Rules and policing them

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 Editor-in-Chief (see below) or another member of the Editorial Board.

Subscriptions

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

- €35 within Europe
- €50 outside Europe

Instructions for contributors

- The *Write Stuff* typically publishes articles of 800–2800 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by email as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

Timelines

Month distributed	Deadline for receipt of articles	Deadline for receipt of adverts
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EMWA European
Medical Writers
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Upcoming EMWA Conference

28ᵗʰ EMWA Conference,
26–30 May 2009, Ljubljana, Slovenia

The 28ᵗʰ EMWA Conference will have a regulatory theme and we will be exploring medical writing in the regulatory domain from many different angles. There will be several new seminars and discussion forum sessions at which you can voice your questions to experienced writers and see how others are tackling similar issues to your own. The conference will be held at the Grand Union Hotel (www.gh-union.si).

The conference will provide members with opportunities to continue their training on the EMWA Professional Development Programme. As always, the workshop programmes will cover a wide range of medical writing topics, ranging from clinical protocols to publication planning. There will be training for beginners as well as advanced workshops for experienced writers wishing to keep their knowledge up-to-date and refresh their skills

**This will be great opportunity to expand your medical writing horizons.
So mark this date in your calendars and plan on joining your colleagues
from across Europe at this event.**

From the editor's desk:

Rules and policing them

by Elise Langdon-Neuner

Is it a mistaken impression, or do we as medical writers have to follow an abnormally large number of rules? Rules seem to avalanche down on us with gathering momentum. Regulatory writers take the brunt. They have to comply with rules laid down by drug-licensing authorities. These impose uniformity for easier handling of licence applications (that's the idea at least). The rules are mandatory and are laid down by the same authorities. The rules say that this is the way things have to be done if you want a licence: if you don't follow them, no licence to market your drug. The incentive to comply with these rules is fairly clear and our next issue will be devoted to regulatory writing. This issue concentrates on rules that are not so clear, ones that we might know less about, or cases where an insight, for example the one given by Adam Jacobs into ethics committees, is helpful.

Rules are a form of control, provided you police them of course—otherwise while the honourable comply voluntarily, business will carry on as usual for the rouges in the community. Rules are like chameleons: their colours change according to the light in which you see them. They can provide protection—or they can be used as a tool of suppression, preying on fear. They may ensure uniformity, but they can be a straitjacket stifling creativity.

The picture on the cover shows three men looking at the screen of a security camera. One is alarmed by what he sees, "is this really happening?" Another has a rather superior expression. He knows what this is all about but is just curiously taking a peek to see what might be caught on screen. Perhaps there is something that he would prefer to remain hidden. The third is fairly laid-back. He stays in the background and accepts the situation as normal. These men typify our reaction to rules—but note that while they are watching the camera the camera is also watching them.

Oliver Cromwell, in one of his speeches to the English Parliament in 1654, said that "necessity hath no law". He referred to feigned and imaginary necessities as the greatest cozenage. What does cozenage mean? It comes from the verb 'to cozen', which is to deceive or induce someone to do something by artful coaxing and trickery. Indeed, we must always be sceptical of the necessity for rules and the motives of those who make them. And we should ensure that those who police rules are themselves policed. The Roman poet Juvenal immortalised this idea in the first century A.D. with his rhetoric question *Quis custodiet custodies ipsos?* (Who will watch over the guardians?)

With these caveats the December issue of *TWS* looks at some areas of rules that challenge medical writers. Some rules are encoded in laws, and breach of these laws incurs a penalty. Medical journals are often reluctant to police authors because they fear that laws of libel and confidentiality will be turned on the journals themselves. An article in this issue by Elaine Heywood, a lawyer specialising in publication law, explains the laws of confidentiality—laws that can also apply to the personal emails we write.

Then there are rules that are feebly or only randomly enforced and as a result inconsistently followed. Ethics guidelines relating to publication in medical journals often fall into this category. For example authorship is in quite a mess in the world of science publication. Criteria defining authorship have been compiled by an exclusive group of 12 journal editors, the International Committee of Medical Journal Editors (ICMJE), but more than one study has found that while some researchers are not aware of these criteria many ignore or disagree with them [e.g. 1]. Even among journals themselves, one survey found that only 29% of 234 sets of instructions to author were based on the ICMJE guidelines [2]. Journals that make their own rules limiting the numbers of authors they allow on a paper more often than not publish articles with more authors than their rule allows [3]. Is the failing compliance with these rules an indication that they are not necessary?

Ethics guidelines are tricky. They only make sense if they are agreed upon by those whose conscience predisposes them to such norms and if they are consistently enforced against those who think they can get away with skipping the ethics because "everybody else does so". Perhaps the lesson from the ICMJE's authorship guidelines is that the very first thing such rules require is consensus. In this respect the efforts of those who have initiated a review of the Good Publication Practice (GPP) guidelines to call for input from anyone affected by those guidelines are to be applauded (see page 198).

In a discussion on the World Association of Medical Editors listserver Eugen Tarnow described failure to enforce guidelines as like "having a gun sitting somewhere for the occasional vigilante to use for bad or good" [4]. He has a good point in implying that guidelines can deceive outsiders into thinking that a community is tackling a problem and can thus take away momentum from those who might really do something effective against the problem. The results of the recent ghost-writing survey of EMWA and AMWA

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(American Medical Writers Association) members should establish whether the EMWA ghost-writing guidelines have really been effective in changing practices since the last survey, which was carried out three years ago.

Two articles in this issue describe the means that are available for biomedical journals to detect misconduct in publication of research. Fraudulent image manipulation is a fast-growing area of concern in connection with misconduct in research. Irene Hammes, who is a journal editor herself, explains the problem in her article in this issue and refers to the pioneering efforts of *The Journal of Cell Biology* in checking images and defining unacceptable image manipulation.

CrossRef is a new policing tool which will allow publishers to compare manuscripts submitted to them for publication against a database of millions of published articles. A report is produced which highlights text that duplicates passages already published in another article. From there, checks can be made for plagiarism. Elsevier is already automatically flagging duplicate articles that are submitted simultaneously to two of their journals. So tools are being implemented that could be the beginning of the end for plagiarisers. However, the prerequisite for policing is clarity about the rules. What is and what is not plagiarism is still not entirely clear. For instance views differ as to whether the use as a template of a few sentences from the methods section of a published article constitutes plagiarism. Debates are also rife about how much self-plagiarism is acceptable.

Then there are standard operating procedures (SOPs). I can't resist the thought that the word 'sop' in one of its meanings is a pitiful offering—something given to placate a person. Regulatory writing apart, the SOPs for medical writers are the rules that govern work processes within a medical writing department. Ruth Whittington's article emphasises the self-protective value of the rules (not only for teams, but also for freelancers) to assure clients that quality controls and good practices are in place and that their data are safe.

There have been murmurings about applying metrics— rules of measurement—to medical writers themselves. Wendy Kingdom ponders this prospect in her article in this issue. Is it possible, let alone desirable, to quantify the quality of medical writing? Doubtless there are things that can be measured, and if we don't all use the same rules for doing so then disaster can ensue. You only need to read the first paragraph of Grey Morley's book review to learn about one such catastrophe. Wendy refers to the number of citations a journal attracts as a metric that might work. However, even this metric is problematic as you will learn from Kari Skinningsrud report on the European Conference on Scientific Publishing held in Oslo. Howard Browman, who spoke about bibliometrics at the conference, emphasised that all bibliometric indices have their limitations and only people with a thorough understanding of the limitations of a metric should apply it when assessing a scientist for promotion or tenure.

On the assumption that the rules are being made for the right motives, rules have themselves a lot of criteria to fulfil. They must be necessary, clear, and brought about by a consensus that is subscribed to by the people who are to comply with them. Then they need to be policed, and checks need to be made to find out whether they are effective. Finally, when it comes to rules, we have to be able to see our way ahead. Fog is fatal. Another picture, beautiful but tragic, illustrates this point. The cross in the foreground commemorates the warden of the mountain refuge in the background. The warden died in a terrible mountain storm in 1919 at the point where the cross stands. The tragedy was that safe refuge was within sight but it was clouded in such thick fog that the warden was unable to see it.

Of course this issue is not just about a load of rules. The new translation section kicks off with a fanfare of an article on a topic of general interest to global medical communicators: English as the lingua franca of science. Gabi Berghammer, the section editor, gives a translator's view. We also have a new cartoonist, Renée Albe, whose work can be seen on pages 176 and 202. Helen Baldwin reports on the results of the survey EMWA conducted to check the satisfaction of our members. The results are interesting. As for *TWS*, you said you liked reading English grammar and style articles most. Included in this issue is an article by Neville Goodman, (co-author of *Medical writing: a prescription for clarity)* about a common imprecise phrase, and a commentary on the article from Alistair Reeves (page 183). Alistair continues his series on 4-letter words, and as usual you can find a sprinkling of boxes with writing tips. Taking up a suggestion from the survey, the first in a series of definition boxes appears on page 197. The brown background distinguishes it from other boxes in the journal.

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Message from the President

by Julia Forjanic Klapproth

Progress is made one step at a time. And we continue to strive to move EMWA forward step by step. In September we furthered our improvement of the EMWA website by adding a new "wikipedia-like" functionality that allows people to write online articles, as well as edit the articles of other contributors. This means that, within the members only part of the website, not only can members write blogs and contribute to ongoing discussions in the discussion forum, but they can also contribute to an online encyclopaedia that is sure to become a valuable resource for our profession. The aim is to provide a website that promotes and enhances ongoing dialogue between medical writers, as well as acting as a repository of information that reflects the combined expertise of the EMWA membership. Of course, a tool like this only serves a function if used, so I encourage you to log on to the website and try it out. Create your own article, or add to one of the existing articles, and let's find out how this can help us all glean from our shared knowledge base.

The recent conference in London also had many new features. One was a conference workbook, which provided the conference programme and social events, a place to write notes and store workshop handouts, details on EMWA, its committees and workshops leaders and useful information about the location of the event. By having this all in one convenient booklet we hoped to make this information more readily accessible and to make your conference experience easier and more effective. If you attended the conference and have seen the workbook, I would be very pleased to receive any suggestions you may have on other useful information that you think would be helpful for participants to have at hand.

In addition, many members have requested that we make our conferences more environmentally friendly. And we have been listening. The conference bag at the London conference was both recyclable and degradable and the badge neck straps were also recyclable. At the end of the conference, badge and neck straps were to be dropped into one of the collection boxes provided so that they can be re-used for future conferences. Again, this is the first step to making our conferences greener, and any other ideas on areas that we can improve the environmental impact of the conference are always welcome.

Progress is also being made in an area outside of EMWA but which will impact on many medical writers. The guideline on Good Publication Practice (GPP) is being revised and updated. This initiative is being spearheaded by the International Society for Medical Publication Professionals (ISMPP; see the call for contributions to the consultation process on page 198 of this issue). As many of us are involved in writing publications for journals and making scientific presentations, it seems only natural that EMWA should in some way be involved in consulting on this update and in endorsing the outcome. I have spoken with Chris Graf, the Co-Chair of the ISMPP Standards and Best Practices Committee, about this and they are inviting experienced EMWA members to review and comment on the first draft of the revised guideline. If you are an EMWA member, have experience in this area and would like to join in this effort as an EMWA representative, please contact Chris Graf as described on page 198, copying in Helen Baldwin and me so that we are aware of which members are participating. This is a great opportunity for EMWA to make sure the medical writer's voice is heard on a matter that affects our working practices.

Speaking of being heard, in the past few years there have been several events (generally articles appearing about issues related to medical writing) that begged for a quick and appropriate reply from a body like EMWA to bring an authoritative statement as the voice of professional medical writers. On those occasions where EMWA was made aware of such events quickly, we have endeavoured to craft replies that reflected the view of the professional writing community. However, it has always been quite ad hoc.

With the goal of changing this and presenting a more professional face to the world, we have decided to create a Press Officer for EMWA. Until now, when EMWA learned of anything newsworthy needing a response, it generally landed on the President's desk. With a Press Officer dedicated to responding to such things, the President will have a quick and effective means of dealing with the situation. For this reason, and to avoid expanding the EC, the function will be part of the Presidential Subcommittee. The position can be reappointed by the President every 2 years.

Many of you may be aware that Adam Jacobs has been an active voice in the public arena, responding to public statements about medical writing and defending our good name. He is a coauthor of the EMWA Ghost-writing Guidelines, which has become a recommended guideline among high calibre journals. When the EC was considering who might be an appropriate candidate for Press Officer, his name came up. Clearly, Adam would bring to the position the necessary background knowledge about what EMWA stands for. As a past President of EMWA and a long-standing member, Adam understands EMWA's concerns and has demonstrated himself a proactive voice for the cause of promoting medical writing. I am therefore pleased to announce that Adam has accepted my proposal to serve as the EMWA Press Officer. I hope you will all welcome him to this role.

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Digital images and the problem of inappropriate manipulation: Can you believe what you see?

by Irene Hames

Until relatively recently, images for publication were prepared and submitted as photographs. Altering these was difficult and required considerable technical skills and access to darkroom facilities. Readers could therefore feel fairly confident that what they were seeing was genuine. This has all changed. The general availability and affordability of digital cameras and image-processing and -editing software (such as Adobe Photoshop) means that it is now very easy for anyone with access to these to alter the images they have captured. Some of the changes made may be subtle—done, for example, to create the flawless complexions and perfect facial features we see in the advertisements in glossy fashion magazines. In other cases the changes may be drastic, and result in surreal and bizarre images. A look at the image manipulation and contest website Worth1000 (www.worth1000.com, so called after the saying 'a picture is worth a thousand words') will show the incredible range of images that users of the site come up with and submit to the various themed contests. Such image manipulation is fun and mostly harmless. But what happens when image manipulation isn't appropriate, for example in the reporting of experimental data? How can we trust that what we're seeing is a true representation of the results?

> *The ability to create with software an image that a researcher 'knows' is a true representation but just hasn't been able to capture can lead down a dangerous and slippery slope.*

It is the responsibility of editors to ensure that the work they publish in their journals is sound and that the integrity of the scholarly record is maintained; that it is not contaminated with incorrect or fraudulent work. In today's culture of easy image manipulation, it is critical that the images being submitted are a true representation of the results of the experimental work carried out. It has become clear, however, that this isn't always the case. Unfortunately, although awareness of the problem of inappropriate image manipulation is increasing, many journals and editors still don't know about the issue, or if they do, are not sure what they can do to deal with it.

Inappropriate image manipulation in scholarly reporting

The *Journal of Cell Biology* (*JCB*, www.jcb.org) was one of the first journals to recognise the potential problem of inappropriate image manipulation and is at the forefront of the effort to educate the scientific community on what is and what is not appropriate manipulation in scientific reporting. The *JCB* created standards because the community had not done so, and is owed thanks for this. An excellent article on the topic was published in 2004, co-authored by the journal's Managing Editor, Mike Rossner, and Editor, Kenneth Yamada [1]. It is very straightforward and readable, and just as relevant today as when it was first published. The issues are simply explained, and many examples of inappropriately altered images are provided. I encourage readers to take a look at this article, and also at the *JCB*'s guidelines to authors on image acquisition and manipulation (http://www.jcb.org/misc/ifora.shtml).

Why do researchers alter images before submitting them? Part of the explanation probably lies in the trend to 'data beautification' [2] and the desire, perhaps unconscious, to present perfect images because others are doing this. There is also likely the fear that anything less than perfect will be at a disadvantage. The ability to create an image that a researcher 'knows' is a true representation but just hasn't been able to capture can lead down a dangerous and slippery slope, resulting in fraudulent behaviour. Witness the recent case of the award-winning photo in which the members of a herd of an endangered Tibetan antelope species (the chiru) were pictured running alongside a high-speed train on China's new and controversial Qinghai-Tibet railway, seemingly unaffected by the noise of the train. There had been considerable protest from environmentalists during the construction of the line, with concerns expressed that the breeding grounds of the chiru would be threatened. The photographer who took the picture camped out on the

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Photograph of Qinghai-Tibet railway with rare Tibetan antelopes. Details of the story are available at http://online.wsj.com/public/article_print/SB120363429707884255.html [3].

> > > Digital images and the problem of inappropriate manipulation...

Tibetan plateau and waited for the antelope to run by at the same time as a passing train. When this situation didn't materialise, he decided to merge two separate images of the train and antelope using Photoshop. The resulting picture, supposedly taken in the summer of 2006 soon after the opening of the line, was published in many outlets worldwide before it was exposed as a fake early in 2008 [3].

What is the extent of the problem of inappropriate digital image manipulation in scholarly reporting? This is difficult to gauge because journals are only just beginning to start checking images, and relatively few currently do this. The Office of Research Integrity (ORI) in the USA has reported a growing incidence of cases of alleged scientific misconduct involving questioned images (i.e. those where there are suspicions of fabrication, falsification or plagiarism). In the two-year reporting period 1989-90 there were 3 cases opened, by 2003-04 this had risen to 21 cases [4]. The *JCB* has also carried out some analysis. During its first 3 ½ years of screening, 1% of the papers accepted for publication were found to contain fraudulent image manipulation, a worryingly high number. In addition, 25% had at least one figure that had to be redone because the manipulation carried out to create those figures violated the journal's guidelines [5]. It is clear, therefore, that there is a great need to educate researchers about what is and what is not acceptable. But because until recently there has been little awareness of the problem amongst journal editors and editorial staff, they haven't really been able to provide guidance to their communities. The situation has also been exacerbated because many senior researchers do not have the level of expertise with image-manipulation software that the junior members of their groups do. Based on personal experience, it is clear that some have missed that certain images presented to them by their students have not been true representations of the data obtained in their experiments. It is vital, therefore, that senior researchers always compare to the original unprocessed data every figure in every manuscript they submit for publication.

1% of the papers accepted for publication were found to contain fraudulent image manipulation, a worryingly high number.

What changes are allowed and which are not?
The two most basic rules when preparing digital images for publication are that:

Firstly, images should be prepared with as little processing as possible and they must be a true representation of the data at the time of acquisition.

Secondly, any digital effect should be applied to the whole image, and is only permissible if it doesn't result in any features being lost or selectively enhanced.

Putting this into practice:

Any digital effect should be applied to the whole image, and should not result in any features being lost or selectively enhanced.

1. Features must not be obscured, removed, or misrepresented, for example by adjustments in brightness and contrast in those areas, or as a result of applying a change across the whole image. Neither should features be added, for example by using cloning tools to duplicate existing ones, moved, or altered or enhanced with retouching or transforming tools.

2. It should be made clear when images have been obtained from different experiments or at different times or from different places. Such images should be separated by clear dividing lines or put into different boxes, and details given in the legend. They should not be spliced together into a composite that appears to be the result of a single experiment or to represent a single unaltered field of view.

3. The background must not be eliminated, either by excessive increases in contrast or brightness, or by using the clean-up tools available in image-editing software (such as the 'clone stamp' or 'healing brush' and other painting and retouching tools in Photoshop). There may be features in the background that might not only affect the current interpretation of the data, but whose significance might not be realised until some time in the future, when new discoveries are made and researchers revisit and re-examine earlier data presented in the literature.

4. All non-linear adjustments, such as changes in gamma settings, must be fully described, as here changes in colour and brightness do not end up being the same for every pixel in an image.

What are journals and editors doing to protect the integrity of the digital image record?
As mentioned previously, it is only recently that editors have started to become aware of the potential problems that might exist with the images authors are submitting to their journals. They are now beginning to address this issue, and authors should be aware that editors are acquiring the relevant knowledge and expertise. Image checking has become a possibility because many journals now have fully electronic submission and review workflows. However, it is time-consuming, especially as many images may be complex and contain a number of parts, and requires specially trained staff. Many journals aren't in the position of being able to devote the resources they would like to this, or that would be necessary to check every image submitted to them [6]. Some are therefore choosing instead to do random spot checks, perhaps on the images in one or two arti-

Digital images and the problem of inappropriate manipulation...

cles in each issue, and to tell authors they are doing this, in the hope that this will act as a deterrent to intentional inappropriate manipulation. Some journals, however, most notably the *JCB*, have chosen to devote considerable resources to image checking and to look at every image in every accepted paper. There is also another consideration. Some editors feel that it is not the responsibility of journals to take on the role of 'data police' and that it is essential that a degree of trust must be maintained in the scientific community [6].

Image checking can be done using the same image-manipulation software packages that authors use to prepare images. Adjusting brightness and contrast can reveal background characteristics, make visible significant hidden features, and show if elements have been duplicated or brought together from different places—a patchwork effect is often revealed. Pixel irregularities on image magnification are another clue to suspect image preparation. Magnification can also highlight minute areas of similarity and so help identify duplications—some of which may have been reversed or rotated, perhaps to try to disguise the duplication. Examples of falsified images and how they were detected can be found in the article by John Krueger from the ORI based on a compilation of information from cases dealt with from 1990 to 2000 [7].

Some journals do random spot checks… some look at every image in every accepted paper.

Journals are starting to educate their communities and providing guidance on image preparation (see, for example, *Nature*, *Journal of Cell Science*, *Journal of Biological Chemistry*, *JAMA*). Most of the guidelines are based on those of the *JCB* (http://www.jcb.org/misc/ifora.shtml). Some journals are also asking authors to sign declarations that their images accurately represent their original, unprocessed data. If irregularities are found, an increasing number are requiring that authors provide the original data for examination. In these cases, journals then need to decide whether or not the manipulations made affect the interpretation of any of the data and advise authors as part of the review feedback. Guidance on how to detect and deal with image fraud is available from the ORI website (http://ori.dhhs.gov), which provides step-by-step instructions and forensic tools that can be used to screen digital images. Although it is not the role of journals to determine whether there has been intent to mislead and deceive, they need to decide what to do if the manipulations are serious and the explanations from the authors unsatisfactory. In such cases, editors may take the step of referring the matter to the author's head of department, institute, or funding body for formal investigation. The Council of Science Editors provides some guidance on this, mentioning that "Although the ORI guidelines for editors indicate that cases of "suspected" misconduct should be reported either to the ORI or to an author's institution, journal editors should attempt to resolve the

problem before a case is reported. This is because the vast majority of cases do not turn out to be fraudulent" [8].

What advice can be given to authors to help them avoid doing things to their images they shouldn't?

Those working with authors to help prepare their work for publication are ideally placed to provide advice and guidance on how to avoid problems with images.

1. Authors should be aware of the issues surrounding digital image manipulation and what is and is not appropriate. Problems with images can cause considerable delays in a manuscript being sent out for review. If the review process has started, it may be put on hold until any suspected or alleged problems have been sorted out. If problems come to light after acceptance, publication may be delayed, or the original acceptance decision may even be revoked if issues can't be resolved to the editor's satisfaction.

