plan, plans to fail." Companies intending to go international should start making provisions for multilingual projects as early on as possible by looking for a suitable translation service provider and giving translators sufficient lead time to familiarise themselves with the company's philosophy and products. Another aspect of preparing for the global market is to take a close look at the company's document portfolio and ask some hard questions about it: are our documents accurate, clearly written, and as concise as possible? Are they impeccably formatted? Is the company-specific

terminology used consistently throughout? Are our texts free of colloquialisms, idioms, and images that are unlikely to work in the target language? Any error or oversight in a source text that's translated into ten target languages will be multiplied times ten.

In early 1998, then British Prime Minister Tony Blair addressed a gathering of Japanese businessmen during his visit to Japan [4, 5], vowing to control public spending to reform Britain's industry and welfare state: "Have no doubt: this Government will not be deflected by short-term considerations. We will take difficult decisions. When it comes to putting our economy on a secure footing for the long term, we intend to go the Full Monty. This is a very English expression. Most of you won't know what it means. It is an expression of absolute determination and I am determined that nothing will get in the way of making Britain a model 21st century economy. The Full Monty is also the name of a new British film. I hope you will have a chance to see it in Japan soon" [6]. Mr Blair made reference to the 1997 British hit movie "The Full Monty," paying tribute to the film's redundant Sheffield steelworkers who, instead of staying on the dole, decided to start a career as male strippers.

Including such culture-bound images is never a good idea when addressing a foreign audience. Even if the words are translatable, they may be devoid of meaning in a different culture. The phrase 'the full monty,' for example, is thought to derive from the tailoring business of a certain Sir Burton who also had premises in and chose to live in Sheffield, with 'the full monty' referring to a complete three-piece suit [7]. The phrase had apparently been in circulation before the film, but it had not appeared in print. The movie's plot was a fundamentally British one, moving the nation's postimperial working-class identity centre stage—and it had not been released in Japan. For all of these reasons, Blair's wordy reference is unlikely to have evoked the intended image in his Japanese audience's mind.

Some things simply don't travel across cultural frontiers. Therefore, the better the shape of your source-language documents both linguistically and technically, the >

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- > smoother the translation process. Once you've reviewed your documents and found a translation provider—what next? Here's a brief summary of things to consider before, during, and after translation.

Defining the purpose of the translation

No text is an end in itself. Rather, it should lead to action or impact attitudes or behaviour. Do not leave your translators in the dark about what you hope to achieve with a given text.

What's the function of the text? Generally speaking, texts are either informational or communicative. Informational texts try to make sense of reality, using mainly descriptive and argumentative language. Texts falling into this category include product fact sheets, biomedical publications, text books, or scientific reports. Communicative texts, on the other hand, establish social relations, using mainly expressive language that conveys feelings or attitudes. Such texts include promotional brochures, editorials, written speeches, or creative and aesthetic texts. Of course, no text will strictly be either one or the other—but categorising texts helps determine how they should best be translated and which register to use. The more the translator knows about the situational context of a translation, the better able he is to make specific choices to produce a made-to-measure translation.

For-publication or for-information translation? Is the translation intended to merely give a few people in your department a rough idea about what a foreign-language text says or will the translation go to press? A translation intended for information purposes only can generally be produced faster than a translation intended for publication. To be sure, even the for-information translation will be an accurate rendering of the original—but it may be less polished stylistically than a translation that's going to be published. Here's an example of how translation of the same text genre, a biomedical publication, may require two diametrically opposed translation strategies:

Picture a research scientist who wants a manuscript translated from German into English. The client's explicit goal is to have the manuscript published in a peer-reviewed journal. In this case, the translator is not doing her job well if all she does is translate the source text and make sure that the grammar and medical terminology are correct. With the declared goal being that translation results in a submittable text, the translator should produce a text that fulfils the expectations of the target-language reader in terms of style and format. This may require moving misplaced information between the different sections of the manuscript, pointing out to the author that the text misses out on some logical links, correcting mismatched references or legends, or bringing the paper in line with relevant publication guidelines, such as CONSORT, STROBE, or journal house style. Ultimately, translation may result in a manuscript that differs substantially from the source text.