2. Authors must take care how images are acquired, and that they are saved in the correct format and at the right resolution. They should be aware that increasing 'resolution' after image capture will effectively result in data being added because pixels that weren't present in the original are added. The article by Rossner and O'Donnell [9] provides excellent and clear guidance on file formatting and image resolution, and advice on how to maximise image quality legitimately.

3. Authors should always keep their original, unprocessed data files. These may be requested by journals and if they can't be produced, the decision to publish may be revoked.

4. Authors should keep a note of the equipment settings used to capture images and also of the various manipulations carried out to produce their final images. Journals are increasingly asking for this information to be provided on submission.

5. Authors should develop a good and systematic file archiving and labelling policy, one that all the members of their groups know and follow. In research, images may be filed and not accessed until the time comes to write up the work. This may be years later, so it is crucial that the images representing various samples, treatments, times, and so on can be readily identified. Archiving errors are one of the most common reasons authors give when discrepancies are found in images and editors request an explanation (Stop press! NB: http://www.the-scientist.com/blog/display/55208/).

6. Senior authors should always be aware of what the members of their groups are doing when producing images. They should view the original raw data, when first captured, not just the final images produced for publication, and feel satisfied that the latter are a true representation of the former. They should set standards and have guidelines in place to educate new members of their research teams.

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> > > Digital images...

An extra tip to help authors increase the visibility of their work

It is always a good idea for authors to send a potential image or images for consideration for the cover of the journals where they submit their work if those journals feature images on their covers. Unless a journal gives specific instructions on when it would like to receive such images, this can be done at any stage of a manuscript's progress through a journal's workflow—from original submission to final acceptance. Many journals are very glad to receive images, especially good ones that have the potential to make stunning or beautiful covers, and will keep on file cover submissions until the time comes to make the choice for the issues in which those articles are scheduled to appear. A note of caution: authors should be careful not to send very large images by email—they can cause great problems and clog up email boxes, which won't endear an author to the editor. It is always best to send a low-resolution version and say that a high-resolution image can be provided if required. That can then often be uploaded to the journal's or publisher's ftp site. Cover submissions are one area where image manipulation is allowed (as long as data are not misrepresented and all manipulations are described) and can play an important role in creating images that have the level of impact editors like the covers of their journals to have. Artistic licence is not only allowed, it is encouraged!

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A public resource for sorting the hype from the evidence in science: Sense About Science

The Sense About Science website is the place to turn for a balanced view on scares and sensations in science reported by the general media. Sense About Science is an independent charitable trust based in the UK which receives input from a wide range of experts. With a motto of "promoting good science and evidence for the public" it has set itself the goal of responding to "the misrepresentation of science and scientific evidence on issues that matter to society". These issues cover a broad spectrum including alternative medicine, evidence-based medicine, GM and plant science, bird flu, MMR vaccines, stem cell research, and weather and climate. A series of briefing documents 'Making sense of…' can be downloaded from the site on such topics as health testing and—intriguing even if you don't happen to be one—there is a guide on science for celebrities. Medical writers might be particularly interested in a downloaded pamphlet on peer review with the appealing title 'I don't know what to believe…'.

This site is easy to navigate and refreshingly readable. It's more than an excellent resource for anybody who falls short of being an expert on every aspect of science in the news—it's fascinating.

Sense about Science URL: http://www.senseaboutscience.org.

Themes of upcoming issues of *TWS*

The March 2009 issue will have a regulatory writing theme. This issue will be guest edited by Sam Hamilton (sam@samhamiltonmwservices.co.uk).

The June issue will have a writing style theme and the September 2009 issue, which will be guest edited by Adam Jacobs (ajacobs@dianthus.co.uk), will have a statistics theme.

Articles (up to 2500 words) and boxes (up to 1000 words) in line with these themes or on any topics of interest to medical writers or of interest to editors, translators, language teachers and linguists working in the medical field are very welcome.

Part III of Françoise Salager-Meyer's series 'Book reviews in the medical scholarly literature' will be published in the March 2009 issue of *TWS*.

Elise Langdon-Neuner
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Confidentiality, libel, peer review and the law

by Elaine Heywood

There are several myths in the science, technical and medical journal publishing world surrounding confidentiality and libel. Do editors hide behind the risk of being sued for libel or breaching confidentiality as reason not to police unethical behaviour or suspected misconduct of authors or peer reviewers? The Committee on Publication Ethics often cite confidentiality concerns as a key issue. Do the risks undermine the integrity of journal publications and even of evidence-based science itself? This article considers the legal position and some of the legal issues that editors face in relation to questions of confidentiality and libel under English law.

Confidentiality

The Prince of Wales, Max Mosley and JK Rowling's young son have all been embroiled recently in cases on the law of confidentiality. However, the issue of confidentiality is not just restricted to public figures or celebrities. Confidentiality is key to the peer review process (unless of course it is an open peer review). A duty of confidence arises when confidential information comes to the knowledge of a person where he/she knows or agrees that the information concerned is confidential, and as a result, should not be disclosed to third parties. The duty may be express or implied. The journal's guidelines to authors and reviewers will be crucial in determining the scope of the duty.

If a journal's policy is that author/editor correspondence is confidential and the journal will not disclose information about manuscripts or peer reviews without an author's or reviewer's permission, an obligation of confidence arises. If the journal breaches this, the author or the reviewer may have a claim for damages for breach of confidence on the basis that he/she submitted material to the journal on the basis that the information would be treated as confidential and it was not. This is the case even if there is suspected misconduct, unless the journal in its guidelines to authors, specifically reserves the right to break confidentiality and pass information to third parties without the author's permission, if misconduct is suspected, or there is a public interest in disclosure.

Confidentiality is necessary to preserve the independence, quality and integrity of the journal and its peer review process. As such, the author will generally not know the identity of his/her reviewers (save in open peer review). However, confidentiality is not always certain. An author might request sight of a hostile review under data protec-

tion legislation, which could then in turn lead to disclosure (see below). A reviewer may breach confidentiality by leaking a damaging report about a drug to a manufacturer. An action for breach of confidence would lie against the reviewer but the reviewer may argue public interest. In both cases, the journal's reputation may be affected.

What about confidentiality of emails? Emails are no different to ordinary correspondence. If there is an obligation of confidence, that obligation will be breached if an email or an email chain is disclosed to a third party. This is a risk in forwarding emails and email chains particularly concerning issues of suspected misconduct and editors should be alive to this, especially avoiding the 'Reply to All' button. If a reviewer makes an allegation of misconduct against an author in an email to an editor and the editor forwards this on to a third party, not only will confidentiality be breached but it is conceivable that an unfortunate editor or journal may end up facing a libel claim from the author for publishing the email to another person. Blake Lapthorn has had to advise on several such threats in recent years, often from aggrieved authors in the US or their institutions.

Another issue that needs to be borne in mind is the data protection legislation in Europe, which derives from the European Directive on Data Protection. For example, under UK legislation, the Data Protection Act 1998, a person is entitled to request their personal data under a 'subject access' request. This can prove problematic for journals as authors could request most information that the journal or editor holds about them, including potentially 'confidential' reviews. Clearly if an author receives a hostile review, he/she is likely to ask to see it.

The Data Protection Act 1998 does however, provide protection to certain classes of confidential information and it is possible that, if journals have a clear and effective data protection policy and provide the right guidance to authors, editors and reviewers, they may be entitled to rely on the confidentiality of the peer review process. In addition, there is an argument that has been tested in the English courts, but not at a European level, that some kinds of information are not 'personal data' as interpreted by data protection legislation, even if they name an individual, but are statements of information about a factual nexus and so the author is not entitled to see the data.

The principal case on this in the UK involves a bank investigation, where the subject of the case was refused permis-

> > > Confidentiality, libel, peer review and the law

sion to see the correspondence about a complaint which was subsequently investigated, on the grounds that the correspondence was not about the individual but about the individual's complaint. This seems rather a thin distinction, although it does represent the current state of English law. The problem journals face is that a refusal to comply with a subject access request can lead to a time-consuming and costly case before the Information Commissioner, and so it is important to act promptly when faced with a subject access request. One option is to ask for a £10 cheque prior to investigating the request, as all holders of information are entitled to require this as a precondition to providing the information, not least to deter nuisance, and this is useful if you suspect the complaint is not in good faith. Our experience, however, is that a large number of requests disappear when a cheque is requested.

Ultimately, confidentiality can be overridden by order of the court and so, if a third party seeks disclosure of confidential documents to be used in litigation, a court may nevertheless order disclosure of such documents. This is common in the US where documents are subpoenaed for use in litigation.

If confidentiality is breached, or disclosure is permitted under data protection rules or by order of the court, the danger faced by the journal is a potential libel claim. Confidentiality does not displace a person's right not to have their reputation damaged.

Say what you mean

Primary objective: to compare efficacy in terms of overall survival time in subjects with advanced cancer receiving chemo1/chemo2 plus mab1 compared with subjects receiving the same chemotherapy alone.

The dreaded slash again: what is being compared here? One group treated with *chemo1* combined with *chemo2* combined with *mab1* and another treated with *chemo1* combined with *chemo2*, or 2 groups treated with *chemo1* combined with *mab1* or *chemo2* combined with *mab1* compared with *chemo1* alone or *chemo2* alone—or even …. ? Whew! This is the mess this slash gets you into.

Think about it: *to compare efficacy in terms of overall survival time in subjects with advanced cancer receiving combined treatment with chemo1 and chemo2 with and without mab1.*

That was what was meant.

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Libel

Libel is defamation in permanent form—an article, review, correspondence or an email—through publication (communication) of a defamatory statement to a third party. A statement is defamatory if it lowers someone's reputation or makes one think worse of a person or a company. An allegation of plagiarism, misconduct, unethical or merely dubious conduct is clearly defamatory. It does not matter that the libel was unintentional or not what was meant or not meant to be seen. What matters is how an ordinary and reasonable person would interpret it. The author, editor and publisher of the defamatory allegation can be sued.

The onus is then on the editor/publisher of the journal to prove the truth of the allegation. Truth, however, is hard to prove, particularly in the absence of clearly documented evidence and defending a libel claim will be expensive and potentially damaging to a journal's reputation.

There are two other important defences which frequently apply—fair comment (statements of opinion as opposed to fact in the public interest) and qualified privilege (a duty to publish information to a third party who has a reciprocal interest in receiving it or a public interest in publishing fairly). However, both these defences are defeated if the author for example, can show malice, which is not outside the realms of possibility in the world of academic rivalry. Malice in the case of qualified privilege means a dominant improper motive for publishing a statement, whereas in the case of fair comment, it has the narrower meaning of absence of an honest belief in the truth of a statement or reckless indifference as to the truth. However, malice is generally very difficult to prove and the burden of proof is on the complainant, which is some comfort to editors.

Note that publication is essential or there is no libel. If an allegation is put directly to an author without wider circulation, there is likely to be no publication. However, even a confidential letter to a reviewer asking for comment on whether an allegation is true or false may amount to publication if the author learns about it. Editors, therefore, need to exercise particular caution when dealing with allegations of unethical behaviour or suspected misconduct.

As can be seen above, under a subject access request, authors are able to request personal data about themselves, including for example, a damaging peer review or correspondence about an allegation of plagiarism which would be libellous of the author. If the author's career and reputation is on the line, he is likely to sue unless the allegation can be clearly proved as true by the publisher.

This presents a dilemma for journals as it is important to safeguard the confidentiality of the peer review process, but it is difficult to guarantee that damaging statements will not leak out.

Confidentiality, libel, peer review and the law

Jurisdiction

What happens in the case of an international journal that has an editorial office in the UK with authors in Europe or an editorial office in the US but an author in the UK?

For breach of confidence, in the absence of an express contractual agreement as to which law applies, the general rule under English law would be that the country where the obligation of confidence was breached would be the country in which to sue. However, under an agreement called Rome II, which applies to EU member states, from January 2009 the applicable law would be the country where the damage occurred. In most cases this is likely to be the place where the duty applies. So, if the journal is a UK journal and the author is French, the applicable law is likely to be English law.

In terms of data protection, jurisdiction depends on who the data controller is and where the data is held.

For libel, an author can bring a libel claim in any country where publication has taken place or defamatory content has been downloaded and where he/she has a reputation to protect. Most authors will want to sue in England because the libel laws are known to be claimant friendly. The position is of course, very different in the US with the emphasis on freedom of expression as opposed to protecting reputation.

Conclusion

Whilst confidentiality is the bedrock to both author/editor correspondence and the peer review process, it cannot be guaranteed. A journal's policy may allow disclosure of serious misconduct to third parties. Further, in certain circumstances, confidential correspondence and reviews may be disclosable under data protection legislation, which may lead to a libel claim. Editors, therefore, are right to be cautious about confidentiality and the risks that it brings. However, there are some practical ways for journals and their editors to manage the risks of claims for breach of confidence or libel, such as:

- to have clear guidance notes for editors, authors and reviewers on the journal's policy on confidentiality;
- to have clear guidance for editors on handling hostile reviews and allegations of misconduct;
- to have a libel policy;
- to provide clear guidance for reviewers on avoiding making libellous or personal comments in reviews;
- to have an email policy; and
- to have an effective data protection policy.

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I have seen
the future and it works

You can always rely on older members of trades and professions to lament the decline in standards since 'their day'. A senior cardiologist bemoans the fact that newly qualified doctors know nothing of medicine. Marketing and advertising veterans complain that brand managers lack initiative and imagination and are wedded to researching every proposition to the point where creativity dies.

As a retired medical writer, I'm no different. OK so I have finally given up my war on the passive voice. I've also given in to writers—doctors and medical writers—who love to use long technical terms when short words in plain English would convey the meaning more clearly. In short, I have wearily surrendered to the kind of writers who will never use three or four words when a couple of thousand will easily do[1].

I remain pedantic, grumpy and—as I have been called once this week—a cranky pants. But do I despair for the future?

Not now I don't, because I have just read in *New Scientist* a beautifully crafted, witty and interesting piece and it comes from a student. First prize in the 2008 Wellcome Trust and *New Scientist* essay competition went to Katherine Robertson, a medical student currently doing a PhD at the University of Cambridge.

Her essay, 'Fusion cuisine: the many talents of the placenta', shows how the laboratory work of scientists ties in with the everyday work of an obstetrician.

The Wellcome Trust quotes Katherine as saying: "I was very excited to win this competition because I think the placenta is often overlooked in favour of more exotic research topics like the brain, but it is every bit as crucial".

"I hope to practise as an obstetrician in the future but winning this competition has also made me think about how I could combine that with writing, maybe for a more general audience".

She wins £1000, a two-week, expenses-paid media placement with *New Scientist* and publication of her essay in the magazine. An EMWA member in the future? I hope so. If only she hadn't slipped into the passive voice once or twice.

Geoff Hall
EMWA President (1999-2000) and Nick Thompson Fellow
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Read Katherine Robertson's winning essay at:
http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_peda/documents/web_document/WTX050707.doc

1   A quotation from the Jake Thackray song On Again

CrossRef: From cross-publisher reference linking to cross-publisher plagiarism screening in eight short years

by Amy Brand

CrossRef is a not-for-profit publisher association whose general purpose is to promote the cooperative development of innovative technologies for scholarly publishing and research. In addition to operating the first collaborative reference linking service, the association recently announced a new service, CrossCheck, to aid editors in screening submitted manuscripts for plagiarism. How did this initiative come about? Where does it fit within CrossRef's broader mission? What specifically is it intended to do and how does it work? These are the questions this article addresses.

CrossRef was founded in 2000 through the joint efforts of a small group of prestigious scientific, technical, and medical journal publishers. At the time, publishers moving their journals online wanted a way to cross-link journal articles while avoiding the common problem of broken links, or '404 page-not-found' errors. A new infrastructure for permanent identification of online information, the DOI (Digital Object Identifier) system, had just been introduced. Publishers who recognized the DOI system as their opportunity to create a cross-platform network joined together in a non-profit, independent association; CrossRef went live as the first collaborative citation-linking network in June 2000.

> *CrossCheck helps academic publishers verify the originality of works submitted for publication*

CrossRef's mission, formally put, is "to enable easy identification and use of trustworthy electronic content by promoting the cooperative development and application of a sustainable infrastructure." In the eight years since its inauguration, CrossRef has evolved along several dimensions. It interlinks the publications of thousands of information providers and offers a variety of services. It registers 16,000 diverse content items each day, seven days per week. Its members include not only traditional academic publishers and societies, but also institutional repositories that house dissertations, working papers, and datasets; government offices that output technical reports; and web-based reference environments with dynamically aggregated pages. CrossRef has become the first place publishers turn when they want to work together on new initiatives to harness technology for better information navigation and dissemination in the complex world of publishing content.

In 2006, the CrossRef membership identified plagiarism screening as a top priority for the academic publishing community and decided to develop an aid for publishers to protect the integrity of the published record. In 2007, CrossRef conducted a pilot with six well-known publishers. The pilot's goal was to assess the feasibility of launching a self-sustaining plagiarism detection service with a business model that encouraged industry-wide participation through low barriers to entry. Specifically, we wanted to:

- understand the logistics and costs involved in creating and maintaining a database of our members' full-text content
- allow some of our members to experiment with the iThenticate user interface and to think about how they might use the system within their particular editorial environments
- understand what publishers are likely to need to do in order to integrate the plagiarism detection step into their existing manuscript tracking and editorial tools

The most important aspect of a plagiarism detection system is that its database contains a critical mass of relevant content; otherwise those checking manuscripts against the system will encounter an unacceptable number of false negatives. We therefore selected our pilot participants with the

> *A human being has to judge if intentional plagiarism has occurred or not*

goal of getting a significant sample of content in two specific disciplines—computer science and biomedical research. Following completion of the pilot the CrossCheck service was officially launched on 19 June 2008.

CrossCheck is intended to help academic publishers verify the originality of works submitted for publication. CrossCheck has two parts, a database of scholarly publications and a web-based tool, iThenticate, to check authored works against that database. The result is a form of computer-assisted editing, in which the process of detecting textual overlap between documents –or otherwise verifying the originality of a document in the absence of any overlap—is largely automated. Clearly, the tool cannot, on its own, identify plagiarism. A human being has to examine areas of overlap in context and use judgment to determine if intentional plagiarism has occurred or not.

Screening tools like CrossCheck are only effective if they are checking texts against a relevant, comprehensive database. Although there are several plagiarism detection tools

in use, they are not well-suited to filtering academic content simply because they have not had access to the relevant (often proprietary) full-text literature to screen against. CrossCheck has a continuously growing database of archival and current scholarly literature, text-fingerprinted for accurate document comparison.

As of June 2008, the CrossCheck database is already slated to cover over 20 million journal articles from the following publishers: Association for Computing Machinery, American Society of Neuroradiology, BMJ Publishing Group, Elsevier, Institute of Electrical & Electronics Engineers, International Union of Crystallography, Nature Publishing Group, Oxford University Press, Sage, Informa UK (Taylor & Francis), and Wiley Blackwell. With the launch, both publisher participation and the CrossCheck database are expected to grow quickly.

CrossRef's partner in this initiative, iParadigms, is a leading provider of web-based plagiarism detection services. Via CrossCheck, publishers can screen documents against billions of pages of open web content that iThenticate has crawled and indexed, in addition to the CrossCheck database itself. When a document is submitted to the service for checking, it does not become part of the database. Instead, the system creates a digital fingerprint of the document based on a special set of algorithms, and that fingerprint is run against the vast database of pre-indexed content. The output of this process is a 'matching report' that lists sources sharing a significant degree of textual overlap with the submitted text.

It is important to note that the service will only help editors identify cases of verbatim plagiarism, along with cases that may entail simple word substitution or sentence addition. The system cannot detect subtle forms of plagiarism like paraphrasing or idea plagiarism, and cannot detect copying of images and graphs, unless they also plagiarize significant textual elements such as captions. At the same time, the system can produce false positives when a portion of text has been legitimately duplicated; examples include boilerplate text, bibliographic references, and mathematical proofs.

CrossRef's current priority for CrossCheck is to recruit as much published scholarship into the database as possible. Even publishers who decide not to integrate screening into their editorial processes at this time are encouraged to allow their content to be indexed so that others can check against it. A 'CrossCheck Depositor' logo will be used by those contributing to the database, to help increase public awareness of the initiative; 'CrossCheck Deposited' tags will be placed on individual publications that have been indexed in the database to help deter future plagiarism.

It is too early to offer definitive advice to editors on where in the editorial process to add the plagiarism-checking step. For now, participating publishers are providing distributed access to the tool, so that internal and external editorial staff can use it as they see fit. While some may opt for routine checking of every submitted article, others will only screen submissions that a reviewer or editor flags. With iThenticate's open Application Programmer's Interface (http://en.wikipedia.org/wiki/API), which allows publishers to integrate the system with their in-house tools, CrossCheck is currently being integrated with several manuscript tracking services, to better streamline editorial processes around the use of the tool. CrossRef is also working with leading community policy organizations to develop best practices to help publishers use CrossCheck effectively and ethically, and is planning a variety of research projects that will help the community better understand the issues and trends surrounding plagiarism.

The database covers over 20 million journal article

In closing, CrossCheck is not just a plagiarism detection tool or a database, but rather a multi-pronged initiative to make plagiarism checking feasible for the academic publishing community. CrossCheck was created by publishers, for publishers, and its success will depend on the CrossRef membership joining in to allow their published content to play a part. Community interest in the initiative is high and the future looks promising for CrossCheck, yet another way publishers are working together through CrossRef to ensure the integrity of the published scholarly record.

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Vital signs

Dear TWS

You seem to have a certain theme in every issue. I wondered if this means that if I write an article for the journal it needs to be written around the specific theme or if I have to wait until my topic is relevant, or how it works?

Claire Gillow
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Note from editor

Every issue of *TWS* has a theme but the articles in the issue do not all relate to the theme. Articles on any topic of interest to medical writers are always welcome.

Inside a research ethics committee

by Adam Jacobs

Any medical writer who has ever written a clinical study protocol will know how important it is to get the protocol 'through ethics'. I'm sure all medical writers are aware how important it is for all clinical research to be done to high ethical standards, ensuring that the safety, privacy, dignity, and autonomy of research subjects are respected. But I suspect there are many medical writers who are less familiar with the mechanics of the ethical review process. For anyone who has ever wondered what happens to that protocol while it is on its journey 'through ethics', read on.

I have been a member of a research ethics committee for a little over 5 years, and in this article I shall share some of the knowledge I have gained of how the ethical review process works. I should point out that my experience is from a UK perspective. In theory, European directives should mean that the ethical review process is similar in all European countries. In reality there are no doubt a few differences, but I hope they are small enough that this article will be of relevance no matter where you are in Europe. If anyone has vastly different experiences in other parts of Europe, I'm sure they'd make an interesting contribution to a future issue of *TWS*.

The first part of the ethical review process is for the chief investigator to submit the application. Depending on the circumstances, this may be done via the central allocation system of the National Research Ethics Service (NRES), or directly to the appropriate ethics committee. There are complicated rules about this (and this is no doubt one of the parts that will vary from country to country) which can be found on the NRES website [1]. The main part of the application is the application form. This is a lengthy form, often running to 30 or more pages when printed out, and is the main document the ethics committee will review. There are other supporting documents that must be submitted with it, such as the protocol and, crucially, the patient information and consent form. When the application form was first introduced, it was extremely cumbersome and was quite rightly criticised for being too burdensome [2]. However, the process has been streamlined since then, and while it is still a substantial amount of work to complete an application form properly, it is a lot easier than it was. In its latest incarnation, introduced this year, it now takes the form of an online system known as the Integrated Research Application System (IRAS) [3]. IRAS takes the information filled in in various fields, and copies them to the relevant forms, so if more than one form is required, the information now only needs to be entered once.

Although the protocol is submitted as part of the application, it is important to realise that the ethical review will be based mostly on the application form. Some members of the committee may never read the full protocol. It is therefore essential that all important details that could possibly impact on the ethics of the study are included on the form. Ethics committees consist of a mixture of expert and lay members, and the lay members will struggle to understand the study if it is written in too technical a manner. The application form must be written so that it can be understood by a layperson, a point which many applicants seem to have great difficulty grasping.

> *The application form must be written for a layperson to understand*

So what are the main things that the ethics committee will consider when trying to decide whether a study is acceptable? We are, of course, very much guided by the ethical principles set out in the Declaration of Helsinki [4] (please note that a new version of the Declaration was released in October this year, so previous versions are no longer valid, see page 198). Patient safety is probably the most important, although this is less often a problem in practice than you might think, as most investigators are very well aware of the importance of patient safety and would not wish to design trials that put it at risk. Nonetheless, some more subtle points of safety may raise their head here, such as the use of X-rays or other forms of ionising radiation. A single chest X-ray, which gives a very low dose, is easy to justify, particularly if it contributes to the clinical management of the patient as well as the research. Something giving a higher dose of radiation, such as a full-body CT scan, would simply not be acceptable in healthy volunteers. If it is needed clinically, it is much easier to approve, and if the patients are elderly or severely ill such that their life expectancy is less than the time it typically takes for radiation-induced cancers to develop, then even very high doses of radiation may be acceptable.

Of course, no study is 100% safe for all research subjects. Investigators who claim their study has no risk are lying. Ethics committees accept that there are risks involved in research, but those risks must always be in proportion to the expected benefits.

Some procedures may not pose any significant risk to the health of the patient, but may nonetheless be unpleasant, painful, or uncomfortable. Arterial blood sampling, muscle biopsy, or endoscopy are all examples. There is generally

Inside a research ethics committee

no ethical objection to those sorts of procedures, provided there is some suitable rationale for their use, and most importantly, the patients are fully informed of what to expect (see below). It would generally be appropriate for research subjects to receive some payment for undergoing such procedures if it is not a normal part of their clinical management (e.g. in healthy volunteers).

One area of frequent concern is privacy and data protection. Data about identifiable patients must be strictly controlled. We are not at all happy if researchers want to include patient names in their study database that they then keep on a laptop computer. While it is generally essential to record patient names somewhere in a clinical study, that record must be closely guarded, and ideally never leave the researcher's office. Most data kept in the study should be anonymised, with patients identified only by a number.

> *One area of frequent concern is privacy and data protection*

Probably the area that my committee objects to more than any other is the patient information and consent form. It is absolutely essential that this be written in a manner that patients can understand and explains all the risks and discomforts of the study clearly and honestly. This is something that many investigators find difficult, and an area where medical writers who understand how to write for patients can make a really important contribution. I've written more about this extremely important part of the ethics process in a previous issue of *TWS* [5].

> *Most of my committee's objections are to patient information and consent forms*

I suspect that medical writers are not involved in the process of submitting studies for ethical approval as much as they should be. Many of the application forms I read are abominably badly written, with confusing language and copious linguistic errors that hamper their understanding. If they were compiled with the help of medical writers, I'm sure they would be a great deal easier to read. The need for experts in writing to help with patient information and consent forms is painfully obvious to anyone who has read some of the garbage that gets submitted all too often. Next time you are involved in writing a protocol, perhaps you could see if your help is needed with the rest of the ethics application?

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Joining an ethics committee

Information on how to join an ethics committee can be found at: http://www.nres.npsa.nhs.uk/patients-and-the-public/get-involved/

Freudian commas

I heard a news item on the radio recently, and judging from the way the item was read out, either the newsreader stumbled over his words, or whoever had written the script had been a little careless with punctuation. I believe the item should have been written "President Bush said he would send his Vice President, Dick Cheney, to Georgia." However, it sounded as if it had been punctuated as "President Bush said he would send his Vice President Dick, Cheney, to Georgia." Some may argue that the mis-punctuated version is spookily accurate, but I'm pretty sure it wasn't the message the writer meant to convey.

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Ig Nobel Prizes for 2007

Keeping up the *TWS* tradition of reporting the annual Ig Nobel Prize awards, which have been described in *Nature* as "arguably the highlight of the scientific calendar," we are pleased to announce that details of the winners are now available on http://improbable.com/ig/winners/. The 2007 Ig Nobel Prize ceremony took place at Harvard University on 4 October 2008. The biology prize went to French veterinary researchers who established that dog fleas jump higher than cat fleas [1]. The medicine prize went to researchers from the US and Singapore who found that participants in a study rated expensive US placebo as more effective than cheap US placebo and cheap or expensive Chinese placebo. All participants were given the same placebo, which they were told was a new opioid analgesic [2].

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Searching for The Holy Grail How valuable are metrics in medical writing?

by Wendy Kingdom

Estimates of the number of copies of *The Da Vinci Code* sold worldwide since its publication in 2003 range from 15 million to 38 million [1]. It is unfortunate that we do not have accurate figures because the number of copies of a book sold is an objective metric. Therefore, it should tell us whether or not Dan Brown is a good author and worth our investment of buying a copy of his book. Alternatively, we could view the star rating metric of this book on the Amazon website and use this for our decision. Sadly, although *The Da Vinci Code* is clearly a 'best seller', it gets only three and a half stars out of five in terms of readers' opinions. Crikey! How much must a 5-star author earn?

The question of applying metrics to medical writing arises periodically because sponsors have a need to evaluate a service before they invest in it. There is a corresponding commercial need by Contract Research Organisations (CROs) to demonstrate their ability to meet potential customers' requirements. However, by definition, metrics have to be things that you can measure, weigh, count or otherwise attach a number to. They are not intelligent, i.e. they are unable to adapt to varying situations and are unable to take account of influencing factors. On the other hand, good medical writing is all about taking the best approach according to the target audience, the data, the purpose of the work etc., which you simply cannot count. Therefore, the logical thing to do is to forget about metrics in medical writing and get back to work. Sadly, this is not the way of the world and if there is a commercial need for metrics, sooner or later we will all be judged by them.

Applying an unintelligent metric to intelligent work inevitably dumbs down the output.

If we really need to identify metrics for medical writing, we can have some fun brainstorming medical writing output and attaching numbers, e.g., the number of pages in a document, the weight of the document, the number of words on a page, and so on. However, if we want to try and be sensible, we might consider the following:

> The number of documents written (i.e. experience).
> Average time to produce a document.
> The number of papers published.
> The number of citations of a paper.
> The number of quality control (QC) findings.

The problem is that even these relatively sensible metrics are all seriously flawed. For example, the number of a type of document written, i.e. experience, tells you no more and no less than how many. It doesn't say anything about how clear, interesting, sensible, suitable, thorough, or consistent the documents were, nor does it say anything about any writer's potential when they are presented with new challenges. It also doesn't tell you whether most of a company's experience was held by one person who has since gone to work elsewhere.

Time to produce a document might give some indication of efficiency, but this metric is influenced by the experience of the medical writer, the complexity of the document, the number of source documents, the volume of data, and the clarity of the source documents. Assuming that a shorter time is a better time in metric terms, does this mean that an inexperienced writer is a bad writer? A journey of a thousand miles begins with a single step (Confucius). Even the most experienced writers started somewhere. Alternatively, if fast is the most important variable, a document can be divided into small parts, each of which can be written by different writers in parallel. The output will be rapid but the document is likely to be disjointed. As soon as we start to ask questions about the variables that can influence any metric, the list of flaws rapidly outweighs any merits.

The number of papers submitted for publication and that are actually published might, theoretically, give some indication of the quality of writing. However, a medical writer needs little experience of writing papers to recognise that many would-be authors are simply deluded about the value of their research. It's tempting to write the letter of rejection from *The Lancet* yourself and not waste any time on the work in the middle, but that is not sporting, nor is it good customer service, so we do our best with what we have. It is no surprise, therefore, to see that poor quality writing is not included in The World Health Organization's top 10 reasons for rejecting a paper (see Box).

Good writing cannot be quantified any more than you can measure good acting, good painting, or beauty.

Despite the obvious flaws in assessing value or ability by counting the number of papers published, this metric has been in operation in academic institutions for many years. Now, researchers rush to publish work early so that they can meet deadlines for their appraisals, heads of departments put their names on papers irrespective of their true involvement in the work, and there is an inevitable consequent reduction in scientific depth per paper published. Was the gain worth the loss? Not in my opinion.

Another consequence of judging academic researchers by the number of publications is that there has been an explosion in the volume of publications, and the number of journals needed to accommodate all of the papers. This means
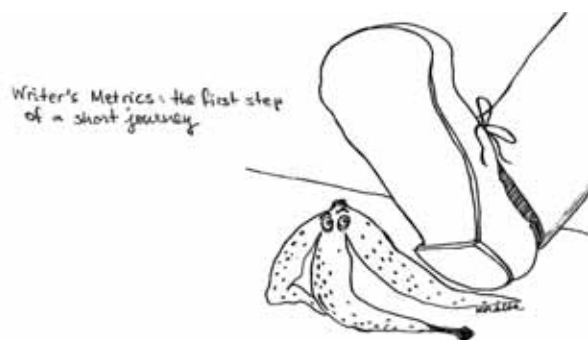
that we now have a bewildering array of journals to choose from when we are interested in a particular area of research. So now we need a metric that helps us to judge the worth of the publications. What can we count? We can count the number of times a publication is cited. Problem solved?

The number of citations is such an important metric that it has a name: bibliometrics. Well, citations are good up to a point but all sorts of games can be played to increase impact scores, e.g., taking one study, producing five papers from it, publishing the papers in series and citing every published paper in the series. There is no metric for evaluating whether one paper would have been more informative to the scientific community than the five separate papers so we don't try. It's too difficult so we don't do it, especially when we already have something that we can count.

Turning now to regulatory writing, there is a real danger that the target audience for any document will cease being the reader (who isn't involved in the metric process) and will become the metric itself. If writing for the public is judged on a readability score, the writer can select from a panoply of pithy words and keep the readability score low. Of course the reader might not be able to understand the text as well as if it had been a lengthier but detailed explanation using longer more precise words, but nobody is counting that so it will cease to matter.

A metric that can appear at first glance to be a relatively sensible measure of quality is the number of QC findings. However, this is not an intelligent metric in that it cannot incorporate factors such as complexity of the study, quality of the source information, time pressures, etc. In essence, QC is a consistency check whereas a good medical writer will make adaptations according to the target audience, the data, etc. Alistair Reeves points out to us how the terminology used in the Medical Dictionary for Regulatory Activities (MedDRA) has been creeping into

Writer's Metrics: the first step of a short journey

pharma-company language [2]. He tells us that he was required to write, 'One patient developed hallucination auditory'. I think that Alistair's example illustrates my point very nicely. The clinical study report and the MedDRA dictionary have different audiences and different purposes. Coding is used to build a computerised safety database across studies and to compile lists, whereas a clinical study report is intended to be read by a human being who wants to know what happened to the study subjects. In Alistair's example, the audience has ceased being the reader of the report and has become a disembodied concept called consistency. By applying an unintelligent metric to intelligent work we must inevitably dumb down the output. Consistency, though unquestionably very important, is not always the most important thing under all circumstances.

Furthermore, if QC findings are used as metrics, the dilemma described above becomes a nightmare. Should the medical writer use the standard medical term in the text and risk a QC finding of 'inconsistency' with the source data, or use the MedDRA term and risk appearing to be an idiot? Yet if the same medical writer used the same data to write a paper for publication, there is no question that the medical term should be used—same medical writer, same data, same metric; different score.

Yet things can get even worse. As soon as we start to use QC as a metric, the value of the QC process will become corrupted and distorted. QC is part of the overall quality assurance umbrella that is intended to assure the ethics and quality standards of a study. It should be a positive, team-building process whereby project teams work together to produce high quality documents. If QC is used as a metric, project teams will break down into groups of individuals unwillingly participating in a point-scoring war. Every finding will be fought over, political battles will be won and lost, and resentments burrowed deeply. This is bad for morale, bad for medical writing, bad for quality assurance and bad for clinical research.

The truth is that good writing cannot be quantified any more than you can measure good acting, good painting, or beauty. If we accept the premise that it is possible to apply metrics to medical writing, before long, computer programs will be written that will conjure up a composite score that is intended to quantify our writing. No doubt the score will be given a technical-sounding name so that it is not obviously analogous to an Amazon star rating but we

Top 10 reasons for rejecting a manuscript

1. Content of the paper not suitable for an international journal of public health.
2. Design of the study not appropriate for the question asked.
3. Lack of novelty and or timeliness.
4. Lack of either or both ethical committee approval and informed consent.
5. Lack of an appropriate search strategy.
6. Conclusions not justified by the results.
7. Lack of a feedback step in descriptions of audit.
8. Insufficient sample size.
9. Lack of a clear message to the public health community.
10. Secondary analyses of demographic surveys or simple prevalence studies that are difficult to generalise.

http://www.who.int/bulletin/contributors/rejection/en/index.html (World Health Organization)

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> > > Searching for The Holy Grail...

will be befuddled into believing that the score has some value. Or worse, our managers and clients will believe that the score has value and will measure us against it. As soon as we know that we are being judged by a metric, we will adapt our writing to improve our scores irrespective of the needs of the audience. Like trying to pick up jelly with your fingers, you can do it but, in the attempt, you change its substance.

My fear is that we are heading towards valuing what we measure because we can measure it, not because the metric is intrinsically valuable. In reality, we decide whether or not to read a book based on previous experience of that author, recommendations by our friends, and reviews.

Sponsors select CROs and freelancers based on previous experience, recommendations, and interviews. Nobody has devised a meaningful metric for medical writing yet because there isn't one. We must accept that and move on.

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A Comment not a Counter

When I was approached by the editor, Elise, about writing an article on the pros of medical writing metrics as a counter argument to Wendy's article, my first reaction was "no problem!" After all, when I worked at a Contract Research Organisation (CRO), I was often asked to supply 'numbers' for potential clients. The 'numbers' were used in response to a client's 'Request for Information' (RFI). Questions such as the following were regularly posed:

- "How many and what type of documents have you prepared in the last 2 years?"
- "How many weeks does it take you from Last Case Report Form in house to Final Clinical Study Report (CSR)?" That one had a veritable minefield of variables attached to it so when possible we responded with the manageable 'Number of weeks from Final Data Listings to Draft CSR'.

Yes, I could certainly come up with 'numbers'! For example, I readily knew how many CSRs had been issued by our CRO's global writing group in a defined period, although I used to worry that this number may have been viewed 'out of context' ... I needed the reviewer to be aware that the number of available medical writers had varied during that time, as had their level of experience and, most importantly, for each CSR there had been factors beyond the writer's control such as the highly variable quality of the data and the varied experience of clinicians, statisticians, and other contributors to the reports.

Looking back more carefully, I recalled my concerns about collating these numbers, frequently asking myself "just how valuable are the metrics we supplied?" Working for a CRO at the time, and later as a freelancer, however, I believed that if you wanted a chance of getting a particular job, then you just had to live with the metric requests, and supply responses with assumptions or annotations where possible.

When I read Wendy's article, I found myself agreeing with everything she wrote. So, how could I produce a counter argument? As Wendy stated "Nobody has devised a meaningful metric for medical writing yet because there isn't one. We must accept that and move on." With nothing more to add, I was going to decline Elise's kind offer when I happened to mention Wendy's article to a colleague.

"Don't abandon them (metrics) ... they must be of some use? Figure out how to apply them" they said but didn't offer any suggestions. I also don't have an answer but their plea did make me wonder about the people who use metrics. So, I spoke to a few colleagues at different pharmaceutical companies that outsource complete trials or medical writing-related tasks such as protocol and CSR preparation. From my, admittedly limited, survey, it appears that there are two approaches regarding metrics.

Some companies simply ignore metrics in relation to outsourcing, with decisions made on the basis of personal experience or recommendation from a trusted colleague. This appears to be the route taken when a clinical team makes the decisions; selectors go with gut reactions, and the chemistry between individual people and groups.

Metrics are of interest, however, where there is an 'Outsourcing Department' or a formal outsourcing procedure. Detailed RFIs including requests for metrics are issued to potential service providers. Responses to the metric-related queries appear to be used to assure the outsourcer that the potential providers are at least in the right 'ball park', that processes are being followed, and predefined standards are being met. In addition, for some companies, gathering metrics from potential providers appears to serve another purpose—showing senior management that a 'fair selection' process is in place.

For writers providing responses to metric requests, this can be a way to get a 'foot through the door' with a new client. The challenge, however, is not only to come up with the numbers but also to provide context, possibly in the form of annotations if the RFI allows. The explanations need to be sufficiently clear such that the outsourcer appreciates that metrics provided by others are not necessarily directly comparable. Of course, ensuring the outsourcer realises this is not something fully in the writer's control.

A final comment: the outsourcing manager who said they were reluctant to throw out metrics completely was also the same person who said they "were slightly suspicious of numbers" ... so, for now, I'm staying in Wendy's camp!

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SOPs–Pitfalls in the process

by Ruth Whittington

Here at Rx Communications we were recently audited by one of our client companies, to ensure that our policies and standard operating procedures (SOPs) were sufficient to ensure the confidentiality and security of their data and projects.

I'm pleased to say that we passed with flying colours, but the temporary mayhem induced by the visit reminded me of a previously difficult experience we encountered early on in our existence, that taught us all a very valuable lesson about SOPs, policies and compliance.

At Rx we've always prided ourselves on our processes—the company was founded on systems and processes that we put in place from day one. I had a firm belief in the need for SOPs. The outcome of this belief was that every major company activity, from sales, finances, to project management and quality assurance, had standard procedures for conducting those activities. All written down, logical, approved and in place. All well and good.

We were particularly proud of our procedures for project management of manuscripts. All 108 steps in the production of a manuscript were documented, and all the processes were in place, from file naming to ensure version control, to how to set up a secure and logical filing system, how to work with clients, authors, writers and reviewers to maintain ethical good publications practice, to tracking the article through to publication. We had it all. Quite unusual for such a young agency, and we used it as a selling point with our clients.

Then in one nightmarish moment, our complacency was rocked irrevocably by accusations of ghost-writing, that reverberated throughout the industry. Wrongly, as it happened—but as we tried to defend ourselves and protect an innocent author, we found to our horror that having our lovely SOPs had failed to protect us.

So, with all these wonderful quality procedures in place, how can things still go so radically wrong? In this article, I want to explore why SOPs are important, how to write them and put them in place, and how to ensure, having gone to all the trouble to produce them, that they actually work as they should.

(You may think, perhaps, as a one-man or woman band, i.e. a freelance writer without anyone else to manage or support, that SOPs are not for you. After all—you are the one who knows what you are doing, you don't need it written down. However, more and more pharma companies are looking for the reassurance that their data are safe, that you have good practices in place, and that you have the quality controls they need. How better to do this than to have policies and SOPs in place that clearly demonstrate your commitment to their requirements? Another useful reason is as a double check that you are maintaining vigilance. It is very easy, with children, other distractions around and urgent deadlines to find your standards slipping. A written document can be an excellent reminder and safety check to ensure you are still on track.)

What is an SOP?

Here is the Wikipedia definition of an SOP as at October 2008:

'A standard operating procedure is a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard Operating Policies and Procedures can be effective catalysts to drive performance improvement and improving organizational results. Every good quality system is based on its standard operating procedures (SOPs).'

Thus, an SOP is a written step-by-step process for achieving something. At Rx, our SOPs start with a statement of what the SOP is, what it sets out to achieve, who should use it, what situations it applies to and when it should be used.

Here are some pointers you may find helpful in drafting your own SOPs.

1. Have a clear idea of what the SOP needs to achieve.
2. Have some form of approval process and version control—in our company, we have an SOP for creating SOPs! This may be over the top, but it prevents people who are somewhat too enthusiastic about control, from putting draconian measures in place. Another useful technique is to keep the old SOPs accessible; i.e. keep a document history. This not only allows people to see what has changed from the previous version, but can also help prevent the wheel being reinvented.
3. Use a template to keep consistency. You can see ours in the example SOP given below: Figure 1 = SOP PM01. We have based ours on :
   a. What the SOP covers
   b. The rationale for the SOP
   c. Who is responsible
   d. The SOP procedure
4. Where possible, clarify processes with flowcharts and diagrams. Most of our publications processes have these, because with complex and lengthy procedures it is much easier to follow on a flowchart.

> > > SOPs–Pitfalls in the process

Operating Procedure		
Title: Project Allocation and Handover		Ref No: PM 01
Created by: XXX XXXX	Approved by: Ruth Whittington	Date:
Supersedes:	No of Pages : 3	

This SOP Covers:
► Rationale for project allocation and handover of projects from business development to project management
► Who is responsible for project allocation and handover
► Procedure for project allocation and handover

Rationale
The appropriate allocation of projects among the project management team (project managers, senior project managers, project leaders, project directors etc.) is imperative to ensure the efficient functioning of the project management team, client satisfaction, and to avoid any conflicts of interest (see separate SOP on Conflicts of Interest) when the company has been tasked with working on projects in similar therapeutic areas/indications involving competitor companies/compounds. The effective handover of new projects helps ensure that projects are managed in a manner that meets overall budgets, timelines, and quality targets, and gives the client a seamless experience.

Who is Responsible?
► The allocation of new projects is done after a team discussion involving the Head of Global Business Development, Project Director, Project Leader, and any other relevant members of the company including possible project managers of the new project.

► Subject to full agreement among the team, this same team is responsible for the effective handover of the project.

► The CEO of the company has ultimate responsibility for the allocation and handover of projects.

Procedure
Upon the emergence of a new project…
► The Project Leader would consider the following in their preliminary decision
  ● Overall project workload of individual project managers available to take on new projects
  ● Potential conflicts of interest
  ● Experience and suitability (and ability) to manage the project
  ● Training requirements (if any)

► The Project Leader would discuss his/her findings and suggestions with the team.

► The CEO ratifies the decision of the team.

► The project is allocated following a comprehensive briefing and handover to the project manager by the project leader and other relevant members of the team.