Alternatively, company X needs a biomedical publication authored by one of its competitors translated from German into English because the publication is thought to contain misleading statements about one of

its products. Company X therefore intends to instigate legal action against its competitor, and the German-to-English translation will be part of the briefing package prepared for company X's lawyers. In this case, the translator must take care to faithfully render every detail and nuance of the source text. The main focus of translation is not to arrive at a stylistically supreme translation getting all of the medical jargon right, but to stick to the source text as closely as possible.

Legally binding or courtesy translation? Is the translation of your company's terms and conditions to be legally binding in the target language or is the translation merely provided as a service to foreign-language readers? If the target text is to be legally binding, make sure your company's legal department is involved every step of the way until final approval of the translation to make sure each item has been correctly interpreted. If push comes to shove, an official translation may have to hold water in court. Alternatively, the translation may be provided merely as a courtesy to your foreign-language clients. In this case, add a note to the effect that the target-language version is a courtesy translation only and that, in case of discrepancies, the source-language version shall prevail.

"Aren't translators in a position to faithfully transfer a text into the target language, maintaining all the nuances and intended meanings of the source text?," you may wonder. Even in a single language, ambiguities abound, and evaluating the meaning of words is often a matter of subjective interpretation.

For example, in a 1991 US court case, the defendant's comparative advertisement claimed that the competitor's product was subject to "catastrophic failure." The plaintiff produced evidence that the medical community targeted generally understood catastrophic failure to mean "a failure resulting in serious equipment damage or patient injury." The defendant countered that the definition of catastrophic failure had been taken from an engineering dictionary, which described the concept as referring to "a sudden failure not associated with typical wear." The court rejected this explanation, stating that there was "no evidence that the dictionary definition reflected a common understanding among targeted consumers" [8].

How much the meaning of even every-day words can be a matter of interpretation becomes clear from the following example from bilingual Canada.

In a 2002 Canadian court case, the defendant was charged with being "in possession of various machines and materials adapted and intended to be used in forging credit cards." In an appeal against the judgment, the defendant's lawyer maintained that the word "adapted" was interpreted by the court as meaning "suitable for" rather than "modified or altered." With the word "adapted" having two equally viable meanings, the lawyer maintained, it was not possible to determine with certainty which of the two meanings the lawgiver had intended, which is why the ambiguity should be resolved in favour of the accused [9].

The Canadian Criminal Code is a bilingual statute both the English and French versions of which are equally authoritative. It is Canadian practice for statutory interpretation of bilingual enactments to begin with a search

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for the shared meaning between the English and French versions. In cases where the words of one language version give rise to speculation, the courts should first turn to the other official language version to see whether the meaning in this language is unequivocal. Because the proper interpretation of the word “adapted” was resolved by clear language in the French version, the appeal was refused [9].

Additional challenges may arise in legal translation when translating between civil and common law cultures as is the case for translations between most European languages and English. Therefore, particularly when it comes to offering legal texts in more than one language, make clear which language versions are to be considered official, because even the slightest ambiguity can affect legal analysis and decision making.

Who’s the audience of your translation? When having a Summary of Product Characteristics (SPC) and Package Leaflet (PL) for a given medicinal product translated, it should be immediately clear to any medical translator that the SPC addresses healthcare professionals and the PL targets patients. With other documents, this may be less obvious. Therefore, be sure to let your translators know whether they will be writing for healthcare professionals, adult patients, or children so they can adapt the language they use to the level of health literacy of their readers.

Does the entire text need translating? Clients sometimes deplore the high costs of translation. You may have a 100-page report that you want translated into English. Think about whether your audience is really going to read all 100 pages—or whether translating the Executive Summary may suffice. Alternatively, you may choose to omit sections not relevant to foreign-language readers. Finally, some source-language documents may benefit from being trimmed down to avoid redundancies and delete unnecessary information—a step that also contributes to reducing translation volumes and costs.

What language variant do you need? Finally, tell your translator whether your translation into English is intended for a British, an American, or an international audience, whether transposition into German is intended for the German, Austrian, or Swiss market, or which regions your Spanish or Portuguese translations are intended for.

Specifying additional services

Supportive services. Many translators also offer services other than translation proper, such as editing, reviewing, rewriting, adapting, gisting, or updating documents.