► The comprehensive briefing and handover of new projects could involve any number of the following items being handed over to the project manager
  ● Approved proposal
  ● Project brief
  ● Client's request for proposal
  ● Notes on discussions prior to project approval
  ● Relevant call reports/meeting minutes
  ● Datapackage(s)
  ● Verbal briefing

► As a general rule, unless there is a conflict of interest, new projects for new clients are managed by the project leader. This is to ensure the development of a good client-agency relationship for future projects.

What is a Policy?

One thing an SOP is NOT, is a policy. This is an interesting distinction, and one that we learned to our cost. Here is the Wikipedia definition of a policy:

'A policy is a deliberate plan of action to guide decisions and achieve rational outcome(s)…… Policies can be understood as political, management, financial, and administrative mechanisms arranged to reach explicit goals.'

A policy gives the overall understanding of the company ideals and culture—it should be consistent with your vision and mission and objectives. For example, a good publications policy for an agency or freelance writer should be comprehensive, covering all types of publications, clear, consistent with any important guidelines and should cover all contingencies—author relationships, data and security issues, what the agency standpoint is if the clients disagree with the authors, for example, dealing with journals etc. The important issue is that it reflects your ethics and standards, and guides the employee to the appropriate SOP that enables them to operate within those standards.

The Pitfalls

So what can go wrong? We had made two errors in our thinking—firstly we had assumed that our ethics and standards were clear in our SOPs so that we didn't need a policy document. This was a mistake, because even if the SOP has a clear rationale, without a policy document to tie it together an employee doesn't get the sense of the bigger picture, and will not look beyond the SOP to apply the principles in other areas of work. Our second and most important error was that we didn't monitor the use of the SOPs sufficiently.

It can be easy, when getting experienced staff from another agency, to assume that they are familiar with the processes and procedures you use, particularly if they appear confident and competent. And of course, when you hire staff it is because you are in a very busy period, so if they appear to know what they are doing, the tendency is to leave them to it. In our own case, we had also brought in staff with roles that we had traditionally out-sourced, and this again caused a problem. It is so much easier to just ask someone sitting at the next desk to assist, rather than go through formal channels and thus remember the other steps that are required first.

And what happened to our SOPs? Left in their folders, where they had been since the induction process for new employees. Unmonitored, we had no way of ensuring that they had been read, let alone being sure they were being followed. Without a policy document as another safeguard, our staff members had nothing else to prompt the right actions.

Simply having yet another company document does not necessarily provide an additional safeguard. Having a policy is very useful, and in the first flush of enthusiasm when a new employee reads all these documents, hopefully some of it stays in the memory sufficiently long enough to prompt further exploration of procedures when a new situation arises at a later date. It is difficult enough for us to ensure that we have read and are aware of the SOPs themselves, although one can usually only achieve a "certain degree of familiarity". The only real way you can find out if your staff are adhering to your SOPs (to an acceptable level) is to do spotchecks.

So we have instituted a system that when I sit in on project financial review (which in our company happens at the beginning of each month) I spend some time flicking through files and asking questions to ensure the staff are adhering to SOPs. This doesn't happen as often as I would like, but generally once a quarter it becomes quickly clear who does and who doesn't fully understand and follow the policy or SOPs.

The aftermath

There are always silver linings to clouds, I find. Following the ghostwriting debacle, we developed a good publications policy that guides our company actions. Is it foolproof? Probably not, but we have established an excellent review process, and as we continue to work with our clients in this area we endeavour to strengthen its application. And while we can't take credit for the entire resurgence of interest in good publications practice throughout the industry, the experience has vastly improved the adherence of agencies and pharmaceutical companies to the standards set by CONSORT and ICMJE. Sadly, it still appears that journal editors and non-industry authors are lagging behind in consistent application of these principles, but as a whole I am optimistic that publications practice is becoming more ethical.

We have also set up an SOP review process that should stand us in good stead, and are slowly putting monitoring sheets and processes in place. In these straitened times it is difficult to find the time for such housekeeping among all the more client-oriented activities, but we do our best.

And another good point—we are so concerned with publication policy and management, clients are using us to help set up their own systems. After all—there is nothing like bitter experience to reinforce good behaviour.

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False increase

I seem to be alone in not seeing anything increasing here, just a higher proportion in the USA:

An estimated 25% of adults aged 50–64 years suffer from at least one chronic illness in the UK (Meier, 2000), a proportion which increases to 34% in the USA (Smith 2006). Why not just: *25% of adults aged 50–64 years in the UK (Meier, 2000) and 34% in the USA (Smith, 2006) are estimated to have at least one chronic illness* (if you can bring yourself to start a sentence with a percent! If not, you could say *a quarter* and *one third*!). If you want to stress the idea of 'more in the USA', then you might try: *More adults aged 50–64 years in the USA (34%; Smith, 2006) than in the UK (25%; Meier, 2000) are estimated to have at least one chronic illness.* Whatever, as far as I am concerned, nothing is increasing here. We just have two figures, one higher than the other.

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Addressing issues or writing what you mean

By Neville W Goodman

Introduction

Above all else, medical writing should be precise. In the vernacular, we should call a spade a spade. There is plenty we do not know, but we should say simply that we do not yet know, not that in the present state of knowledge some facts are not yet certain. I think medical writing is becoming less precise, at least that there is increasing use of imprecise phrases. The verb 'to address' is a typically imprecise word, especially when used in the phrase 'addressing the issue' [1]. I used this as an exploratory index of imprecise medical writing.

Methods

I searched MedLine 1950-2007 (Dialog Datastar) in May 2007, in eleven five-year periods starting with 1950 to 1954 and ending with the three-year period 2005 to 2007. I used the logical expression NEXT, which finds a second word following a first word within the next five words, to search for *address* or *addressing issues*, *questions* or *problems*. I searched separately in all fields and in title only. I compared the number of hits with the more precise phrases *ask* (or *asking*), *pose* or *answer question*, and *solve problem*. The numbers of hits were adjusted to correct for the increasing number of published papers, and scaled to allow direct comparisons of how usage changed with time.

Results

No issues or questions were addressed until the period 1975-9. Three problems were addressed in 1970-4, the first in an abstract in 1972 [2]. (There were six hits addressing problems between 1950 and 1969, but these were all presidential addresses.) By the period 1980-4, addressed issues were well established: addressed issues, questions or problems occurred in 601 papers, while asked, posed or answered questions, or solved problems occurred in 1684. In the last complete five-year period (2000-4) addressing (11375) was more popular than asking, posing, answering or solving (8840). Figure 1 shows the relative changes in usage, and also shows that all phrases have become relatively more common.

This increase in occurrence of all phrases is largely because of the increased inclusion of abstracts searchable on Medline: the searched phrases are more likely to occur in an abstract than in a title. In 1950-4, the 37 occurrences of solving problems were all in titles; in 2000-4, of the 3285 occurrences, 217 were in titles. Figure 2 shows that non-addressing is relatively much the same as it was in 1980-4.
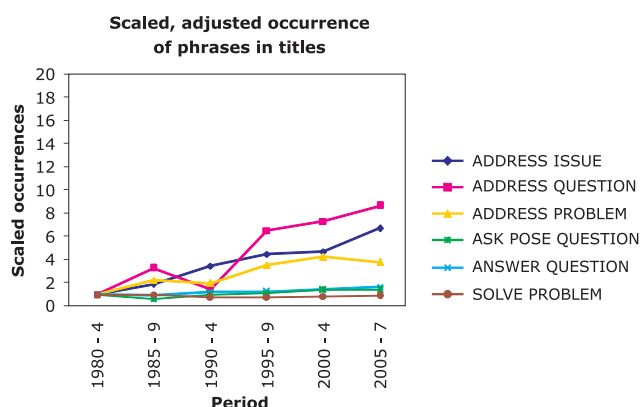

Figure 2: Occurrence of phrases in titles, adjusted for the total number of published papers in each period, and scaled to the index period 1980-4.

In 1950-4, authors were three times as likely to solve problems as ask, pose or answer questions. Problem solving has remained relatively constant over the years, unlike questions (see Fig 3).

Discussion

Medical writers did without addressing entirely for the first 25 years of MedLine, but 'addressing issues' is now the most popular general description of a study. Language changes over time, but it is a shame if it changes from the clear to the vague. Only two things can be addressed: envelopes and audiences. All questions are posed or asked; some are answered. Other addressing is waffle, risking the inference of an action that may not be intended [3]. Addressing issues raises waffle to a higher level [1]. Style guides warn that issue is not a synonym for problem [4], and suggest that the writer does not have a clear idea of his
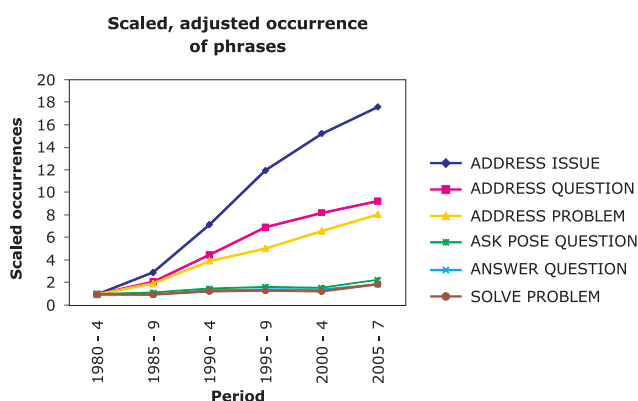

Figure 1: Occurrence of phrases in any field, adjusted for the total number of published papers in each period, and scaled to the index period 1980-4.

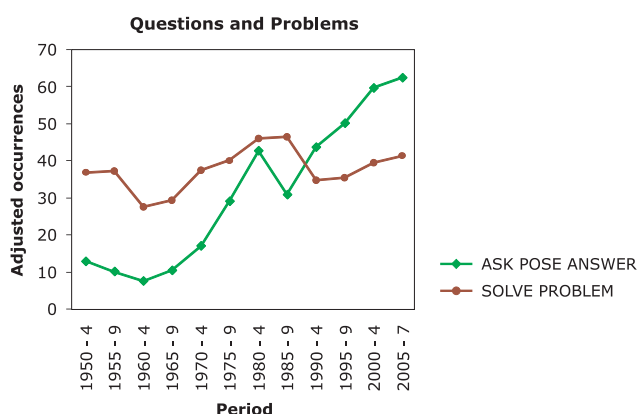## Addressing issues or writing what you mean

Figure 3:   Occurrence in titles of asking posing or answering questions and of solving problems, adjusted for the total number of published papers in each period.

or her meaning [5]. At the least, the verb address postpones a proper description of what has been done, or is unnecessary repetition. There is a good example in one of the three papers from 1975 that are the first to address issues [6]. The authors write, "Two sets of questions are explored. The first set bears directly on the issue of gaining access to care. The second set addresses the issue of the acceptability of the services received." The last two sentences are easily abbreviated, with no loss of meaning: *The first set is about gaining access to care, the second about the acceptability of the services received.*

Addressing issues is a vogue phrase. It is common in everyday speech, which is a likely reason for its increasing use in medical writing. It is not a good reason, and careful writers should strike it out.

Why asking, posing or answering questions has become so much more popular than solving problems I have no idea, nor any views on whether it is a good or a bad thing.

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De-gendered or de-sexed?

'De-gendered toilets spark row'. On reading this headline I thought it was another example of the misuse of 'gender' when 'de-sexed' toilets would have been correct. The headline appeared in the BBC's online news on 30 September this year [1]. It seems that in response to trans students who felt uncomfortable using the men's toilets, Manchester University have changed the 'ladies' to 'toilets' and 'gents' to 'toilets with urinals'. As toilets can't have a sex (or gender), one can figure out that the heading is not directed at the toilets themselves but at the accommodation of the emotional sexual identity of transgender and transsexual people. So it seems that the BBC has got it right [2].

1. http://news.bbc.co.uk/2/hi/uk_news/england/manchester/7643175.stm
2. De Looze S. All Gendered up. *The Write Stuff* 2004;13(3):73-5.

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Could de-sexing toilets be something for women lawyers?

After Ken Russell, who is a professor emeritus of Metallurgy and Nuclear Engineering, had given evidence in court, a lawyer representing one of the parties asked him if he would be prepared to work with his client on more cases. The request was made in the men's lavatories, which Russell found somewhat amusing. He later mentioned the proposition and the location in which it had been made to a woman lawyer who, displeased, retorted, "There are entirely too many deals going down in men's rooms". Russell acknowledges that she has a point but with the demise of men-only clubs for business discussions he thought women professionals might face a tricky problem getting rid of men-only lavatories—perhaps they should form an alliance with Manchester University (see box above).

Source: http://improbable.com/

Have you noticed how often people get commas wrong when 'but' is about?

The following sentence was published in the *BMJ* 2008;337; page 726, col 3, para 2:

Individual stakeholders might well recognise the problem, but because it's complex, antibiotic resistance often becomes no one's responsibility.....

Thanks to **Neville W. Goodman** (nevwgoodman@mac.com) for this contribution.

The new Purple Guide is out

The Purple Guide is an MHRA guidance document on Pharmacovigilance in the UK. It is new as there has not been one before and it covers marketed as well as non-marketed products, similar to the Orange Guide (for GMP). See: http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON028548

Thanks to **Belinda Pierce** (bpqs@dsl.pipex.com) for sending this information

Stop press!

A new book by Hans Weiss presented on 17 November raises serious questions about doctors and the pharmaceutical industry. Unfortunately at the moment it is only available in German.

Weiss H. *Korrupte Medizin. Ärzte als Komplizen der Konzerne*. Kiepenheuer & Witsch, ISBN 978-3-462-04037

Address, key and sorted

I noticed *to address* creeping into use in the way Neville describes at the end of the 1980s. No doubt it is also being used with its new (imprecise, as Neville feels) meaning in all sorts of fields outside medical writing by now. Neville says that it is *common everyday speech*, but I think that its use does still seem to be largely restricted to the business sphere. I can hardly imagine anyone outside work saying: *Let's address that problem at the weekend when we have a bit more time*. In this situation, I think people are still much more likely to say *discuss*, *talk about*, *deal with*, *tackle*, *think about*, *try to solve* or the like. This may be because I am not in touch with vernacular English every day. I read plenty, but do not hear it spoken as often as people living in English-speaking countries. I consider that *to address* establishing itself with this new meaning is evidence of the relentless evolution of language, but I, like Neville, am not happy using it this way. To me *We addressed the following issues: …* means *There was a lot of talk about the issues, but no conclusions were reached*. As *TWS* readers are aware, I do capitulate eventually on some issues, but I have a feeling that it will be some time before I will on this one. Whatever, I fear it is a lost cause, but this should not encourage you to use vogue words or phrases!

Another vogue phrase which we may no longer be able to stamp out is *This is key* or *This is key in* or *to something …'*. *Key* is, of course, an adjective (and a noun and a verb). Until the mid-1990s when I began to notice this new use of *key* on its own as the complement combined with the verb 'to be', *key*, when used as an adjective, almost always modified an immediately subsequent noun and was preceded by an article or not: (*The) key factor(s) in our success will be …* . Or it was used as a subject (noun) with an article: *The key to our success will be … .* Now, *Key to our success will be …* and formulations such as *This is key* as a complete sentence (i.e. not followed by *to our success* or another phrase) are rapidly gaining ground. Describing his new job, a friend from Philadelphia recently wrote to me: *the second major project is to help the technical teams to manage their existing vendors and my CRO experience will be key*. This not how *key* would have been used 15 years ago, but is in common use now, so again we see the evolution of language. I have a feeling that, like *address*, this one will stay. It may take me some time to start using it this way—if I ever do. Sometimes, new locutions of this sort die a natural death. But I don't think these will.

A good example of another that didn't is: *That's sorted*. This is not written in formal English (i.e. is spoken or is used in emails), and 30 years ago when I left England, no-one would have dreamed of saying this. If they had, they would have received puzzled looks, because then it was normal to say *That's been sorted out* or *settled*, and *That's sorted* meant nothing. I still don't feel comfortable using this, I think because I live outside the UK, but my 85-year-old father in the UK does, so this shows that this has penetrated well.

Using *address*, *key* and *sorted* in the above ways is not actually an error, and that's perhaps where we should draw the line when deciding whether to use new locutions or not. But as we linguists know, drawing the line where an error starts is often very difficult, not only in English …

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4-letter words and others (4)

by Alistair Reeves

I have two 4-letter words and 2 suffixes with 4 letters for you this time: *stop*, *done*, *-fold* and *-free.* We extend to 5 letters with *about* and to 6 letters with *nearly*, and then shrink back to *do*, *at* and *of*. It is surprising what you can say about words with 2 letters! 3-lettered *man* rounds things off this time.

Stop

After treatment stop and *after treatment start* are formulations I frequently read on CIOMS forms[1] and in subject narratives, even amongst examples I see prepared in the UK—and I have to say: they just have to be changed. At best, they could be explained away as jargon; they are actually just plain wrong and betray a lazy writer. I also occasionally see *after stop (start) of treatment*. The same also applies to other words, such as infusion (e.g. *after infusion stop* or *after stop of infusion*). Here, I am considering only the use of *stop* in this way, but most of my comments also apply to *start* and other words used in this way such as *infusion*.

Stop is a noun and verb, and it has 13 meanings as a noun in the Oxford English Reference Dictionary [1]. The only one that comes near to its use as a noun in *after treatment stop* is: 'the act or an instance of stopping; the state of being stopped'. On the surface, this looks OK and means that stop might be used in this way, but the examples provided betray the way that stop in this sense is used as a noun. Only collocations are given: *to put a stop to*, *to bring to a stop*, *to come to a stop*. None of these locutions are suitable for formal scientific and medical texts. You could not, for example say *After treatment was brought to a stop* (usually reserved for runaway horses or vehicles, or garrulous people and the like), or *After we put a stop to treatment* (usually reserved for something which is bothersome, and even rumours; of course, treatment may be bothersome, but you know what I mean). You might probably just about get away with *After the bleeding was brought to a stop.* But then you might as well just say *After the bleeding was stopped*, because this sounds better and is shorter. And this reflects what you should be saying instead of *After treatment stop* or *After stop of treatment*. You should be using stop as a verb and saying *After treatment was stopped* and not *after treatment stop*. That's just how it is. Even if your tables have column headers that say 'treatment start' and 'treatment stop', this is probably just for the sake of brevity in the table and should not be used in text.

Care must be taken when using *stop* and *end* as verbs and nouns. When using them as verbs, their meaning is related to transitive use (with an object) and intransitive use (without an object) and whether in the active or passive voice. Some verbs are only intransitive (e.g. *arrive* cannot take an object: *The train arrived at 16:00*), but most verbs can be used with or without an object, and this applies to *end* and *stop*. *After treatment stopped* (active, intransitive) is an unusual formulation, suggests that the treatment came to a spontaneous end, and is rarely used. *After the infusion stopped* (also active, intransitive), however, is less unusual, because an infusion generally goes over only a maximum of a few hours and usually comes to an expected end. *After the patient stopped treatment* (active, transitive) usually implies that the patient wilfully curtailed treatment, but can also be neutral and can just mean after the expected end of treatment (for whatever reason), so the context has to be carefully checked. *After treatment was stopped* (passive, intransitive) is used frequently and almost always means that treatment was deliberately ended earlier than expected, most probably by the attending physician. The same applies to *after treatment was ended* (also passive, intransitive). *After the end of treatment* (no verb) or *after treatment ended* (active, intransitive), however, are neutral and are used either when treatment came to its expected end or when it was ended prematurely, so again, the context has to be checked carefully.

The above is probably part of the reason why I don't use *stop* very much when talking about ending treatment, because there are better words, such as interrupt, suspend, discontinue, withdraw, or finish, which actually describe different actions more precisely, and I like the word *end* rather than *stop* (a personal preference). You should be careful with *terminate*, however: it is often just used as a fancy alternative to *stop* or *end* as a verb. And the same applies to *termination*, when all you mean is *end* or *ending* as a noun. When used intransitively (*The study terminated on 12 January 2007*) as opposed to transitively (*We terminated the study because recruitment was slow*) *terminate* generally means that whatever was terminated reached its expected end. But because *end* is just as good, you may as well use just *end*.

All this talk of starting and stopping brings me to the word *onset*. But we'll reserve that one for the next issue.　　> > >

> > > 4-letter words and others (4)

Do and Done

As far as I am concerned, it is quite acceptable to *do* tests, studies or analyses, for example, or have them *done*. Many writers prefer to use *perform*, *conduct*, or *carry out*, and there is really nothing that can be said against these verbs, except that they are longer than *do* and are sometimes appropriate because they form part of collocations ('The spokeswomen said that it would be almost impossible *to carry out the wishes* of the government committee'; 'The *investigation was conducted* in the strictest confidence'). Any extra shades of meaning other than *do* that they might once have had in our context have now been thoroughly beaten out of them by overuse. Especially *perform*: it would be nice to think that writers in our field could be persuaded to give *perform* a rest, allowing it to continue to do good service when describing circus feats or the staging of plays, but this is (verging on) a lost cause. There are writers who (perhaps after some thesaurus-searching for a 'different' word, or because they think they sound 'better') choose to use such verbs as *execute* (reserve this for shooting at dawn) or *accomplish* (reserve this for the successful completion of a difficult task that you may well be proud of) instead of *do*. Next time you write any of these, review your sentence to see whether simple *do* would be just as appropriate.

-fold

You have choices when you use the suffix *-fold*: you can use digits or text and hyphenate it or not. It is therefore immediately obvious that whatever you choose, you are not going to be *wrong*. But choices often mean unnecessary controversy and therefore wasted time. Repeated discussion of the 'correct' way to write *-fold* is definitely a waste of time. My preferred rank order for these choices is: *10-fold*, *ten-fold*, *tenfold*, *10fold*, and I would only use *10fold* if a client absolutely insisted. I consider *10 fold* and *ten fold* incorrect. Decide which you prefer, defer to the preference of others without comment, but always try to remain consistent.

-free

Unlike *-fold* and other suffixes, *-free* does not show the tendency to amalgamate with the word it follows. There are no rules here, and authors determine whether and when amalgamation happens by gradually (maybe sometimes even suddenly) starting to write a word and a suffix together (*stepwise* instead of *step-wise*, for example). It may look wrong at first, and you may resist, but after an indeterminate time these amalgamations often start to look all right, and they come into general use. This does not seem to happen with *-free*. Carefree exists, of course, but I have yet to find another *-free* that is regularly written together. Duty-free, drug-free, trouble-free, germ-free, lead-free: *-free* seems to want to remain free of its precedent.

About

I very decidedly gave up my prejudice against *about* several years ago, and deliberately started writing it instead of the pentasyllabic *approximately* and *approx*. I had always claimed that *about* was only spoken until then, but suddenly thought: *Why do I think this?* I definitely had some misconception that *approximately* 'sounded better'. There was also that nagging worry that I should really explain the abbreviation *approx.* the first time I used it and never bothered to do this because 'everybody must know what *approx.* means'. I also realized that I was being internally inconsistent: I make all these claims that we writers should make our texts a simple as possible, and then I go and use a word that has 5 syllables instead of 2! It took more than just a few months, but now I am quite comfortable writing such things as *About 250 mL serous fluid were drained from the pericardium ...* or *A 65-year-old man with biliary cancer developed tachycardia about 3 months after the start of treatment ...* .