Developing style guides in the source or target language. Translators generally work with their own proprietary style guide to ensure that the texts they deliver are uniform in style and formatting. For companies working in more than one language, a style guide—a set of standards for the writing and design of documents—should be available for each. Style guides contain instructions on punctuation (e.g., use of spaces, commas, dashes, or quotation

marks), spelling (e.g., capitalisation, names, titles, units of measurement, mathematical and scientific symbols, abbreviations, acronyms, hyphenation, or transliteration), the design of tables and figures, or specific terminology to be used or avoided. Particularly typographic conventions can vary greatly between languages.

Glossaries and terminology databases. Glossaries and terminology compilations increase the consistency of both your source and target language documents by documenting and promoting correct usage. A glossary is a list of terms in a particular domain of knowledge with the definitions for those terms. It generally appears at the end of a document and includes terms within that document which are either newly introduced in the text or uncommon. Terminology denotes a more formal discipline which systematically studies the labelling of concepts particular to a given domain of human activity. The simplest form of compiling company-specific terminology is a (bi- or multilingual) word list. Alternatively, terminology software, often integrated with other computer-aided translation (CAT) tools, may be used. An entry in a terminology database also includes meta-information on a given term, such as its source, definition, or synonyms, and may look as follows:

Figure 1 Entry in a terminology database

en: proprietary medicinal product	de: arzneispezialitäten
source: directive 2001/83/EC	source: richtlinie 2001/83/EG
def: any ready-prepared medicinal product placed on the market under a special name and in a special pack.	def: alle arzneimittel, die im voraus hergestellt und unter einer besonderen bezeichnung und in einer besonderen aufmachung in den verkehr gebracht werden.
context:	context:
note:	note: ‘fertigarzneimittel’ is the term used in the German AMG
synonym:	synonym: fertigarzneimittel (see note)

Computer-aided translation (CAT) tools. Translators will be able to advise you on whether they think using a computer-aided translation (CAT) tool makes sense for your company’s documents. The core of most CAT tools is a translation memory (TM). TMs consist of text segments in a source language and their translations into one or more target languages. These segments can be paragraphs, sentences, or phrases (individual words are the domain of terminology bases rather than TMs).

The concept of TMs is based on the notion that sentences used in previous translations can be recycled. A TM breaks the source text into segments (e.g., sentences), looks for matches between the source text and previously translated source-target pairs stored in the database, and displays any matching pairs as translation candidates. The translator can accept a candidate, replace it with a new translation, or modify it to match the source. When instructing the TM to search for 100% matches only, it will retrieve only segments of text that are a perfect match to the segment you need translated. Alternatively, fuzzy matching algorithms

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- > retrieve segments that are similar to the new source-text segment and can be adapted manually (Figure 2).

Figure 2 Translation memories: reusing previously translated text

previously translated language pair stored in the TM	en:	WonderDrug should be taken with food to minimise the risk of gastrointestinal irritations.
	de:	Um das Risiko einer gastrointestinalen Irritation zu minimieren, sollte WonderDrug mit einer Mahlzeit eingenommen werden.
new sentence to be translated	en:	WonderDrug should be taken with food to minimise the risk of gastrointestinal irritations.
100% match available in the TM	de:	Um das Risiko einer gastrointestinalen Irritation zu minimieren, sollte WonderDrug mit einer Mahlzeit eingenommen werden. <100% match>
new sentence to be translated	en:	NovelDrug should be taken with food to minimise the risk of gastrointestinal irritations.
92% fuzzy match available in the TM	de:	Um das Risiko einer gastrointestinalen Irritation zu minimieren, sollte WonderDrug mit einer Mahlzeit eingenommen werden. <92% match>

As a rule of thumb, the larger a document, the more standardised its language, the more frequently it is updated, and the better formatted it is, the more beneficial a translation memory is going to be, increasing both the consistency and the turn-around time of translation. Conversely, for short, one-off texts using highly creative language, use of a translation memory may not be the most time-efficient approach.

When you've got loads of electronically available documents in both the source and target languages and opt for the use of a TM, your translator may suggest 'aligning' these source and target language documents to make them available for future use in a TM.

Certified, legally certified, or notarised translations.

Although both the name tags and legal requirements vary from country to country, a certified translation, typically required for official use by a non-governmental organisation, is a fully checked professional translation. The translator certifies that he or she is fluent in both the source and the target languages and that the translation is complete and accurate to the best of the translator's knowledge and ability. The translation is generally stamped and numbered and returned with a translation certificate. A notarised translation is a translation that is signed and dated by the translator in the presence of a notary public. Notarisation indicates that the identity of the person signing the certification is confirmed by the notary public and that the translator has declared on oath and in writing that the translation is true and faithful. Finally, a legally certified, or sworn, translation is one that is done or approved by a court-certified translator. Such translations are required by certain organisations and especially courts.