Nearly

I am in two minds about *nearly*, and I didn't used to be. I was once firmly in favour of using it only when speaking or writing informally: *The patient's diastolic blood pressure decreased in one week by nearly 20 mmHg*. Although there is still something that sounds rather spoken about it to me, I have recently found myself thinking that *nearly* probably sounds all right in certain situations, and sometimes I actually write it. It is the respectable adverb of near, and, as such, I shouldn't be objecting to it in written use. But I still find that I do. What do I feel I have to use instead? *Almost*. And what does this tell us? Probably all it tells us is that I was just prejudiced against *nearly* for years and am finally giving a perfectly acceptable word its due.

The word *circa* (usually abbreviated to *c.* and not *ca.*) also exists in English, of course, but for some strange reason, it has not established itself as widely as in other languages in science and almost always only precedes a historical date consisting of only the year, for example, after a quote from a historical manuscript: *Taken from Thomas Wilson, Arte of Rhetorique, c. 1550 ...*;.or when describing a painting: *... School of Hieronymus Bosch, c. 1493*. Although it probably would be understood, it looks very strange in the following: *The patient had a blood pressure of c. 180/115*. *About* is definitely preferable to this, or, if you haven't taken the leap yet, *approximately* or *approx*. But please do get out of the habit of using *approximately* when you could just say *about*.

At

At has a specific and frequent use in our context that it not so common in vernacular English. It is often used when describing what was shown by an examination. To say that something was found *at X-ray* or *at ultrasound*, or *at postmortem* is quite acceptable (I have just deleted the hyphen inserted into postmortem by the autocorrect function in Word. Don't be terrorised by Word: switch these things off!), and sounds better than *by* in all instances, although *by* is not wrong and is also used. But it is different with the term *physical examination*. Although *A discrete rash was found at physical examination* sounds normal, *A discrete rash was found by physical examination* sounds unusual, but *A discrete rash was found on physical examination* does not. *On X-ray*, *on ultrasound*, or *on postmortem*, however, would never be used. Further evidence of the unfortunate (for the writer) peripatetic nature of the English preposition.

Of

I include *of* for one reason now, although there are many other reasons to discuss the use of *of* in English: it is used incorrectly by writers in Continental Europe in one specific way when they are reporting on clinical trials. *Patients of this study …* is not correct. *Patients in this study* is what is most frequently used, and *Patients from this study …* may also be appropriate: *Patients from this study with a final DBP > 90 mmHg were not included in the supplementary analyses. From* is also used when required by a verb: *We selected patients from this study for the analysis of … .*

Man

It is just as easy to say *humans* as *man*. I have now switched to the former completely (and, I am proud to say, spontaneously. By that I mean, I don't spontaneously write *man* and correct it to *humans*), but I still do see *man* being used when 'all human beings' is meant. There are women who do not object to *man* used this way, but I suspect they are a small minority, so that is no argument.

A client recently insisted that I put *male patient* and *female patient* in subject narratives because "they are not just men and women, they are patients". If I have my choice, I say: A 55-year-old *man* with gastro-oesophageal cancer was treated for 4 weeks with X and developed X. Why? We all know he was a *patient,* and the poor *man* had gastro-oesophageal cancer.

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Reference:
1. Pearsall J, Trumble B. *The Oxford English Reference Dictionary*. Oxford: OUP, 1996.

Working from home—The best of both worlds?

Like many other EMWA members that I've met, I realised whilst doing my PhD that I enjoyed writing up the results of experiments far more than actually performing them. Medical writing was, therefore, the obvious choice of career and so I became an office-based medical writer in a Contract Research Organisation. When office-based, I'd often dreamed (as I'm sure many do) of working from home, with an idyllic vision of being able to do the washing, go for a run and clean the house in my lunch breaks, instead of working or surfing the internet whilst trying not to drop breadcrumbs into my keyboard. However, living only 11 miles from the office, with great transport links, didn't really give me much excuse to realise that vision.

Whilst I was pregnant with my second child and literally the day before we were due to exchange contracts on a new house, my husband dropped the bombshell that his job was being moved from London to Switzerland. The timing of the announcement, coming just as we were about to commit ourselves to a massive mortgage and months of home renovations, made us think that maybe we should take the plunge and move.

I wanted to return to work after having my baby (yes, I'm weird that way) but my husband's job was moved to Zurich, a good hour away from my company's Swiss office, and at least that far from those of most other companies that employ medical writers. The life of a freelancer had never really appealed as I love being part of an office with all the associated support, job stability and opportunities (as well as social life and gossip). Medical writers at Quintiles are normally office based at one of our medical writing team hubs but because I'd been with the company for several years, it was agreed that I could work from my new home in Zurich rather than have to leave a job that I enjoyed.

Adjusting to working from home was, fortunately, easier than I expected. Although I'm officially employed by my company's Swiss office, I'm still managed from the UK and I consider myself to be part of the UK team in spirit, if not often in person. I miss the everyday office banter and the frequent nights out, but with my mobile phone and MS Office Communicator, I'm as available as ever, plus I keep in the gossip loop! I have a view of Lake Zurich, instead of Bracknell town centre and staying late at the office to catch up just means going into the study after the kids have gone to bed. The kids have a fantastic lifestyle and my 4-year old is already a competent skier. They also get to see their grandparents much more than when we lived in the UK, even though they live in the UK themselves. However, my vision of the perfect work-life balance hasn't quite worked out. Although I work about 80% of a full-time contract, I face the perennial problem of working mothers in that the majority of my earnings go on childcare. Also, there simply isn't time at lunchtime to cook, clean or go for a run. In fact, the house is messier than ever because I have lunch at home and I still find myself dropping crumbs into the keyboard. My weight is also creeping up, as I frequently raid the fridge, whereas when I was in the office, I felt too ashamed to visit the chocolate machine more than once a day. All things considered though, I think I've probably got the best of both the office- and home-based worlds.

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A report on the European Conference on Scientific Publishing in Biomedicine and Medicine (ECSP2)

by Kari Skinningsrud

The second ECSP congress took place at the National Hospital (Rikshospitalet) in Oslo on 4-6 September this year with 145 participants. The main aim of the conference was to broaden researchers' understanding and knowledge of the rapid changes in the scientific communication and publishing environment and its direct impact on the research community. Two major themes were addressed; the first was about Open Access (OA) publishing and the second about measures of research quality. The conference gathered the most authoritative opinions on these issues and shed light on many interesting facets of STM (Science, Technology and Medicine) publishing.

The chairman of the European University Associations' (EUA) steering group on OA, Dr Noorda, emphasised the importance of widening the user perspective from just the academic community to the general public, health professionals and business innovators. In March 2008, the EUA adopted a policy on public access to reviewed academic publications, which is just one of many examples of a global move towards OA. Alma Swan from Key Perspectives Ltd talked about what hinders and helps OA and how we can get there. Getting researchers to add their papers to a repository is one way of achieving OA, but increased awareness about such possibilities is clearly needed as only 40% of life science researchers are familiar with OA. Policy awareness does not seem to change behaviour, but mandates do and increased visibility via Google leads to more citations and greater impact. The embargo factor is a hindrance, 24 months is not good but 6 months is bearable. Most publishers agree to make metadata available for the final manuscript, and then researchers can go onto Google and make contact with the author if they want more information.

Robert Kiley from Wellcome Trust started by pointing out that the message is very clear for Wellcome- funded researchers—free accessibility in UK PubMed Central within 6 months of publication. The Trust supports OA to improve quality of research by developing repository-based services to meet the needs in the UK research community, improving the research process through improved integration of literature and underlying data and maximising access to research outputs. Wellcome meets all publishing costs if there is an OA author-pay option, but publish-

> *Wellcome meets all publishing costs if there is an OA author-pay option, but publishers must give something in return.*

ers must give something in return, for example deposit the final manuscript in a repository. Now most publishers have agreed to Wellcome's specification, regardless of their publishing models. The top 30 Trust-funded institutions get block grants from Wellcome to cover the OA publication costs. If block grants are not available, the Trust supplements individual research grants. Robert Kiley finished off his talk with UK PubMed Central (UKPMC), which has been available for the research community for 2 years. More funding has been approved to be able to expose the contents of UKPMC to text mining solutions and add additional content such as clinical trials, guidelines etc.

Stephen Pinfield from the University of Nottingham gave his speech on how institutions can help authors move on to OA and cover the costs. UK research councils, Wellcome Trust, the European Research Council, NIH and the Australian Research Council have OA mandates. The database SHERPA Juliet lists funders and their OA policies. SHERPA Romeo lists publisher copyright and self-archiving policies. All institutions should set up a repository and in fact, most have these days. The costs for OA should be covered by the institution rather than by the library. According to Pinfield, OA costs can be taken from project budgets and overheads to form an institutional funding stream for OA. For example, if publication occurs after a grant is closed then that is when the institutional funding stream kicks in.

Kaitlin Thaney from Science Commons gave a talk on how Science Commons works with publishers, academics and institutions in order to make content and scientific data available. She spoke about Creative Common licences (CC) as an answer to copyright challenges in the digital world. She said authors should be given control; they are the publishers of scientific data. The goal is to create legal zones of certainty for scientific data on a 'research web'. The first publishers to have adopted the research web idea are BioMed Central, PLoS and Hindawi. Academics need policies to help them retain rights to self-archive their work. Institutions who are looking to implement OA policies need OA policy guides and white papers. Håkan Carlsson from Göteborg University in Sweden said that about 20% of all published research is or will soon be OA. Those who pay the research are increasingly demanding that it is made OA.

Barbara Kalumenos from the International Association of Scientific, Technical and Medical Publishers (IASTM) spoke about the PEER (Publishing & Ecology of European Research) project which aims to get evidence about the

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effect of embargos of varying lengths to the various stakeholders. The project started 1 September this year. Graham Lees, editor and owner of *The Scientific World Journal* (TSWJ), gave a talk on 'The Future of Journal Publishing'. When starting a journal, who should pay - readers or authors? Graham thinks both, because not all authors can pay for OA.

Anthony van Raan, Director of the Centre for Science and Technology Studies at Leiden University, gave a fact-packed presentation about his work on measuring citation patterns and impact (based on articles, individual scientists and research groups and institutions). The tools that Anthony's group have developed over the past two decades are extremely powerful. Until recently, the base data he and his colleagues have used came from Thomson Reuters (the ISI databases) but they now also include data from Elsevier's Scopus service. Anthony's conclusions were that bibliometric analysis is a very useful, informative and penetrating methodology for assessing research effort, but that it should never be used in isolation, only in conjunction with other assessment regimens, particularly peer review.

> *Authors agree that too much emphasis is given to impact measures based on citations… commentators recommend a more balanced approach to assessing research "quality".*

Mary Van Allen, Manager of the Research Services Group at Thomson Reuters (aka ISI) talked about 'Beyond Impact Factors'. A new website called Researcher ID allows researchers to create an authority file of their own papers and get a real-time display of their citations, h-index (quantifies both the actual scientific productivity and the apparent scientific impact of a scientist) and so forth. The big idea here is to provide a collaboration network diagram, which can be displayed by geographic region or down to individual institution. Clearly, Web of Science is working hard on developing new metrics from its databases. A question as to whether Web of Science intends to give citations from different journals a different 'importance' was answered in the negative, partly because weighting is a subjective issue and partly because there is no consist approach—many papers published in *Nature* and *Science* are never cited (apart from self-citation).

Richard Gedye (Chair of COUNTER and the UKSG Working Group on Usage Factors and Research Director in the journals division at Oxford University Press) spoke about measuring usage of articles – or rather, of journals, as that is the base point used by COUNTER. He described the research programme that has been carried out by the UKSG on usage, including qualitative surveying of librarians and authors and large-scale online surveying of the same constituencies. The more metrics that can be brought into play the better. Richard reported that both UKSG's

survey and the previous one by the CIBER Group showed that 70% of authors are enthusiastic about a usage-based measure for assessing research journals. Richard also reported that plans are underway for a study to outline the metrics currently being assessed, whether any of them are suitable and how publishers can establish a consistency over how they report usage. There was some discussion over the significance of download numbers.

Then we heard from Howard Browman, Principal Research Scientist at the Institute of Marine Research, Storebo in Norway, speaking on the use and misuse of bibliometric indices in evaluating scholarly performance. Howard gave an overview of existing metrics, of 21 'problems' with the Journal Impact Factor, and emphasised that ALL bibliometric indices have such limitations. Only people with a thorough understanding of these limitations should apply the metric indices in practice (i.e. assessment of an individual for promotion or tenure); it should never be done by uninformed panels of assessors. Howard showed data that confirm that the Pareto Principle holds for any individual scientist's citations (i.e. a minority of articles get the majority of the scientist's citations) and this also holds when whole journals are studied. He also showed that almost 50% of articles in the Web of Science database have never been cited at all. Journals with high impact factors have a high degree of editorial pre-screening (editors screen before manuscripts are sent out for review) and a relatively low acceptance rate. Howard's questions:

> *One speaker questioned whether journals and articles will continue to retain their significance and brand importance.*

are we saying that 80% of articles published are of low quality? Are 80% of journals of little significance? Or is there something there that is not captured by citations? We are accustomed to focusing on the 'quality' (i.e. highly-cited) end of the published corpus, but what about the rest? Authors, according to the CIBER study, tend to agree that too much emphasis is given to impact measures based on citations, and other commentators too are recommending a more balanced approach to assessing research 'quality'.

The final speaker was Ed Pentz, Executive Director of CrossRef, the scholarly publishers' facilitator of the reference-linking system (currently with 550 publishers and 15000 journals. CrossRef now has 35 million items including journal articles, books, book chapters and so forth. He explained that the Digital Object Identifier (DOI) was developed to create a unique and less vulnerable identifier to articles than URL (web links often do not work after a while). The DOI is unique, while the URL it refers to may be updated if for example a journal changes its address. DOI is much used now, currently with more than 20 million clicks on DOI links per month.

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Ed Penz questioned whether journals and articles will continue to retain the significance and brand importance that they presently enjoy. The rise of informal 'Web 2.0' tools for communication and the linking to new kinds of content are changing the paradigm. So are new kinds of 'publication', such as databases (e.g. protein sequence databanks) that are already assigning DOIs to items and wikis as a platform for (almost-formal) publishing. The latter are not yet assigning DOIs, but the indications are that they are moving in this direction. Blogs are citing DOIs, even if they are not assigning any, and we are now seeing aggrega-

tions of blogs (e.g. Science Blogs), and scientists looking to such developments to give recognition to their work outside of the traditional mechanism of citing journal articles.

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Basic Results Reporting at ClinicalTrials.gov and 'Prior Publication'

We have received questions concerning the posting of results at ClinicalTrials.gov (http://clinicaltrials.gov) in compliance with US Federal law and 'prior publication' decisions by journal editors.

As you may know, US Public Law 110-85, Title VIII, mandates the submission of 'basic results' data for certain clinical trials of drugs, biologics, and devices, effective September 27, 2008. The law applies to trials that are not Phase 1 or small device feasibility studies, and that have at least one site in the US or, if conducted completely outside the US, involve interventions manufactured in the US and regulated by the FDA, regardless of who sponsors, finances, or conducts the trial. Certain other trials may also be covered by the law. In general, these summary results data must be submitted within 12 months of the completion of data collection for the primary outcome measure. The law also requires submission of results for pre-specified secondary outcome measures registered at ClinicalTrials.gov. Delays in submitting results may be granted for certain reasons, but not generally for journal submission. There could be significant penalties for failure to comply with this law.

These 'basic results' include summary data tables of baseline characteristics, participant flow, outcomes, and adverse events. With the exception of several brief freetext fields for providing descriptions of the data, no narrative information is included (e.g., there is no discussion or conclusion section). There will be no patient level data.

The June 2007 ICMJE Update on Trial Registration [1] states that "the ICMJE will not consider results posted in the same primary clinical trials register in which the initial registration resides as previous publication if the results are presented in the form of a brief, structured (<500 words) abstract or table (p. 2)." The ICMJE recently reaffirmed this position at its 2008 annual meeting in Philadelphia.

Further, a January *BMJ* editorial [2] urges other journals to consider publication of results reported under the law to ClinicalTrials.gov for the following reasons:

'Firstly, disclosure will be a legal requirement, so there is nothing editors can do about it if they still want to publish important trials of drugs and devices. Moreover, journals will continue to add value by publishing useful and readable trial reports that clinicians, the media, and patients can interpret and use. And, most importantly, the results disclosed for the FDA will not have been externally peer reviewed and will be preliminary. Peer review not only provides a stamp of quality assurance, it often leads to reanalysis of results (p.170).'

In July 2008, a *PLoS Medicine* editorial endorsed "timely and accessible reporting at all stages of clinical drug and device development."[3] In particular, the following statement has been added to its Author Guidelines:

'PLoS supports the public disclosure of all clinical trial results, as mandated for example by the FDA Amendments Act, 2007. Prior disclosure of results on a public website such as clinicaltrials.gov will not affect the decision to peer review or acceptance of papers in PLoS journals.[4]'

More information on the 'basic results' database can be found at http://prsinfo.clinicaltrials.gov/fdaaa.html.

Please also feel free to contact me if you have any questions about this new feature of ClinicalTrials.gov.

Deborah A. Zarin
National Institutes of Health,
U.S. Department of Health and Human Services,
Bethesda, Maryland, United States
dzarin@mail.nih.gov

References:
1. ICMJE. Clinical trial registration: looking back and moving forward. Jun 2007. Available at http://www.icmje.org/clin_trial07.pdf. Accessed on September 22, 2008.
2. Groves T. Mandatory disclosure of trial results for drugs and devices. *BMJ*. Jan 2008 ;336:170.
3. The PLoS Medicine Editors (2008) Next Stop, Don't Block the Doors: Opening Up Access to Clinical Trials Results. *PLoS Med* 5(7): e160 doi:10.1371/journal.pmed.0050160. Available at http://medicine.plosjournals.org/archive/1549-1676/5/7/pdf/10.1371_journal.pmed.0050160-L.pdf. Accessed on October 17, 2008.
4. PLoS Medicine (2007) Author guidelines: Reporting guidelines for specific study designs. Available: http://journals.plos.org/plosmedicine/policies.php#reporting. Accessed November 11, 2008.

EMWA Member Satisfaction Survey

by Helen Baldwin

From late-July until mid-September this year, EMWA's executive committee (EC) organised an anonymous online survey to find out how satisfied you, EMWA's members, are with your association and to seek new ideas for how to improve the organisation. This article gives an overall summary of the survey results which, I am happy to say, were mostly very positive. In addition, detailed articles about specific areas will be written by the Editor of *The Write Stuff* (*TWS*), the Education Officer and the Web Manager: These articles will appear in the March 2009 issue of *TWS*.

The survey was completed by 364 respondents, i.e. 42% of the total of 860 EMWA members at the end of August 2008. This was an excellent response rate compared with those usually obtained for surveys of this type (around 25%). I believe this reflects the enthusiasm and personal investment that many of us feel for EMWA. Of course, motivation to win the prize draw may have played a small role too! Whilst we're on the subject, I am delighted to announce that a new freelance member from the UK, Julie Taylor, was the lucky prize draw winner and she received an Amazon voucher for £95 (equivalent to €120). Congratulations to Julie!

Julie Taylor won the EMWA survey prize draw. Her comment? "I'm delighted to win the prize draw, particularly as I only joined EMWA in the summer!"

Membership profile
The first few survey questions were designed to learn more about our members, including where they work and which benefits of EMWA membership they find most useful.

How long have you been a member of EMWA?

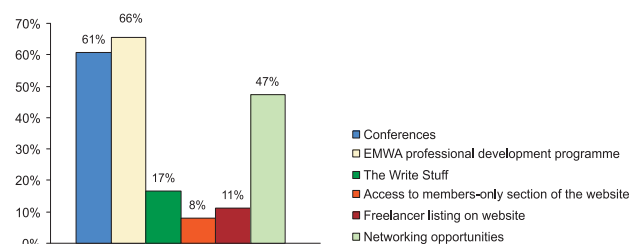*(Bar chart: For less than 1 year 29%, For 1-4 years 44%, For 5-8 years 16%, For more than 8 years 12%)*

The greatest proportion of survey respondents had been members for 1-4 years (44%), followed by those who had joined in the last year (29%). This reflects the fact that EMWA is a rapidly expanding organisation: in the last year our membership has increased from 700 members to nearly

900! Nevertheless, many of the 'old faithfuls', who've been with EMWA since its modest beginnings, are still with us and also responded to the survey. Thus the results come from a representative cross-section of new and older members.

Who do you work for?
33% of respondents worked for pharmaceutical companies, 26% were self-employed freelancers, and 18% worked for contract research organisations (CROs). Other employers were medical writing companies (7%), communications agencies (6%), academic institutions (3%) and biomedical journals (0.3%). A few respondents had unusual jobs: for example one respondent worked for a criminal justice department—so I'd better make sure I write the truth, the whole truth, and nothing but the truth about these survey results!

What made you decide to join EMWA? (Tick up to 3 options)

(Bar chart with values: 61%, 66%, 17%, 8%, 11%, 47%. Legend: Conferences; EMWA professional development programme; The Write Stuff; Access to members-only section of the website; Freelancer listing on website; Networking opportunities)

The survey explored the respondents' original motivations for joining EMWA and their motivations for renewing their membership. The responses were very similar for both questions—which is reassuring as it suggests that the respondents' EMWA membership had fulfilled their original expectations. More than 60% of respondents cited the EMWA professional development programme and conferences as their main reasons for joining and for renewing their membership. Networking was also cited as a reason by approximately half of the respondents. Encouragingly, whilst only 17% of respondents cited *TWS* as a reason for joining EMWA, twice that number cited our journal as a reason for renewing their membership!
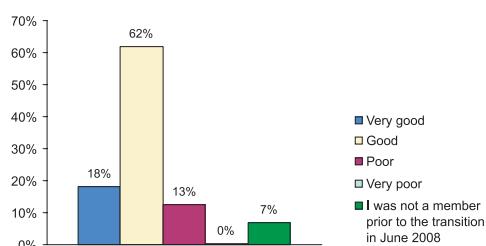
EMWA's head office
We asked three questions about satisfaction with EMWA's head office, focussing on quality of communication, frequency of communication, and on membership administration. As we had recently changed head office supplier at the time of the survey, and there had been insufficient time to make a fair assessment of the new head office, we specified that the questions related to the service provided before the transition to the new head office.
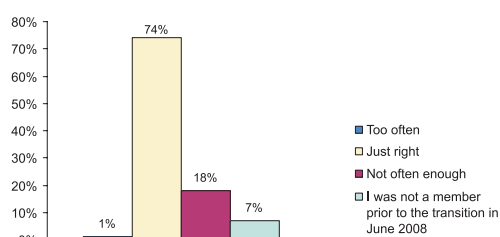
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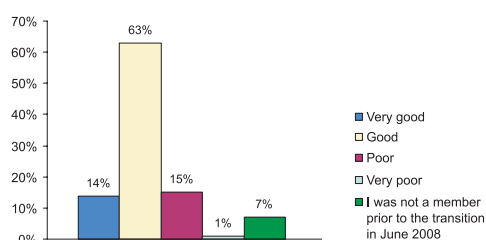## > > > EMWA Member Satisfaction Survey

Before the transition to the new EMWA head office in June 2008, how did you rate the quality of the communication from EMWA head office to you?