Always check what level of legalisation is required for a particular translation; in many cases, a certified translation may be sufficient. Of note, however, none of these levels of legalisation say anything at all about the quality of the translation—an important point to consider when it

comes to medical translations that need to be legally certified. Court-certified translators are generally specialised in legal translation, but they may have little expertise in translating medical texts. In this case, have a medical and a court-certified legal translator collaborate.

To back translate or not to back translate... Back translation—translation of a translated text back into the language of the source text that is made without reference to the original—has traditionally been used as a quality-control step to determine whether a text has been accurately rendered in the target language and is free of additions or omissions. For sure, high-quality translations do require a tight and thorough review process, but not everybody (including myself) is convinced that back translation is the best way to do it.

Every text can be translated into another language in many equally correct ways. Similarly, there are many equally correct ways a given translation can be translated back into the source language. Although I can see how a back translation could spot grave inconsistencies, additions, or omissions relative to the source text, it is unlikely to say anything about the stylistic, terminological, grammatical, syntactic, or semantic quality of the original translation— aspects that will still need to be reviewed separately. Not only does back translation double the cost of translation, it also takes a linguist or other expert to check the back translation against both the source and target texts—an additional time and cost factor. With thorough quality assurance in place (see below), the need for back translations is likely to be minimal.

Obtaining a translation quote

Have a sample text handy. When contacting a translator for a translation quote, have a sample text ready to send to the translator. Most translators will be hesitant to give even a rough quote unless they have first seen the source text. Even a cursory look at the source text will give the translator a good idea of how much it takes to translate it. The professional ethics require that the translator consider confidential any information or document supplied by a potential client.

Individual translator or team of translators? Taking into account your time- and deadlines, can the volume of translation be handled by a single translator or will a team be needed? Based on rough estimates, one translator can handle about 2000 words a day on average. Therefore, when you need a 6000-word document translated by tomorrow morning—no way can a single translator handle this. When working with a team of translators, some time should be allowed for coordinating the translation process between all team members to make sure translation memories can be exchanged, terminology can be harmonised, and the final translation can be checked and revised to avoid patchwork.

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One target language or many? Do you need your English text translated into German only—or into a number of western European languages, Russian, Chinese, and Japanese? In the first instance, you may choose to work with an individual translator—deadline and translation volume permitting. If you need several target languages, including languages using different character sets, you are probably going to opt for a translation agency coordinating the entire multilingual process for you—from selecting and negotiating prices with the translators to collecting the terminology, having the translations revised and getting the documents typeset.

How to determine the level of competence of translators? Obviously, translators should have a thorough knowledge of both the source and target languages, translating competence, and cultural and technical skills. According to European standard EN 15038 [10], these competences should be acquired through (1) a formal higher education in translation, (2) an equivalent qualification in any other subject plus a minimum of two years of documented experience in translating, or (3) at least five years of documented professional experience in translating.

Yet, when it comes to highly technical and complex subject areas such as medicine, fulfilling a set of formal, yet vague, requirements may not be enough [11]. Ultimately, the proof of the pudding is in the eating. Ask for references or samples of translated text. You may not find out whether translators are sufficiently proficient in your subject area unless you have worked with them. Also, it will take some time for even the most experienced translator to become fully familiar with your company and products. Therefore, the closer the relationship with your translator, the more effective the translations are going to be. Overall, however, translators should not be learning about a particular subject area at the client’s expense [4]: The more demanding your subject, the more critical it is to work with translators who already have a thorough understanding of your specialty.

The text excerpt given in Table 1, an arbitrarily selected publication [12, 13] from one of the latest issues of a German medical society, highlights how important it is to work with translators who are truly at home with a given subject field and text genre. According to the journal’s website [14], the print edition publishes articles in German only, whereas the online version provides scientific articles in both German and English; translation into English is performed by the publisher. Although the sample translation in Table 1 does not, to be sure, contain any serious errors, it disregards some basic principles of translating—and good writing. The resulting disparities between source and target and the rather unwieldy style result in a text which, I believe, ill-represents the German authors of the original text to their international readership. Therefore, particularly for translations that will go to press, make sure that the translators you select are experienced and well-versed in what they are expected to do.

Table 1 The proof of the pudding is in the eating: a real-life translation sample

Beeinflussung des Fettstoffwechsels durch systemische Vitamin-A-Derivate – Welche Empfehlungen leiten sich daraus für die dermatologische Praxis ab? [13]	The impact of oral vitamin A derivatives on lipid metabolism – What recommendations can be derived for dealing with this issue in the daily dermatological practice? [12]
Diese Übersichtsarbeit vermittelt in komprimierter Form einen, für den Dermatologen relevanten, Überblick über die einzelnen Vitamin-A-Derivate und der zu erwartenden Beeinflussung von Fettstoffwechselfparametern. Zudem enthält die Arbeit eine Konsensusempfehlung zum Umgang mit und Management von Laborwertveränderungen vor, während und nach einer systemischen Vitamin-A-Derivat-Therapie, die es dem Dermatologen im Praxisalltag erleichtern soll, für den einzelnen Patienten ein individuelles Therapiemanagement zu formulieren. Die Konsensusempfehlung ist eine gemeinsam erarbeitete Stellungnahme der „Deutschen Dermatologischen Gesellschaft“ (DDG) in Kooperation mit der „Deutschen Gesellschaft zur Bekämpfung von Fettstoffwechselstörungen und ihren Folgeerkrankungen“ (DGFF [Lipid-Liga] e. V.).	This review paper gives a brief, concise overview of the vitamin A derivatives and possible effects on lipid metabolism that can be expected. Additionally it contains a recommendation for secure handling of abnormal laboratory values before, during and after oral therapy with vitamin A derivatives. The aim of this article is to provide practical help and confidence in dealing with vitamin A derivatives in daily clinical practice. The publication was created in cooperation with the Deutsche Dermatologische Gesellschaft (DDG) and Deutsche Gesellschaft zur Bekämpfung von Fettstoffwechselstörungen und ihren Folgeerkrankungen (DGFF [Lipid-Liga] e. V.).

The stylistically distinct German phrase *vermittelt in komprimierter Form* is somewhat clumsily translated into English as “gives a brief, concise overview,” a tautology suggesting that the translator was unsure about which adjective was more suitable and then used both. The same sentence contains another tautology, i.e., in the phrase “possible effects ... that can be expected.”

The phrase “secure handling,” which may appropriately be collocated with ‘confidential data’ or ‘thin glass,’ does not work when combined with “abnormal laboratory values.” Although rendering *systemische Vitamin-A-Derivat-Therapie* as “oral therapy” is not altogether wrong because the result is the same, ‘oral’ stresses the mode of application and ‘systemic’ the type of effect the drug exerts (e.g., on the patient’s lipid metabolism).

Two concepts that are referred to throughout the German text, i.e., *Konsensusempfehlung* and *Dermatologen*, are lacking from the English translation—both essential aspects of the entire publication. The English sentence “The aim of this article is to provide practical help and confidence in dealing with vitamin A derivatives in daily clinical practice” lacks three aspects contained in the German original, i.e., (1) a reference to the effects of vitamin A derivatives on laboratory parameters—the focus of this publication, (2) a reference to dermatologists, and (3) a reference to tailoring treatment to the needs of the individual. Finally, both societies are spelled out in German without providing a translation to help non-German readers understand who these societies actually represent. (In the list of author affiliations, *Bekämpfung von Fettstoffwechselstörungen* was translated as “Fight against Fat Metabolic Disturbances”—leaving one to wonder just how fat such disturbances could become.)

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- > **What about copyright?** Make sure that the text you send for translation is not protected by copyright. It is not the translator's task to check whether the rights for translation have been obtained. Conversely, as a general rule, any translation is itself protected by intellectual property rights, just like any other original piece of writing. Unless otherwise agreed, what you buy from the translator is the right to use the translation for the purpose specified in the service agreement. If you wish to reuse the translation for a purpose other than the one originally agreed upon, talk to your translator. This has the added advantage of being sure that the translation will then also be adapted to suit its new purpose.

Printing translator credits. It is good practice to credit translators. By acknowledging their contribution, you motivate translators to supply high-quality work. Named translators will probably want to approve the galley proofs of the final publication to be sure that even last-minute changes were correctly implemented. Do not see this as yet another tedious and superfluous duty—but as an additional quality-control step that is to everybody's benefit.