Before the transition to the new EMWA head office in June 2008, how did you rate the frequency of the communication from EMWA head office to you?

Before the transition to the new EMWA head office in June 2008, how did you rate the quality of administration of your membership?
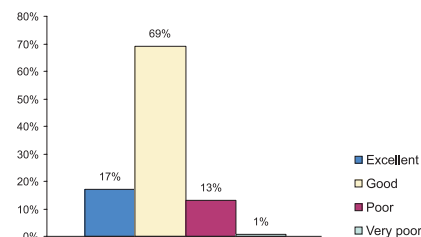

For all three questions, the majority of respondents were satisfied or very satisfied with head office. However, 13% of respondents rated the quality of communication from head office as 'poor' or 'very poor', 18% rated the frequency of communication as 'not often enough', and 16% rated the quality of their membership administration as 'poor' or 'very poor'. We plan to perform another satisfaction survey next summer and hope to see an improvement in this area.

EMWA conferences

An important aspect of EMWA's activities is the conferences. We asked several questions about members' opinions of the value for money, conference administration, choice of cities, quality of hotels, and choice of themes at recent conferences.
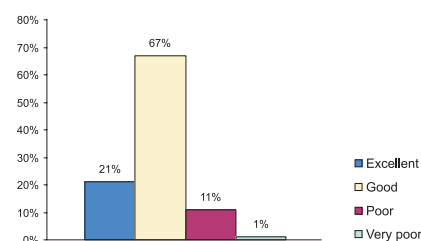
22% of respondents had not attended any conferences, 54% had attended 1-3 conferences, 19% had attended 4-8 conferences and 5% of respondents had attended more than 8 conferences (those 'old faithfuls' mentioned previously—of whom I am proud to be one!) When asked which conference they usually attended, 60% of respondents said the spring conference, 13% said the autumn conference, and 27% said they usually attended both conferences.

How would you rate the value for money of EMWA conferences?

Value for money of EMWA conferences was rated as 'excellent' or 'good' by the large majority of respondents (86%), while 14% of respondents rated value for money as 'poor' or 'very poor'. Conference registration and workshop fees have not increased for several years. The workshop leaders provide their services for free, which is a major factor allowing us to keep our fees substantially lower than other training organisations. Nevertheless, we do appreciate that attending a conference can be costly by the time you add together the registration fee, workshop fees, social events, and travel and accommodation expenses. As mentioned later in this article, the EC is working closely with head office to choose accessible and reasonably priced destinations as well as hotels that fall within a reasonable budget. Furthermore EMWA is very active in looking for sponsorship and other sources of revenue, such as advertising, to offset against the expenses of running the organisation.
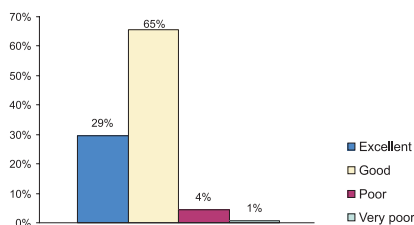
How would you rate the pre-conference registration procedure for the last conference you attended (including receipt of confirmation, invoices, and preworkshop assignments)?

It was encouraging to see that 88% of respondents considered their last pre-conference registration procedure to be 'excellent' or 'good'. However, 12% of respondents judged this procedure to be 'poor' or 'very poor'. The EC were aware of problems with invoicing and provision of pre-workshop assignments for previous conferences, and this was discussed in detail at the AGM in Vienna in 2007. Following that, our previous head office made great efforts to improve these procedures for the Barcelona conference in May 2008 and this was reflected by the fact that 88% of survey responses to this question were positive. Since performing the survey, further improvements have been made to the pre-conference procedures: An online conference registration system was successfully implemented for last month's conference in London. In addition, we are looking into ways to further improve the procedures for supplying preworkshop assignments to participants, which may be done via the website at some time in the future.

EMWA Member Satisfaction Survey

Recent conference locations were Barcelona, Basel, Vienna, and Lyon. The next 2 conferences will be held in London and Ljubljana. Overall, what is your opinion of the cities chosen for EMWA conferences?

95% of respondents were very satisfied with the choices of locations of our previous and future conferences. Most of the comments were positive and can be summed up by this one: "Interesting cities, worth a visit, and great for spending free time".
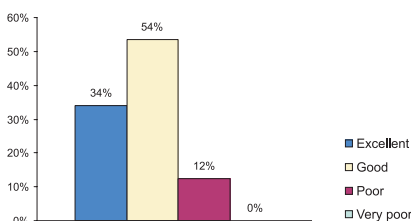
Are there other cities in which you would like the conference to be held?
Cities suggested by more than 10 respondents were: Berlin (33), Stockholm (20), Rome (17), Paris (17), Prague (15), Edinburgh (13), Hamburg (12), Amsterdam (12), and Munich (11).

The most popular countries and regions suggested were: Germany (74), Eastern Europe (53), Scandinavia (51), Italy (43), UK (30), France (27), Benelux (21), Spain and Portugal (20), Greece and Cyprus (9), Ireland (9), Switzerland (8), and Austria (3).

Those of you who suggested Germany will be pleased to know that we are planning to hold next year's autumn conference in Frankfurt and we are seriously considering Berlin for the 2010 or 2011 spring conference. However, some of the suggestions are unlikely to be selected as future destinations as they are notoriously expensive for conference facilities.
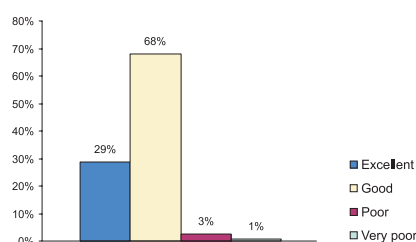
If you attended the recent conference in Barcelona, what was your opinion of the conference centre hotel?

The conference hotel in Barcelona was judged as 'excellent' by 34%, 'good' by 54%, and 'poor' by 12% of respondents. The main criticisms were that it was very expensive and rather a long way from the city centre. Of course it is wonderful to be in the city centre so that members can easily pop out for a spot of sightseeing between workshops. For example the conference hotel in Vienna in 2007 was ideally located from this point of view. The challenge we are faced with is that EMWA conferences have increased in size over the last few years, and finding centrally located,

reasonably priced hotels with adequate conference facilities is not an easy task. Nevertheless, our new head office suppliers, MCI, have a whole department dedicated to conference management and are very experienced at negotiating excellent hotel rates for their clients. So we are relying on them to come up with some great suggestions for future conferences. Also, the good news is that next year's spring conference will be held in the Grand Hotel Union in Ljubljana which is substantially less expensive than the hotel in Barcelona.

The last 2 spring conferences have had special themes: 'Medical communications' and 'medical translations'. The theme of the next spring conference in Ljubljana will be 'regulatory writing'. What is your opinion of these choices of themes?
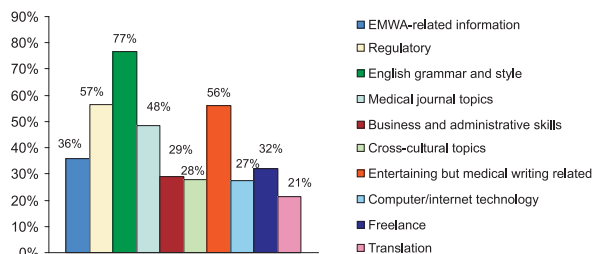

We were delighted to learn that the choices of conference themes were judged to be 'excellent' or 'good' by 97% of respondents. We also asked for ideas for future themes and were inundated with excellent suggestions—thank you! Some of the most popular suggestions were: 'Transition to an electronic era', 'publications', and 'clinical research'.

The Write Stuff
The Editor, Elise Langdon-Neuner, is preparing a detailed article about the survey responses relating to *TWS*. Her article will be published in March 2009, so I will only give a brief summary here. It was nice to learn that 63% of respondents always read *TWS* and 35% sometimes read it. The majority (89%) prefer to read the printed version, whilst 9% read the emailed pdf version and only 2% read it on the website.

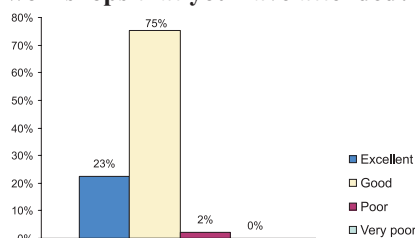**Which types of articles are of greatest interest to you?**

The most popular articles were 'English grammar and style' (77%), 'regulatory' (57%), and 'entertaining but medical writing related' (56%). Many interesting suggestions were given for future editions and almost one third of respondents said they would like to contribute to *TWS*. That's great news—so get writing!

> > >

> > > EMWA Member Satisfaction Survey

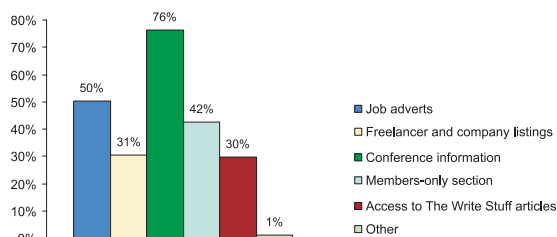## EMWA Professional Development Programme (EPDP)

The Education Officer, Stephen de Looze, is writing a detailed article about the survey responses to questions about the EPDP. It was encouraging to see that 92% of respondents were satisfied with the choice of workshops in the EPDP and that 98% of respondents felt that the quality of the workshops was good or excellent. Respondents' comments were very helpful in guiding discussions on the future of the EPDP that were held during the meeting of the EMWA Professional Development Committee in London last month. The comments included some very interesting suggestions for new workshops, which Stephen will present in the next issue of *TWS*, together with a call for new workshop leaders.

Overall, how would you rate the quality of the EPDP workshops that you have attended?

Although we received many compliments about the EPDP, several respondents criticised EMWA's management of the EPDP credits and certificates. Again, the EC are aware of this problem and have been making improvements. Under the guidance of the Education Officer, our new head office has taken on the challenge of verifying that all existing credit records are correct and up to date, and of introducing new procedures to ensure that this essential aspect of EMWA's activities is managed professionally. Members have recently been able to access their credit records online and have been asked to check them and to contact head office if there are problems. Nevertheless, with almost 900 members, investigations into credit errors will take a few months and head office asks us to bear with them for a little longer.

The EMWA website

The Web Manager, Shanida Nataraja, is writing a detailed article about the survey responses to questions about the website and her article will published in the March 2009 issue of *TWS*. I will only provide a brief summary here. EMWA's website was completely revised this year and we were very pleased to see that 92% of respondents judged the new website as 'excellent' or 'good'.

Which aspects of the website are of most interest to you?

The most popular features of the website were conference information (76%), job adverts (50%) and the members-only section (42.4%). We asked whether there is anything not currently included on the website that you would like to see in the future: Plenty of interesting ideas were provided and Shanida will review these in her article in the next issue.

Log in details for the members' area of the website are now personalised. If you have not already done so, please register on the website for your personalised log in details or contact head office for more information.

EMWA committees and subcommittees

Only 6% of survey respondents had ever served on a committee or subcommittee for EMWA. However, 24% of respondents said that they would be interested in participating in the future. This is excellent news as EMWA needs you!

One respondent said: "Sometimes EMWA can appear too much run by the 'old school', who all know each other, and so it can be intimidating for new people to join the committees". The EC are aware that some members see the committees in this way. However, the reality is that most of the EC officers would gladly step aside for someone new but we don't know who you are! We always try to encourage members to get involved and are very grateful for your ideas on how to do this. The idea of subcommittees— which was officially instigated in 2007—sprang from this desire to involve members without them having to necessarily take all the responsibility on their shoulders at the outset (as this seemed to be one of the main reasons why members didn't want to stand for election for official EC positions). Information about the subcommittees and how you can get involved can be found on the website. Also, thanks to an idea given by a survey respondent, we are planning to instigate 'meet the committee' lunchtime tables during the conference: one committee member will sit at each table and if members are interested in learning more about an EMWA function they can join that table for an informal chat. The following EC positions are coming up for election at the Ljubljana conference in May 2009: Public Relations Officer, Honorary Secretary, Treasurer, Education Officer, and Vice President. If you would like to nominate yourself or another member for any of these positions please contact me, head office, or another member of the EC. We will be delighted to hear from you!

Finally, thank you again to all of our members who took the time to complete this satisfaction survey. The results are extremely interesting and encouraging, and they are helping us to focus our efforts into making EMWA an even better and more professional association than it already is today.

Helen Baldwin
EMWA Vice President, vicepresident@emwa.org
On behalf of the EMWA Executive Committee

A case history of EC membership—or how I became involved

I joined EMWA in 1999 and during my first 7 years I attended around 25 workshops and made friends with many other members. As a freelancer working alone, EMWA really opened my horizons for training and networking and I often wished I could give something back to the association that had helped me so much—but I didn't really know what I had to offer.

Finally, an experienced workshop leader, Pamela Johnson, convinced me that we should develop a workshop together ('From Clinical Study Report to Manuscript'). I was very reluctant (i.e. downright terrified) at first and it was a lot of hard work to develop the workshop. However, when we gave the workshop the first time in Lyon in 2006, it went really well and it was approved for credit. Suddenly I felt really proud and excited and I realised that my hard work had paid off! Since then I have given the workshop 5 more times on my own and it seems to be popular.

After that my involvement with EMWA just snowballed: I joined the EMWA Professional Development Committee (EPDC) in 2006 and then became Vice President in 2007. Now I can't understand why I waited in the wings for so long instead of stepping forward much earlier. I'm really glad I did finally get involved: it's very interesting and challenging to help manage such a fast-growing professional organisation as EMWA and I'm really proud to be a part of it!

Helen Baldwin
helen.baldwin@scinopsis.com

Call for nominations for executive committee positions

The following positions will be up for election at the 2009 Annual General Meeting: Vice President, Treasurer, Public Relations Officer, Education Officer, and Honorary Secretary.

This is an early announcement to give you plenty of time to consider whether you would like to nominate yourself or if there is somebody else you wish to nominate for one of the posts.

Each position has an important function in the organisation. In addition, as a member of the executive committee (EC), you or your nominee will be involved in the decision-making process behind the scenes. EC membership is an opportunity to contribute your ideas and help form the future of EMWA.

Any EMWA member can be nominated for the position of Treasurer or Public Relations Officer. For the position of Education Officer, candidates must have served on the EMWA Professional Development Committee. For the Vice Presidency, the candidate must have served on the EC or represented EMWA in an official capacity in the last 5 years. Nominations can be given to Head Office or any current EC member no later than 1 February 2009. Candidates will need to prepare a written summary about why they feel suited for the position, which will be published in the March 2009 issue of *The Write Stuff*.

This is an opportunity to get involved in the medical writing community. Being on the EC is a good way to gain management skills and it looks great on your CV. So think about the idea and start nominating.

Julia Forjanic Klapproth
President EMWA
Julia@triologywriting.com

Other ways to become involved

In addition to the Executive Committee, EMWA has several other committees all of which need volunteers to keep the work moving forward. These committees include:

- **EMWA Professional Development Committee (EPDC)**: This committee is chaired by the Education Officer (education@emwa.org) and is responsible for overseeing EMWA's Professional Development Programme (EPDP). The committee meets twice a year at EMWA conferences. All committee members are workshop leaders and their role is to support the Education Officer with activities such as selecting workshop proposals for inclusion in the EPDP, mentoring new workshop leaders, approving new workshops under assessment, ensuring the continued quality of existing workshops, and definition of EPDP standards and procedures. Members must have served on this committee in order to be eligible to stand for the position of Education Officer.
- **Education Officer's Subcommittee**: This subcommittee is chaired by the Education Officer (education@emwa.org). The subcommittee consists of volunteer EMWA members with a special interest in professional training. This subcommittee manages the list of observers for workshops under assessment and can also help the Education Officer with any other EPDP-related task.
- **Presidential Subcommittee**: This subcommittee is chaired by the President (president@emwa.org) with help from the Vice President (vicepresident@emwa.org). The subcommittee consists of volunteer EMWA members who provide support to the President in his/her various functions including organisation of EMWA conferences.

- **Finance Subcommittee**: This subcommittee is chaired by the Treasurer (treasurer@emwa.org). The subcommittee consists of volunteer EMWA members with a special interest in finance who provide support to the Treasurer in his/her various functions.
- **The Write Stuff, Editorial Board**: This subcommittee provides support to the Editor (editor@emwa.org) and consists of the assistant editor, copy editors, and columnists, all of whom are volunteers. These people play an essential role helping behind the scenes with the preparation of EMWA's quarterly journal.
- **Web Team**: This subcommittee provides support to the Web Manager (webmanager@emwa.org) and consists of volunteer EMWA members with a special interest in web site development and management. The EMWA website is constantly being improved and updated thanks to the hard work of this team.
- **Public Relations Contacts**: This subcommittee provides support to the Public Relations (PR) Manager (pr@emwa.org) and consists of volunteer EMWA members in several countries who act as "PR Contacts". Their role is to help promote EMWA in their country and to answer questions from potential new members.

Being on an EMWA subcommittee is a great way to get involved in EMWA behind the scenes and to see whether you would like to join the Executive Committee in the future. If you would like to find out more about any of the subcommittees, please contact any of the Executive Committee or Head Office. Remember, EMWA is an association run by its members for its members—we need your help—so come and get involved!

Who's Who?

Individual changes between baseline and Visit 6 were small or were within the normal range, except in Subject no. 304, who's blood pressure was 137/82 mmHg before baseline.

The *who's* here is unforgivable (it should be *whose*, of course, but I don't need to tell you that!). And why are we telling the reader about the blood pressure level before baseline in Subject no. 304 when the subject of the sentence is 'Individual changes between baseline and Visit 6'? And why 'small or were within the normal range'. Does this mean that they might have been large, but remained within the normal range, and we regard this as

the same as small? Wouldn't it be enough to say Individual changes between baseline and Visit 6 were in the normal range, …? This, of course, still leaves us with the problem that Subject No. 304's blood pressure may well have been above normal at baseline, but we don't know whether the change was into the normal range or above it. Subject No. 304 should definitely be the subject of a new sentence.

Alistair Reeves
a.reeves@ascribe.de

Patients with a past ...

We all have a past (which some of us may regret), but not many of have a pre-past (maybe this is the one we don't need to regret!). But patients often seem to have a pre-past:

A 45-year-old man with a pre-existing history of hypertensive crises was treated with Drug A for 14 days and developed acute hypertension.

I would like to think that I will never see this sort of sentence ever again. Unfortunately I will. And I will change it once again to:

A 45-year-old man with a history of hypertensive crises ...or *A 45-year-old man with previous hypertensive crises ....*

Some purists would insist on *medical history* here. I say: let them be purists.

Alistair Reeves
a.reeves@ascribe.de

Another myth

I have been concentrating on things other than myths about English this year, but this one recently cropped up at a training event:

Myth 40: If you start a sentence with digits, the noun after the digits has to be capitalised.

Before going into this, I refer readers to the March 2006 issue of *TWS*, where I discussed the myth that you must not start a sentence with digits [1]. If you cannot bring yourself to start a sentence with digits, then you will not be faced with this problem because you will write *One hundred and twenty-one* for the example below.

Do you write: *121 patients were enrolled* or *121 Patients were enrolled*?

My simple answer to this is that you do not need to capitalise the word *patients* here, nor is there a rule that you must.

Alistair Reeves
a.reeves@ascribe.de

Reference:
Reeves A. Myths about English. *TWS* 2006 ;15(1):22-24

Ghostwriters responsible for the world's financial crisis?

That's it then. On reading an article Miguel Roig sent to me it became plain to me that ghostwriters really do have something to answer for. I had always been convinced that the world finds itself in its present financial pickle because the people running our companies just aren't clever enough. But how did they get their qualifications to run the companies in the first place? Ghostwriters writing personal statements for university entry, their term papers and dissertations for them, that's how!

http://www.thesmartset.com/article/article10100801.aspx.

Elise Langdon-Neuner
langdoe@baxter.com

Miguel Roig is a professor in psychology at St John's University in New York and the author of an excellent website entitle 'Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing' see:http://facpub.stjohns.edu/%7Eroigm/plagiarism/

A little play on the impact factor

Even if you are not remotely interested in journal impact factors, and I suppose there are some people who are not, St Peter's short interview in *Genome Biology* with a recently deceased genome biologist at The Pearly Gates is not to be missed. St Peter explains that being a good scientist and a devoted family man, and any good deeds you might have done are no longer of any consequence because a new system has been introduced whereby entry to heaven depends on your 'impact factor'. The scientist protests that surely someone's whole life can't be summed up in a single number. Well, this is not what St Garfield thinks, declares St Peter. The desperate scientist tries to persuade St Peter that the whole idea is ridiculous. Creative people were doomed on earth once scientific assessment became dependent on impact factors.

Reference:
Petsko G.A. Having an impact (factor). *Genome Biology* 2008 9:107 available at http://genomebiology.com/2008/9/7/107 (unfortunately a subscription is required)

2ⁿᵈ EMWA-ICR Joint Symposium

Writing protocols: collaboration and compromise or conflict and confusion?

24th February 2009

London, UK

The process of designing, writing, and reviewing protocols is always challenging and is too often fraught with conflict and confusion. The aim of this second joint EMWA-ICR symposium is to bring together the different players involved in protocol writing and to provide a forum for them to discuss and debate their different points of view. Presenters and panelists will include experts representing the different facets of clinical research, including medical writing, monitoring, project management, ethics committees and the investigative site. We hope the outcome will be an agreement to collaborate and compromise–rather than open warfare–but you'd better come and find out for yourself!

PLACES LIMITED SO BOOK NOW!

Attendance fee: £225 ICR or EMWA members - £325 Non-members

See the EMWA website (www.emwa.org) or ICR website (www.icr-global.org) for the full programme and details of how to register.