Defining the level of quality assurance required. How thoroughly a text should be reviewed will depend on the purpose of your translation. Thus, for a for-information translation that's merely going to be read by a handful of people, a rough translation may be sufficient. In the case of an image-building brochure to be printed on glossy paper and distributed to hundreds of customers, a more elaborate review process will be needed. Here, European Standard EN 15038 [10] provides helpful guidance by defining four quality-assurance steps, i.e., checking, revision, review, and proof reading (see below).

A word on pricing. Translations are normally charged by word, standard line (50–55 characters including spaces), or page of either source or target text. This basic fee includes checking of the translation for correctness and consistency by the translator. It may also include revision and review by external experts as deemed necessary by the translator. However, additional review cycles and quality-assurance steps may not be included in the standard translation fee and should be detailed in the service agreement. When comparing prices between translation providers, find out more about what they actually include.

Commissioning the translation

Get everything you've agreed on in writing. To guard against misunderstandings and disappointments, it is a good idea to get all of what has been agreed with the translator in writing.

Be sure to provide the translator with the final version of the source text. It may be tempting to get your project rolling as early on as possible, but having a translator work on a draft will, in most cases, end up being more time-consuming—and expensive—than waiting for the final version. In addition, sending your translator different text versions will increase the likelihood of errors and oversights slipping into the translation.

Background material. Along with the final version of the source text, provide the translator with relevant background information and other resources, such as terminology lists, your company style guide, previous target-language versions of the document, similar documents, legal requirements, or publications referenced in the text.

Contact person. Name a company representative as a contact for the translator who will stand by and help the translator sort out any questions that may arise during translation.

Translators—a curious lot. Translators are among the first readers of your texts—attentive and critical ones at that. By deconstructing the original text and constructing a new one in the target language, they are likely to spot inconsistencies or sections that may require clarification. And they will ask questions about them. Also, translations may be returned with translator's notes explaining why a particular translation decision was taken or highlighting terms or phrases that may allow for more than one interpretation. By entering into this dialog with your translator, translations will often contribute to improving the original text.

checklist for outsourcing translations

defining the purpose of the translation

text function (informative or communicative) and text genre (e.g., scientific report or marketing brochure)
for publication—or for information
legally binding—or for reference only
audience to be addressed (e.g., healthcare professionals, adult patients, or children)
does entire text need translating—or will translating specific text portions or gisting be sufficient
language variant (e.g., british vs american english)

specifying additional services

editing, reviewing, adapting, rewriting, updating, gisting
compiling a style guide
creating and maintaining a terminology database or glossary
using translation memory or aligning existing translations
(legally) certified or notarised translation
back translation

obtaining a translation quote

have sample text (and confidentiality agreement) ready when asking for a quote
deadlines and translation volume
one translator, team of translators, or agency?
determine the level of competence of the translator (through references, CV, and hands on work)
have copyright issues been sorted out?
agree on whether to include translator credits
define level of quality assurance and number of review rounds required
pricing (e.g., per word, line, or page of either source or target text)

commissioning the translation

get all of the above in writing
provide translator with the final version of the source text
provide translator with any available background information as well as parallel texts
name a contact person

quality assurance

checking
revision
review
proofreading

concluding the translation process

give feedback to the translator
let translator have approved final version of the translated text or a printed sample copy

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Quality assurance

As mentioned earlier, there are several possible levels of quality assurance [10]. Which of these is selected for a given project and who will be responsible for which step should be agreed upfront. Ideally, translators, clients, authors, typesetters, and graphic designers should work together in assuring the quality of their collective effort.

Checking the translation. The first step is for translators to check their own translation to make sure that the meaning has been correctly conveyed and there are no omissions, additions, or errors.

Revising the translation. In a second step, the translation is revised by a person with source and target language expertise other than the translator.

Reviewing the translation. In a third step, the translation may undergo monolingual review, e.g., by a target-language subject-matter expert. Translated texts are often sent for in-country review to have native-speaker company experts decide whether they are happy with the translation in terms of both content and wording.