Definitions box

Orphan drugs

No pharmaceutical company wants to invest in a drug, the sales of which would never recoup its development costs. As a consequence, pharmaceutical companies are often unwilling to develop drugs for rare diseases. The Orphan Drug designation exists to encourage the development and commercialisation of drugs for the treatment of such rare conditions. An orphan drug designation, or more properly Orphan Medicinal Product designation, is a regulatory tool of European, American and Japanese regulators that gives regulatory protection to companies developing a medication for a rare disease. In the EU, a medicinal product is designated as an orphan medicinal product if: it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union at the time of submission of the designation application (prevalence criterion), or; it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and without incentives it is unlikely that expected sales of the medicinal product would cover the investment in its development, and; no satisfactory method of diagnosis, prevention or treatment of the condition concerned is authorised, or, if such method exists, the medicinal product will be of significant benefit to those affected by the condition. The company has first to apply for orphan disease designation, which, when granted, means that the regulatory authority has approved that company to work on a rare disease. Once the new treatment is approved, orphan medicinal product status is given to the product in development. The company then has 10 years of protection in Europe and 7 years in the US. During that period no other company will be granted a licence for that product in the same indication. Companies with a product that has been granted orphan medicinal product designation benefit from incentives such as: protocol assistance (scientific advice during the product-development phase); marketing authorisation (10-year marketing exclusivity); financial incentives (fee reductions or exemptions); national incentives detailed in an inventory made available by the European Commission.

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For more information see:
http://www.emea.europa.eu/pdfs/human/comp/29007207en.pdf

Cold commas

The following phrase was encountered by a medical writer in the course of his work: "... and each void was individually frozen at -20°C immediately after defæcation in the freezer provided."

Such uncomfortable toiletry could be avoided by the use of commas.

A new Declaration of Helsinki

A new Declaration of Helsinki was issued in October 2008. The approval steps leading to the 2008 approved version are available at: http://www.wma.net/e/ethicsunit/helsinki.htm .

GPP2: New 'Good Publication Practice' Responsible and ethical clinical publications

GPP: A decade later

Good Publication Practice (GPP) [1, 2] is the first port-of-call for publication professionals looking for guidance about publishing clinical and preclinical information, especially when this information has been gathered, analysed, or written with pharmaceutical, biotech or medical device company support.

But consider this: the first ideas for GPP were formed during a retreat of the Council of Biology Editors (now Council of Science Editors or CSE) a decade ago [2, 3].

"When we published GPP we always intended to revise it and keep it up to date but we never found the time or funding for this. While I'm still proud of what GPP has achieved and believe the underlying principles are still relevant today, things have definitely moved on in the 10 years since it was first discussed, and I am delighted that the International Society for Medical Publication Professionals is taking a lead in developing GPP2" says Elizabeth Wager, first author of the original publication.

GPP2 will follow the mission laid out by the original GPP authors and "encourage responsible and ethical publication of the results of clinical trials sponsored by pharmaceutical companies" [2]. Like its predecessor, GPP2 will deliver 'best practice' ethical guidance about peer-reviewed publications and presentations at scientific meetings, as well as recommendations for 'non-peer-reviewed scientific communications' [2]. New sections will provide guidance on recent developments in medical research and reporting, such as clinical trial registration and results disclosure.

You can help

Working with support from the International Society for Medical Publication Professionals [4] (ISMPP) the GPP2 steering committee will open consultation on the first draft of its new guidelines.

"With all that's happened over the years since the publication of GPP, this update could not be more timely. ISMPP is proud to spearhead this initiative, which will serve to strengthen the credibility of industry-sponsored clinical publications. One of the goals of ISMPP is to be involved in initiatives that educate and benefit our members, and this one is certainly high on our list", says Gene Snyder, ISMPP President.

To contribute to this consultation you must have more than 10 years experience in three or more of the following areas:

- Setting publication policies in commercial organisations
- Design, conduct, and reporting of clinical trials
- Legal and regulatory requirements on conducting, registering, and reporting clinical trials publications as part of a clinical development programme
- Common editorial and journal practices, including peer review
- Scientific or medical writing and editing

Chris Graf
ISMPP, Co-Chair, Standards & Best Practices Committee;
Associate Editorial Director, Wiley-Blackwell

Elizabeth (Betts) Field
ISMPP Cofounder; President, Field Advantage Medical Communications

Contribute to GPP2. Contact Chris Graf by email: chris.graf@wiley.com or phone: +44 1865 476 393 no later than 14 November, 2008.

References:
1. http://www.gpp-guidelines.org/ Accessed 12 September 2008.
2. Wager E, Field E, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin*. 2003;19:149–154.
3. Council of Biology Editors is now Council of Science editors, http://www.councilscienceeditors.org/. Accessed 12 September 2008.
4. http://www.ismpp.org/. Accessed 12 September 2008.

In the Bookstores...

An informative but not essential or comprehensive guide to units, symbols and abbreviations.

D.N. Baron and H. McKenzie Clarke. Units, Symbols, and Abbreviations: A Guide for Authors and Editors in Medicine and Related Sciences (Sixth Edition). The Royal Society of Medicine Press Limited, 2008. ISBN 978-1-85315-624-3 (paperback) GBP £7.95, Euro approx. 9.86. 56 pages.
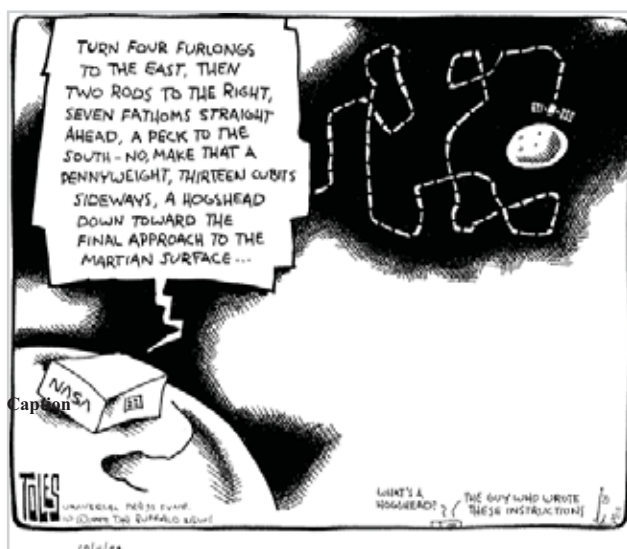
If you think units are rather unglamorous and boring, just take a look at the 'Metric Martyrs' in Britain. In their fight to be able to sell their goods in the old imperial measures, this group of shop owners have set themselves up as the defenders of Britishness against the faceless bureaucrats of Brussels. Still, at least they insist on clearly specifying their units, even if it is hard to work out in your head whether tomatoes sold at 90p/lb in the grocers are better value than those sold at £1.98/kg in Tescos (answer: no difference if my calculations are correct). Worse was the mix-up in 1999 between NASA and a contractor—Lockhead Martin—that was involved in building the Mars Climate Orbiter. At a critical moment in the mission, the NASA scientists realized the $125 million probe was entering a much

lower orbit than expected. As a result, the spacecraft was burnt to a cinder in the thin Martian atmosphere. It later turned out that the company had programmed the spacecraft's control thrusters to expect imperial units of measure—also known as "standard units" in the United States—when the agency was transmitting its data in metric units. Whoops, it seems those standard units were not so standard. And I thought rocket scientists were supposed to be clever.

Outside the United States, the metric system—or International System of Units (Système International d'Unités: SI)—is almost universal. However, even in science, the system is by no means ubiquitous, and many scientific journals, particularly in medicine and related sciences, will mix and match units. So would the book *Units, Symbols, and Abbreviations* be of use for writers and editors for navigating potential pitfalls of units? In general, for a small book (56 A5 pages), it contains quite a lot of readily accessible information, and with a list price of £7.95, it is hardly expensive. As the name implies, the book also covers other aspects of terminology, such as abbreviations and symbols. It is organized into four chapters, the first dealing with units and the second an alphabetical reference section on symbols and nomenclature. The final two chapters are on layout of references and proof correction marks.

I found the book well referenced, particularly for the introduction to the SI system in chapter 1, which also contains some good advice on usage (for example, "Symbols are international and cross-disciplinary and so should be used whenever possible, especially in equations"). In chapter 2, although the book does not pretend to include an exhaustive list of all abbreviations and terminology, there are often references to where such information can be found.

Many of the references were in the form of URLs that could be readily accessed, something that freelancers who work from home without a good academic library nearby could appreciate. This brings me to what I also think is the main limitation of this book. Much of the information is readily available on the Internet if you know how to search for it, although this holds true to a certain extent for any reference book. And for those who do already have weightier reference books such as the *AMA Manual of Style* (produced by the American Medical Association) or *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers* (produced by the Council of Science Editors) it is hard to imagine this book providing much additional knowledge.

There were certain pieces of information that could perhaps have made such a reference book more useful. For example, if you wanted to know what units are preferred for expressing total cholesterol levels, you would not find that information in this book (though other somewhat more obscure information is included, such as the exact equivalence in joules [preferred SI unit] of an electron volt—$1.602176487 \times 10^{-19}$ in case you are interested). When it does pronounce, for example, on whether mmHg should be used for measuring blood pressure, it says that you should preferably also give the SI equivalent in pascals (1 mmHg

= 133.322 Pa) although I certainly don't recall any medical texts with pressures given in pascals.

Chapter 3 on layout of references gives an overview of the Vancouver and Harvard systems. Most journals have their own explicit instructions for layout and format of references and, rather than referring to this book, editors and writers would be well advised to go to the instructions for authors of the target journal and look at some recent sample articles if possible. There is a short section on digital object identifiers (DOIs), but further details on referencing online material would perhaps have been useful. The final chapter on proof correction marks may be useful to those who have to correct proofs and galleys. The trouble is that these proof correction marks are the ones recommended by British Standards, and may not be applicable to other countries. Certainly, they are different to the ones I use for correcting proofs for the typesetters of a Spanish publisher.

So would I recommend this book? I think if you already have other comprehensive style manuals such as the *AMA Manual of Style* or *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers* the answer would be probably not. If you only occasionally write or edit material for academic publication, and you do not wish to splash out on these more expensive reference books, then this latest edition of *Units, Symbols, and Abbreviations: A Guide for Authors and Editors in Medicine and Related Sciences* could be worth looking into.

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A career in regulatory medical writing

Deborah A Early: Are you thinking of a career in regulatory medical writing? A 'how-to' guide on getting started. Waratah Communications, 2008. ISBN-13 978-0-9819218-1-5; ISBN-10 0-9819218-1-7 (Paperback booklet).USD $14.99.

Before widespread use of the Internet, the discipline of regulatory medical writing may arguably not have been well-known to those outside the clinical research industry. Indeed many of us who make a living from it confess to having stumbled upon this noble, but less than, high profile profession.

Deborah Early sings loud and proud about regulatory medical writing as a career option in her excellent booklet 'Are you thinking of a career in regulatory medical writing?' In this guide to getting started, Early summarises the background information necessary for an industry outsider to understand the documentary requirements for licensing of medicines and how regulatory medical writers enable those requirements to be met. Her style is technical yet concise, as is appropriate to the subject matter, and her enthusiasm for the job shines through.

She gives sufficient allocation to soft topics such as the types of personalities with the makings of a good writer; typical careers paths; remuneration and jobs within the industry—whether in Clinical Research Organisations (CROs), pharmaceutical companies or the freelance sector. She takes nothing for granted and highlights basic techniques to enhance writing skills, not always immediately apparent to the uninitiated.

Over half of the booklet deals with technical matters relevant to the profession including training, organisation of medical writing departments and an overview of basic regulatory documents such as the protocol, clinical study report, narratives, safety reports and various ethics-related documents.

The concise glossary is sufficient to provide a taster of industry jargon without scaring off would-be writers! Early even sets an assignment for prospective regulatory writers that highlights the principles of team working, working to deadlines and task prioritisation—essential pre-requisites for success in the profession. A list of web resources and a quick quiz round off the booklet perfectly.

The US focus of the document might have been better internationalised, but that is not to say its relevance is overly diminished for those seeking a career in the European regulatory environment. A European distributor is notable by its absence as copies need to be ordered in US dollars and are sent from the US, both of which inevitably raise purchase costs for those outside the US. Should Dr Early venture east, she might like to deposit a stack with a European distributor, family member or friend who would undoubtedly find them flying off the shelf to various interested individuals and University Careers Advisory Services throughout Europe.

This booklet is an excellent, concise and well-written guide for prospective regulatory medical writers and makes a great job of raising the profile about one of the best-kept job secrets in the industry!

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Innovative project develops inspirational goals for European diabetes funding

DIAMAP/EURADIA Press Conference at the EASD meeting in Rome, Italy, September 2008

People with diabetes should be the beneficiaries of medical and health research in the form of either effective treatment or prevention of the condition. More research in itself should not be the goal of organisations that provide funding nor the people who plan and carry out research. However, this is apparently what happens currently across Europe and provides the premise that underpins the DIAMAP project.

DIAMAP Coordinator, Professor Philippe Halban has stated, *"There is a lack of collective vision and coordination and unclear scientific rationale for public or private funding of European diabetes research. It is hardly surprising diabetes research in Europe is not as effective as it could be, despite its historical and continuing strength"* [1].

DIAMAP is an innovative two-year project to chart a Road Map for Diabetes Research in Europe. The project, coordinated by EURADIA, began on 1 April 2008 with funding from the European Commission. As an Alliance of NGOs and pharmaceutical companies, EURADIA aims to ensure that all diabetes stakeholders in Europe, including people with the condition, researchers and health care professionals are represented and have a voice in the project. EURADIA has been instrumental in highlighting the need for increased and better coordinated funding for European diabetes research; past activity can be seen on the website **www.euradia.org**.

There will be two strategic phases to the DIAMAP project:

- Year 1: Survey of diabetes research and funding landscape
- Year 2: Development of diabetes research goals and the final Road Map for Diabetes Research by expert groups.

A Project Steering Committee of EURADIA members representing patients, academic science and industry, is providing guidance for DIAMAP. The project is now well underway and the expert groups have been working for the past few months, following a carefully designed strategy to build up information on past scientific achievements and to follow on with creative goals that can inspire future funding. Participants in each of the DIAMAP expert groups can be seen on the DIAMAP website (**www.diamap.eu**) along with project newsletters summarising activity.

Importantly DIAMAP is simultaneously carrying out a large-scale survey into diabetes research and funding activity across Europe. Reports that emerge from the survey database will be an invaluable indicator of current levels of funding across research fields that can be evaluated with a degree of accuracy not previously possible. For the first time it will also be possible to have a clear overview of the European diabetes research landscape. This does require input into the database by anyone involved in diabetes research, as called for by Professor Halban [1].

The Road Maps will ultimately be compiled into a single report to provide the European Commission, funding agencies, academia and industry with a strategy to combat the weaknesses and to maximize the strengths and opportunities for diabetes research in Europe. We hope that all those involved in diabetes research will be inspired to take part!

Reference:
1. P Halban, U Smith. Order! Order! Order in the House! : DIAMAP: a road map for European diabetes research. *Diabetologia* 2008 Oct;51(10):1765-7

DIAMAP: A road map for diabetes research in Europe. Funded by the European Commission Framework 7 Research Programme (FP7 200701).

For further information on the DIAMAP please contact Sarah Hills Project Manager (Sarah.Hills@euradia.org). To participate in the online Research Questionnaire go to: **www.diamap.eu**.

This article is being submitted to several journals across Europe in order to publicise the project.

Webscout:

The secret world of medical slang

by Joeyn Flauaus

All professions develop a secret language that is incomprehensible to outsiders. So it is no surprise that doctors, nurses, medical staff, and non-medical hospital staff have created their own vocabulary that is almost universally understood. The so-called medical slang is used widespread but you won't find it in any medical texts, journals, or dictionaries. Medical slang is using acronyms and terms as a code to describe mystifying medical conditions as well as personalities and behaviours of patients. It is a way to cope with stressful and overwhelming situations.

Examples of Medical Slang:

Double- O Doc - A doc with a license to kill. Basically means a very stupid doctor.

GOK - God only knows - a reference to a doctor's bewilderment at a particular set of symptoms presented by a patient.

HT - He's Toast. A person with very poor prognosis.

LOBNH - Lights on But Nobody Home.

TEETH - Tried Everything Else, Try Homeopathy.

UBI - Unexplained Beer Injury (British emergency-room acronym).

Most of the medical slang terms found in the Internet are from the UK and the US. However, medical slang is used worldwide and can be found in numerous languages.

Although medical slang may serve to vent frustration it also takes the focus off the patients deserving empathy. Most of the terms would offend patients if they knew what the terms meant. In general, the use of medical slang is declining as medical slang is nowadays considered unethical and unacceptable. In addition, there is the risk of being sued by patients if they find an offensive medical slang term on their patient record.

I have put together a selection of literature and websites on medical slang to provide you with more insights about the topic.

Medical slang in British hospitals

Dr Adam Fox, a paediatric allergist in the UK, has published an exhaustive dictionary of medical slang in *Ethics & Behaviour* [1]. In the article he is discussing the usage, psychological, ethical, and legal aspects of medical slang.

"The House of God"

The book, *The House of God* [2], a novel of life and death in an American hospital, describes the circumstances that lead to the evolvement of medical slang in order to deal with difficult and stressful situations. With this novel, the author introduced the most famous of all medical acronyms "GOMER" (Get Out Of My Emergency Room). The term describes a patient heading towards a death that aggressive medical care may only make more painful.

http://www.messybeast.com/dragonqueen/medical-acronyms.htm

This website provides a comprehensive glossary of doctor's slang, medical slang and acronyms as well was veterinary acronyms & slang.

http://www2.warnerbros.com/ertv/medical_gloss.html

This website provides a short list of medical terms and slang straight from the popular TV show ER (Emergency Room).

If you find a web site that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at: Joeyn.Flauaus@sanofi-aventis.com.

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References:
1. Fox AT, Fertleman M, Cahill P, Palmer RD. Medical slang in British hospitals. Ethics Behav. 2003;13(2):173-89.
2. Samuel Shem "The House of God" - Dell Publishing; 1st edition (1979)

"NEXT!"

Journal watch:

Publication of clinical trial results, and guest authoring and ghost writers

by Melanie Lee

Publication of clinical trials

Clinical trial results are primarily disclosed by publication in peer-reviewed medical journals. The Food and Drug Administration (FDA) in the United States (US) mandated in the FDA Amendments Act 2007 that all trials supporting FDA-approved drugs and devices must be registered at their inception, and their basic results (demographics, number of participants who dropped out or were excluded from the analysis, and the numeric and statistical results of all primary and secondary outcomes declared at initial trial registration) should be publicly posted by the National Institutes of Health (NIH). Since 2004, members of the International Committee of Medical Journal Editors (ICMJE) have required, as a condition of consideration for publication, that all clinical trials be registered in a public trials registry before patient enrolment.

Previous research has highlighted the general problem of publication bias and incomplete or selective publication of trials in the medical literature. Lee and colleagues [1] have now analysed the literature to evaluate the publication status of trials submitted to the FDA in support of newly approved drugs, to determine how many of them are published in biomedical journals that a typical clinician, consumer, or policy maker living in the US would reasonably search. This cohort study included trials supporting new drugs approved from 1998–2000, as described in FDA medical and statistical review documents and the FDA approved drug label. PubMed and other databases were searched up to 01 August 2006, to determine publication status and time from approval to full publication in the medical literature at 2 years and 5 years. In the FDA reviews there were 90 approved drugs supported by 909 trials; only 43% (394/909) of these were published. 76% (257/340) of trials described in the FDA approved drug label, and classified as 'pivotal trials' by Lee and colleagues, were published. Multivariable logistic regression for all trials by 5 years post approval showed that the likelihood of publication correlated with statistically significant results (odds ratio [OR] 3.03, 95% confidence interval [CI] 1.78–5.17), larger sample sizes (OR 1.33 per 2-fold increase in sample sizes, 95% CI 1.17–1.52), and pivotal status (OR 5.31, 95% CI 3.30–8.55). Multivariable logistic regression for pivotal trials by 5 years post approval showed that the likelihood of publication correlated with statistically significant results (OR 2.96, 95% CI 1.24–7.06) and larger sample sizes (OR 1.47 per 2-fold increase in sample size, 95% CI 1.15–1.88). Publication at 2 years post approval was predicted by statistically significant results and larger sample sizes. Therefore, more than half of the trials supporting FDA approved drugs remained unpublished $\geq$ 5 years after approval. Publication of pivotal trials and trials with statistically significant results and larger sample sizes was more likely.

Ramsey and Scoggins have evaluated the publication of registered clinical trials in oncology [2]. They first identified oncology trials in the NIH ClinicalTrials.gov registry and then evaluated the proportion of the trials that had been published in journals listed in PubMed.gov. Of the 2,028 trials that met the inclusion criteria, 17.6% were available in PubMed. 21.0% of trials registered before 01 September 2004 were published, compared with 11.9% of trials registered after this date. 59.0% of trials sponsored by clinical trial networks, compared with 5.9% of studies sponsored by industry, were published. The results were reported as positive findings in 64.5% of published studies. Therefore, less than one in five cancer studies registered with ClinicalTrials.gov have been published in peer reviewed journals. The authors call on research sponsors, researchers, and journal editors to redouble their efforts to encourage publication of registered clinical trials in oncology [2]. Writing in *The Guardian*, Ben Goldacre comments on the findings of Ramsey and Scoggins and highlights the importance of negative data for doctors to make decisions when prescribing medication, and for academics to understand why ideas have failed when they are planning future studies [3].

Guest authorship and ghost writing

There have been further discussions about the issue of ghost writing. Liesegang and colleagues [4] have reviewed transparency in medical literature in the wake of the rofecoxib controversy, in which Merck allegedly concealed the true authorship of articles, using outside consultants or ghost writers to prepare manuscripts and then naming prestigious authorities as guest authors [5]. They considered the role and responsibility of authors, medical writers, and statisticians and how they should be acknowledged. They endorse the 11 point agenda recommended by the *Journal of the American Medical Association* (*JAMA*) editors, and detail their own policies to achieve more transparency and to disclose more comprehensively all the major individuals who participated in the research and manuscript preparation [4]. The actions they propose are in accordance with the ICMJE, the medical writers associations, and the pharmaceutical company guidelines.

The *JAMA* editor has received several letters in response to an editorial by DeAngelis and Fontanarosa, which discussed integrity in medical science [6, 7]. The letters cover a range of issues, including the attractions and benefits of guest authorship. The *JAMA* editor has also received a

Publication of clinical trial results...

number of letters in response to a recent review by Ross and colleagues [5, 6], which evaluated guest authorship and ghost writing in publications related to rofecoxib in a case study of industry documents from rofecoxib litigation. Several researchers challenged claims that they were guest or ghost authors on reviews they have published, and criticised the methods used by Ross and colleagues in their analysis [6]. In reply, Ross rebuts their criticisms and provides further explanation for his conclusions.

In a recent correspondence, Adamson and colleagues discussed ethical medical writing, author accountability, and compensation [8]. They used the example of preparing a clinical trial manuscript to give a detailed analysis of the different individuals involved, their role in the process, and the appropriate way to acknowledge their contribution.