Reading the galley proofs. Proofreading the typeset and layouted document is the last quality-assurance step—one which, unfortunately, is often omitted simply because it's not considered important. However, remember that, when it comes to translation, typesetters and graphic designers have to work with languages they neither read nor understand. During proofreading, therefore, the translator makes sure that all characters and typographic symbols have been correctly transferred from the word-processing to the desktop publishing application, words are correctly hyphenated, all target-language conventions have been fulfilled, and last minute changes—and there's always a few of those—have been correctly implemented.

LAST QUALITY-ASSURANCE STEP

- all characters correctly transferred
- all typographic symbols correctly transferred
- words correctly hyphenated
- last minute changes correctly implemented

Concluding the translation process

Pharmaceutical companies generally have sound quality assurance and review cycles in place for any of their critical documents, particularly those that go out to regulatory authorities or physicians in the market. Have translations of these documents undergo the same thorough review as the original texts.

Give feedback. Specifically, involve the translator in your in-house review cycle and provide him with an approved final version of the text. This will help translators learn your business and implement company preferences next time round. Finally, if you want to make your translators really happy, let them have a printed sample copy of that glossy brochure you produced.

A word in closing

What has been summarised on these pages will often not take more than 10–15 minutes to discuss—minutes that are well spent. Experienced translators will ask you for much of the information presented above. If I'd told you right from the start that you merely needed to follow your translator's lead, you may not have read through the entire article. But now that you have, you won't be surprised about how inquisitive translators can be.

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Bilingual copyediting: Beyond translation

by Aksel Seyahi and Ariel Surface



Scientific development depends on the accurate and efficient presentation of evidence-based research. Clearly, research must meet stringent requirements in its execution and interpretation to make a significant contribution. Poor writing of even sound scientific research however may misdirect the reader towards conclusions not supported by the study.

An illustration: A study presents the results of a surgical technique. The imprecise or over-confident presentation of the positive results then leads physicians, believing the results by virtue of the study being published in a reputable journal, to overuse this indication. As all surgical procedures involve some risk and cost, some patients receive unnecessary surgery, gain nothing and may even be harmed, often resulting in delay of the most effective treatment.

Situations such as the one presented above and many others like it may undermine scientific progress as well as the health and well-being of patients. Considering the difficulties in presenting clear, precise and accurate manuscripts, the copyediting of manuscripts for a bilingually published journal creates several important challenges for medical writers.

With the continuing and steady rise of English as the lingua franca of science, publishing in English has become a prerequisite for journals to raise their international profile. Over the past 130 years, the percentage of English-language journals listed in Medline has risen from 35% to 89% [1]. At present, roughly 9 out of every 10 new journals are published in English. Nevertheless, to facilitate the communication of science, publishing in the local language may still be preferred.

One such journal is *Acta Orthopaedica et Traumatologica Turcica* (AOTT), the official journal of the Turkish Society of Orthopaedics and Traumatology. AOTT will soon celebrate its fiftieth birthday. In accordance with its name 'ACTA', the journal, published originally in Turkish, has long been dedicated to the activities of Turkish orthopaedists. While AOTT domestically obtained a reputation to be proud of over the years, it did not receive numerous international submissions and citations.

The inclusion of AOTT in Medline in 2003 and the Science Citation Index Expanded in 2009 were two main milestones for the journal. As a new member of the Index, AOTT lagged behind its peers in international recognition.

To increase AOTT's international profile, the editors made the critical decision to institute English as the official publishing language.

There were 4 important reasons behind this crucial change: 1. To limit the migration of local scientific research to foreign journals, 2. To ensure that local studies reach a wider audience, 3. To attract a greater number of international studies, 4. To boost the number of citations and thus increase the journal's impact factor. Changing the publication language from Turkish to English after 50 years was certainly a radical decision. So as not to break with the journal's proud 50-year tradition of publishing in the native language, the editors decided to continue producing a Turkish translation alongside the official English version. In addition, to continue to attract local authors, submissions in Turkish were also accepted. This solution appeared to pave the road for a soft transition.

Prior to the transition to English, AOTT had the great fortune to work closely with a dedicated, practiced editor, Hasan May. His work in ensuring that imprecise writing of good science was corrected allowed the editorial board to focus less on the quality of the writing during the review process. These issues were, however, not clear to the editorial board until the move to English.

At the beginning of 2010 the problems now facing the editors began to show themselves. An unexpected delay in the first issue and increasing delays in ongoing issues exposed the publisher's struggles in the copyediting of the journal. These issues resulted in its withdrawal, necessitating a search for a new publishing company. Unfortunately the second company also abandoned the job after publishing the final two issues of 2010, leaving AOTT without a publisher for the second time in one year. After assessing the situation, the editors decided to implement a new model to detect problems and ensure the regular publishing of AOTT in 2011.

To achieve the success of this new focus, an editor was appointed as the publishing coordinator to assemble a copyediting team. Under his control, two medical writers, one of them a native English speaker, were recruited. Together, this core team began work on the issues of 2011. Rather than using several stages of control, the team handled the English and Turkish translations together, going sentence by sentence. The first few manuscripts were enough to see the challenges of bilingual copyediting, which is far beyond a simple process of translation. Incomplete and

unclear translations were the first problem. Most English texts were far from acceptable, even translations certified by web-based international editing services, which naturally did not take into account the Turkish version for comparison.

The problem was deeper than simple grammar and spelling errors. Grammatically correct sentences could be scientifically incorrect, vague or even incomprehensible. Careful comparison of the translation with the original version exposed major structural problems; titles that did not reflect the main point of the study, undefined hypotheses, inappropriate methods to test the hypothesis, inadequate discussion of the results, and conclusions that were not supported by the results.

Other challenges resulted from little differences between the original Turkish version and the English one, requiring the simultaneous copyediting of both. This approach highlighted errors in translated and sometimes original English texts. These fundamental problems led the team to implement a skeptical approach, catching further conflicts even within the design and internal working of the studies themselves and transforming the copyediting process into a final strategic review process. Such serious problems within an editorially accepted article would normally necessitate consultation with the editorial board and numerous queries to be sent back to the author. As a result several articles had to be re-written by the copyediting team.

However, the addition of the coordinating editor in the redaction team was soon seen to be a great advantage. Integrating the orthopaedic knowledge of the editor with the redaction team's linguistic proficiency provided a sound foundation for the copyediting process. Working together, the team was able to correct the problems in the reporting of the study design and the structure of the article without having to constantly refer to the author. Having the same team work on all aspects of the copyediting process, including translation, ensured a uniformity in the journal's language and style. Additionally, the editor's support gave the medical writers more freedom, allowing them to take a wide range of initiatives and greater risks in the shaping of the articles as well as bringing a greater sense of ownership in their work.

From the editorial perspective, having a medical editor in the copyediting team was an important quality control step, relieving the tension and concerns resulting from the struggles of the previous year. Following this new system, AOTT was able to return to its original publishing schedule.

The new copyediting process necessitated changes in the way the journal was published. A publisher was of course still needed to undertake the physical and online printing of the journal. The copyediting team, after handling all corrections and consultations with authors, now sends

the articles in their final versions to be published. The total cost of publishing has been slightly reduced; the dramatic lowering of publishing costs offset the new costs of hiring two full-time medical writers.

The story of AOTT's transition highlights many of the common challenges facing non-English speaking journals when adopting English as the language of publication. While copyediting has long been regarded as a simple polishing of manuscripts before their publication, AOTT's editorial team discovered the importance of combining technical and linguistic knowledge. This integration served to ensure the accuracy of the journal's scientific reporting, surely one of a scientist's main responsibilities.

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Vital signs

Dear TWS,

I read Adam Jacobs' article (*TWS* 20(2):108-109) with some concern. I am sure that he has pointed up a general problem—as in fact the book review printed five pages later also illustrates.

Why do so many people who should know better seem to think that the purveyor of a medicinal product would, if left to his own devices, report objectively on his product, but is sadly (poor dear) forced by commercial pressure to contract the reporting out to a medical writer because medical writers, an evil-minded brood, are the only people wicked enough to put a suitably product-favourable spin onto the report?

My experience of medical writers, and I don't think any reader of *TWS* would disagree with me, is that they try to err (if one can) on the side of objectivity, the risk of a 'slanted message' being introduced only when the medical writer's draft is later revised by the sponsor's publications manager and marketing editor (though, in fairness, this is also a relatively rare occurrence).

What can be done about this I have no idea. But thanks are due to Adam for sharing his experience, which however I am afraid will not be unique.

Paul Woolley

Berlin

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Twenty-four workshops will be on offer covering a wide range of medical writing topics for medical writers to update their knowledge and skills. This is also an opportunity for those wishing to obtain credits towards their foundation or advanced EMWA professional development programme certificates.

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