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8. Adamson LM, Whitman M, Jacobs A, Bunting-Early TE. Ghostbusters should only bust ghosts. *Nat Biotechnol* 2008;26(10):1067–8.

How successful are we at understanding syntactic ambiguity?

Syntactic ambiguity is a property of sentences that may be reasonably interpreted in more than one way, or reasonably interpreted to mean more than one thing. Ambiguity may or may not involve one word having two parts of speech or homonyms.

Syntactic ambiguity arises not from the range of meanings of single words, but from the relation between the words and clauses of a sentence, and the sentence structure implied thereby. When a reader can reasonably interpret the same sentence as having more than one possible structure, the text is equivocal and meets the definition of syntactic ambiguity. Let's analyse some classic examples:

1. **Visiting friends can be boring**. *Visiting* can be boring although one can leave whenever one wants. In that sense, it is not like '*visiting friends*' who, if they stay too long, can be boring, especially if you are too polite to tell them to leave because it's your bedtime.

Now, let's disambiguate:

Friends who visit [others] can be boring.	For one to visit friends can be boring. (i.e. visiting itself is boring)
visiting friends = subject	visiting friends = subject
visiting friends = noun phrase	visiting friends = noun phrase
visiting = pre-modifier	visiting = verb (subject deleted)
friends = head noun	friends = object
can be = verb phrase	can be = verb phrase
boring = complement	boring = complement

2. **Flying planes can be dangerous.** Either *flying planes is dangerous*, or *flying planes are dangerous*.

3. **Time flies like an arrow.** Although we unambiguously understand it to mean *'Time flies in the same way that an arrow does'*, it could also mean:

- measure the speed of flying insects like you would measure that of an arrow (thus interpreted as an imperative), i.e. (You should) time flies as you would (time) an arrow.;
- measure the speed of flying insects like an arrow would (this example is also in the imperative mood), i.e. (You should) time flies in the same way that an arrow would (time them).;
- measure the speed of flying insects that are like arrows, i.e. Time those flies that are like arrows;
- all of a type of flying insect, 'time-flies', collectively enjoy a single arrow (compare *'Fruit flies like a banana'*);
- each of a type of flying insect, *'time-flies'*, individually enjoys a different arrow (similar comparison applies);

As Groucho Marx is said to have observed, *'Time flies like an arrow; fruit flies like a banana'*.

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Out on our own

Thanks to Ingrid Edsman for sharing her experiences with us in this issue as a newcomer to freelance writing. She has plenty of advice for those starting up in Sweden, and lots of general advice for those outside Sweden, concentrating on her office equipment. I (Alistair) agree with her that it is not worth skimping on office ergonomics. One of my best investments was an expensive office chair recommended in the German 'Test' Magazine. I had endless neck and back problems when working as a salaried employee, but since I have been working at home and started my freelance life with a 10-week course of acupuncture for the neck and back and my new chair, I have had only one very short period of back trouble in 6 years.

Sam tells us in this issue about her second year as a freelancer, not without ups and downs, but definitely coming out 'up'! A German colleague, Lutz Gegenheimer, who has been a freelance writer for 13 years and an EMWA member for almost as long, answers our ten questions. I received a few emails about invoicing from new members,

so I put together some information on invoicing in Germany. I can only speak for Germany, so please let us know from other countries whether there are special aspects you have to observe and how you go about things.

In the next issue, freelance participants at the 27th EMWA Conference in London will be telling us how much it cost them to attend and whether they think it was good value. We will also be reporting on the Freelance Business Forum and on changes to the Freelance Listing on the new EMWA Website. And we hope we will be publishing some contributions from **YOU** on topics relevant to freelance medical communicators.

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Toolkit for freelancers

by Ingrid Edsman

Skriva en artikel i *TWS* Freelance Section om att starta eget i Sverige? The inquiry set my mind going. What could I tell about starting up as a freelancer in Sweden? Could I add anything to the previous articles in *TWS* on starting up in other countries? They have given a good picture of going freelance, and most of it is applicable to all newcomers to self-employment: developing a business plan that includes services provided and financing, registering the business with the authorities, finding customers, writing agreements, and marketing. Were there any areas left to cover? I started to think about all the equipment that I bought when I set up my office early this year. What were all the items, technical and non-technical? Maybe I could describe these in more detail? So, here is my personal view on tools of the trade. I will mention a few trade names, but I can assure you that I have not been sponsored—yet. I also want to give you some information on Sweden specifics when setting up a business.

Tools of the trade

Hardware

With the business plan written, the financing cleared, and the first customer on their way in, it was time to equip my home office. It was 'tool time'. I started with the technical tools and on top of the list was, of course, a computer. I took advice from more computer-skilled people than myself and got a laptop with XP as operating system, having heard negative comments about Vista. I also bought a 22-inch widescreen, which allows me to view two full-size A4 pages side by side and handle two documents at the same time, and that is definitely easier on the eyes.

Need-to-have software

Deciding on basic software was easy. MS Office with Word, Excel and PowerPoint is certainly a tool of the trade and the first of my business critical programs, a need-to-have. I felt compelled to buy MS 2007 because it was the latest version, but I am not happy with the graphical pres-

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entation of the menus. I wish Microsoft had let things alone with the 2003 version. The second need-to-have software was Adobe Acrobat 8.0 with its security and binder/package features; the latter is great for generating CSR appendices. The third program on the business-critical list was an antivirus program, and I chose Norton, which functions well on my private PC.

Nice-to-have software

The nice-to-have software included electronic dictionaries, a mind map program and an accounting program. As a non-native English speaker, I frequently use dictionaries and having them online, just one click away, is very convenient. The dictionaries are embedded in the WordFinder search engine, and it gives me instant access to all dictionaries including my own user-defined dictionary with life-science specific terminology. The commercial dictionaries that I have selected as part of this solution are Norstedt's Swedish-English/English-Swedish Dictionary, Collins English Thesaurus, and Stedman's Medical Dictionary. I also have a single licence for Oxford Advanced Learner's Dictionary. I still do have a library of paper books and I use them regularly, but for daily writing I use the online versions.

Some years ago I read an article called 'Creative daub', which was about mind maps, and from then on I have been drawing mind maps to structure all kinds of information. The MindManager software has helped me think and organise information in a visual, non-linear way, e.g. jotting down and structuring ideas for this article. At meetings, I have discovered that mind maps trigger lively discussions and spontaneous actions.

In contrast to mind maps, there is nothing spontaneous about accounting. It just has to be done. I am brave and have decided to handle my own bookkeeping and accounting. Not because I am interested in economics, but because I want to have control over my own business. I may have second thoughts when I have to draw up the annual accounts next year! There are several accounting programs around and I have selected one designed for sole traders, Visma Enskild Firma. It is easy to use and I have made a habit of registering every in- and outgoing payment immediately to keep the records continuously updated. Several financial reports can be generated within the program and they give me a good overview of my income and expenses.

Backups

How to handle and secure the data and set up a well functioning data environment? This is how I do it (with a little help from my friend). All software is installed on my laptop and the data are stored on a separate device. This device, Drobo, has four hard drives with simultaneous mirroring, making it safe from hard-drive failure, and an add-on system for sharing data across networks. After a day's work, I back up the data manually from Drobo to a third

computer used only for backups. To be on the safe side, I also make backups once or twice a month on an encrypted memory stick, which is stored in a safety-deposit box at the bank. This procedure may seem overly cautious for securing the data, but as a hard-drive-crash-survivor, no measure is too cautious.

Communication

Communicating with clients and transferring data are also areas for technical solutions. When I worked within the pharmaceutical industry, we had online departmental meetings via NetMeeting and teleconferencing and that functioned very well, e.g. for sharing documents. I wanted to have the same possibility in my company, particularly for the document review process, and I have successfully participated and hosted online meetings using NetConnect meet24 and MS Office Live Meeting, both set up by the client. It is really an advantage when all meeting participants view and work in the same document. The meeting accounts are quite expensive though, so I have not signed up. My usage will be intermittent and therefore pay-per-use, a service provided by WebEx, is an alternative. Online meetings usually have integrated teleconferencing, but I have not tried it. I use my mobile with hands-free earphones and that works well.

Last, but not least, the Internet. I already had a reliable broadband connection for private use and I added a mobile connection as backup and for working out of the office. Early on I decided to have the company represented on the Internet and I had a rudimentary website set up. It is presently being updated and once the new website has gone live, I will register on the EMWA freelance listing, which is said to be a good source for client contacts. I waived the fax machine and till now there has not been a demand for one; e-mail is sufficient.

The office

With the technical tools in place, I turned to the office equipment. After two weeks of intense writing, I had acquired severe backache and realised that I had to do something about my home office. The Mousetrapper, a pointing device with a finger-controlled rod, and a long-time companion on my office desk, was obviously not enough to cope with the wear and tear on my body. I called an ergonomist, who made a house call and inspected my work place, resulting in the widescreen and a new office chair—by far my biggest investment—a good one comes at around SEK 6,000 (about € 600). As winter is approaching and days are getting shorter, I will soon invest in a bright office lamp. I took ergonomics for granted when I was an employee. As self-employed, it is equally important to have proper ergonomic design to avoid future problems with strain injuries.

A final word about office tools: a paper-shredder is not really a big deal, but I recommend using one to dispose of sensitive documents.

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Setting up a business in Sweden

When I had decided to set up my own business, I was fortunate to have a sole trader in my immediate family—an inspiration and an invaluable source of information for all small and big issues that emerge for a novice in business. Of course, this helped my transition from employment to freelance work immensely. But I also got very useful information from Nutek, the Swedish Agency for Economic and Regional Growth (Verket för näringslivsuteckling, www.nutek.se). Nutek has an Entrepreneur's Guide (Företagarguiden) that tells you where to find public authority information that is relevant for starting and developing businesses in Sweden. There are Start-up Days (Starta-företag-dagar) all over Sweden and you can call the Start-Up Line (Startlinjen)! In the brochure *Starting up a business* (*Starta företag*), you can read about planning, types of business enterprise with pros and cons, bookkeeping, accounting and types of insurance. In addition you will find a business plan template and a start-up checklist that may be customised for your own needs.

Registration and taxes

In some countries you can opt for value added tax (VAT) (mervärdesskatt [moms]) depending on your turnover. In Sweden there is nothing optional about taxes, except when to declare VAT: monthly, quarterly or annually if your turnover is less than SEK 1 million a year. When you start your own business, irrespective of legal form, you have to apply for an F-tax certificate (F-skattsedel) and register for VAT at the Swedish Tax Agency (Skatteverket). The F-tax certificate shows that you pay your own PAYE (pay-as-you-earn) tax and social contributions. As a sole trader, you may want to register with the Swedish Companies Registration Office (Bolagsverket) to protect your business name; all other types of business have to be registered. Registering your company is quick and easy—you can register with the Swedish Tax Agency and The Swedish Companies Registration Office at the same time at the joint website www.foretagsregistrering.se. The Tax Agency runs seminars on different tax issues free of charge and you can sign up for individual advice. I had an hour of free counselling with two tax officials discussing VAT within the EU.

There are other websites you may want to look at, e.g. Jobs and Society Start-Up Centre (Nyföretagarcentrum, www.nyforetagarcentrum.se) and The Swedish Trade and Industry Register (Näringslivsregistret, www.bolagsverket.se/snr/), and have a look in the magazine for entrepreneurs, *Running your own* (*Driva eget*, www.driva-eget.se). I have a subscription and it is worthwhile. There is a yearly Entrepreneurial Fair (www.egetforetag.se) with seminars and exhibitions, where I expect to pick up some hands-on advice.

Insurance and banking

Business insurance appears to be under constant debate among freelancers. Many Swedish insurance companies offer packages of business insurances providing the most common types of insurances that a newly started company needs. A typical basic insurance designed for small size companies covers property, business interruption, liability for property damage, and legal protection. There may be an optional part specifically for advisory consultants covering liability for damages for financial loss. I have taken out the basic insurance and added the optional part as a precaution; it is 'hängslen och livrem' ('belt and braces').

The Swedish banks offer special business bank accounts. A standard package includes online banking with a current account linked to a debit card and a bank giro, and a business account with high interest rate and no limit on withdrawals. Also included is counselling and all this at a reasonable cost; I pay SEK 600 a year (about €60).

Marketing

A brochure about marketing for entrepreneurs (*Marknadsföring för nyföretagare*) can be found at www.nutek.se. Marketing, networking and finding clients go hand in hand. I have found that life-science organisations are a great way of extending your professional network. They arrange interesting seminars and workshops, where you meet representatives from a wide range of companies within life science and have discussions in an inspiring atmosphere. I have certainly made my company more visible since I started going to the events arranged by SwedenBio (www.swedenbio.se). The combination of networking and educational activities may also be found at local universities. I live close to Karolinska Institutet in Stockholm and being a KI alumna, I am part of the KI Alumni network, which keeps me informed of the latest research news from KI and helps me stay in touch with old and new contacts.

The future

It seems like I am spending my time on purchase, business administration and self-improvement. What about the actual work, the writing? I have had a good start and written a couple of clinical study reports and I am presently working on a manuscript for publication. I look to the future with confidence. Running the business sometimes takes precedence over the writing; that is inevitable. But I believe that with a well-organised and smoothly run business infrastructure, I am better prepared for dealing with multiple clients without panicking about deadlines. And if there is only one client at a time, I will be able to complete the assignment swiftly and devote any spare time to life outside work, e.g. singing close harmony in a vocal trio—but that is another story.

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My second year in business: Update on freelance medical writing activities, October 2007 - September 2008

by Sam Hamilton

It feels as if I have barely started out and simultaneously that I have been doing it for ever—I feel born to it! I am of course talking about freelancing. In previous issues of *The Write Stuff* (*TWS*), you heard about my journey to freelance medical writing and my first year in business. As I embark on my third year, I take stock of and share with you an account of my second year in business. Exciting projects, returning and new clients and the holiday time I wanted (more or less) have melded into an addictive mix I absolutely love!

Months 13 -15

October- December 2007

By October, it was becoming apparent that the large protocol writing project managed by my friend Helen in the US, was at the very least likely to slide significantly. Helen in particular had spent a great deal of time bidding, securing the contract and assembling her transatlantic team to execute the 47-strong protocol library project for a major American pharmaceutical client. Processes were in place and we wrote, quality controlled and submitted a grand total of …one protocol in Q3 2007. We received great feedback, but Helen then began to hear whispers of changed priorities, possible mid-term project deferment and later, company redundancies. After maintaining dialogue with the client for several months, it slowly became clear that this huge project had simply 'gone away'. My strategy to continue to source other work throughout had left me unaffected, but Helen learned a salutary lesson. It took her several months to bring new avenues of work to fruition, but I am delighted to report that she is working at full capacity once again.

> *Exciting projects, returning and new clients and the holiday time I wanted have melded into an addictive mix I absolutely love!*

Another friend of mine took early retirement from her very successful regulatory affairs consultancy, and she was kind enough to recommend my services to some of her clients. As a result, new work came in the form of a virology protocol re-write for a niche German regulatory affairs consultancy. This was followed by an Investigator Brochure review and update of the clinical sections for the same client.

Having been accepted in quarter 3 2007 by EMWA's Education and Professional Development Committee (EPDC) as a workshop leader for an advanced EMWA course entitled 'Scheduling and Proposal Writing: The Clinical Study Protocol and Report', I honed the materials to pretty much the final package by Christmas 2007. I just had to hope that there would be room for my workshop in the May 2008 Barcelona programme. I expected a final decision after the Christmas holidays.

It was my great pleasure to work on a project which Alistair put me forward for with one of his French clients who required clinical-regulatory writing expertise on a virological project. This project was to run and run over a period of 6 months, as it evolved and was extended. The developing document was of strategic and commercial value to the company globally, and for me this represented an interesting twist on the usual angle of writing pure regulatory documents. The material really was cutting edge and the writing was highly rewarding given my background as a post-doctoral virologist. The client was a delight to work with which always helps as new challenges arise and as scope evolves.

We spent the children's October half-term break on a week's family adventure holiday in Jordan. We swam in the Dead Sea; visited Petra and rode on donkeys up the precipitous steps to the monastery; camped in the spectacular rock and sand desert of Wadi Rum out under the stars; took a desert jeep safari; rode camels; visited the biblical city of Jerash and finished at the Red Sea where we snorkelled—Aanya (6 years) and Cameron (9 years) for the first time!

More specialist virology work appeared after our holiday from a different quarter as I began to develop a relationship with a London-based specialist Contract Research Organisation (CRO) which had sprung out of a renowned university academic group responsible originally conducting Investigator-led clinical trials. My initial brief was to assist the developing group with documentary and template requirements for specific virological protocols. After developing the first template, I went on to write an actual protocol they were contracted to design and conduct for their client. What a luxury to populate my own template! The deliverable was happily free from those annoying template-associated glitches one frequently encounters but cannot explain or solve!

Christmas holidays were looming as I tried to balance work and put in an appearance at all the delightful seasonal school events which, for Paul and I, help make parenting of primary school age kids so much fun. In the week before the holidays, I was somewhat run ragged through attending events, nights out and long hours at work to complete as much as I could before year end. However, hard work paid off and I enjoyed the full two-week holiday with my family.

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Months 16-18

January – March 2008

The New Year brought the good news that my workshop would have its first airing at the Barcelona meeting.

A second virology protocol from the London-based CRO followed hot on the heels of the first. Almost before I had completed this, the group approached me about writing a whole raft of manuscripts on legacy projects for submission to peer-review journals. There were a few interesting virological topic areas and together with their Head of Intellectual Property, Research and Development, and I began to work out a strategy and timelines for manuscript writing going forward. I prepared the first draft manuscript and advised on publication strategy for another. Preparing all the manuscripts would likely be an evolving medium-term undertaking.

I was approached by a friend and fellow freelancer, Iain Colquhoun, to help out with updating the Summary of Product Characteristics (SmPCs) for a range of well-known established-use medicines, in line with the January 2007 paediatric regulation. I worked on two of these Expert Statements and found the work made a refreshing change and was very enjoyable, not least because of working alongside my friend.

My first quarter seemed incredibly short given that we had another holiday planned towards Easter which was earlier than usual this year. We had decided to visit Paul's sister and her Australian husband in Sydney and planned to incorporate a 4-day stopover in Bangkok. After much self-wrangling, we decided to take the children out of school for a week to enable us to have almost a month away. It turned out to be a great decision as the kids learned so much on their travels that missing a week of school ultimately seemed neither here nor there. Family time was peppered with some real adventures, the best of which was hang-gliding over the spectacular coastline south of Sydney. The hero of the moment was our son, Cameron, who had the best ride of the day, soaring like a bird and whooping for joy as he and pilot Curt landed effortlessly (and upright) on the golden sand below Bald Hill.

Months 19-21

April – June 2008

I returned to see that the project with my French client had developed and I was contracted to write further sections of their strategic global dossier. I felt that I was really getting to grips with their economic and business perspective. My final material was submitted in June just ahead of product launch. What had felt like a huge challenge initially had turned out to be a marvellous personal development and learning opportunity.

I was really looking forward to the May 2008 EMWA meeting in Barcelona as I had decided to become a little more involved than in previous years. As well as delivering my own (under assessment) workshop, which, incidentally, was made substantive by the EPDC, I observed another 'under assessment' workshop and fed back comments. Alistair and I hosted freelance lunch tables (which was probably a bridge too far given my pre- and post-lunch activities that day) and the Freelance Forum as usual. I also volunteered to guest edit a forthcoming issue of *TWS* which would come out just ahead of the regulatory themed Ljubljana May 2009 conference. It seemed sensible to make the theme for that issue 'lesser know regulatory issues' or similar. I knew this was a major undertaking but, encouraged by Elise, I felt ready for the challenge. The social side was great fun as always, with time to catch up with friends and make new ones. I met up with an old friend whom I had not seen for many years since we were both in project management together. A medic by profession, she had since soared to Head of Pharmacovigilance for a major Spanish Pharma company, but we found we still had plenty in common and were able to pick up where we left off ten years previously. I rounded off the conference by promising Julia that I would think about her kind invitation to join the President's Sub-Committee and the Ljubljana Content Organising Sub-Committee.

On returning home, more work arrived at (very) short notice from my London-based client who required help with protocol synopsis development and subsequent protocol writing. I project-managed my client and their client teams and over a few short and very packed weeks, and delivered the goods in time for a very tightly scheduled Independent Ethics Committee (IEC) meeting.

> *The work seemed, at last, to be finding me, despite my not actually noticing this transition!*

Recalling the lessons from Helen's experience, I was aware that I had written quite a lot of material for this single client during the past couple of quarters, and reminded myself to spread my net wide enough so that overall business would not suffer should any one or two particular clients go quiet for a period. As I was now building up my clientele, I felt I was at least heading in the right direction and a reminder from my husband Paul that I had not actually undertaken any formal business development activities since last November 2007 settled me again. The work seemed, at last, to be finding me, despite my not actually noticing this transition!

I took up Julia's offer and we had the first teleconferences for both committees.

I sounded out a friend and previous client team member, Tracy Farrow, Medical Writing Manager for ClinTec International, to assess her interest in co-developing an EMWA workshop with me. Both Steven de Looze and I felt there was scope for a workshop on Standard Operating Procedures (SOPs) in the programme, and I knew of Tracy's expertise in this area. Happily, Tracy agreed and we worked hard to compile and submit all our draft materials before our planned summer holidays. We then worked with our mentor and finalised all documentation by mid July. The new foundation workshop entitled 'SOPs:

My second year in business...

Processes and authoring' together with my scheduling and proposal writing workshop were both scheduled in to the November 2008 London conference programme.

I paid my first corporation tax at the end of June. In the UK, start-up businesses are given an 18-month tax holiday. That is to say that one does not pay any tax until 18 months have elapsed from the first day of trading. I had been steadily collecting the tax in a high interest internet account throughout the year, so I was able to make the payment painlessly.

I had been contracted to write a clinical study report (CSR) for one of my northern England-based clients and planned to write the shell report after my holiday. However, it seemed that my client's client wanted to see a shell sooner than I had time to write it, in order to comply with their board members' wishes. I advised my client to seek alternative resource if she needed to whilst I was away, but I decided to take the laptop on holiday with me, in any case, to keep abreast of developments.

Months 22-24

July – end September 2008

I am slightly embarrassed to say that as the children broke up from school for the summer, we once again set off on our travels, this time to Biarritz in southern France, via Amsterdam and Paris. We took the car ferry enabling us to take our 'gear' with us. 'Gear' is Paul's loose term for bikes, canoes, life jackets, boogie boards and wet suits! We did actually have great fun using it all, and on returning home, I finally gave in to his request for a new garage to house it all in. Building work started and stalled annoyingly throughout the rest of the summer and was completed towards October.

'Gear' is Paul's loose term for bikes, canoes, life jackets, boogie boards and wet suits!

Incidentally, my idea of monitoring progress by checking emails whilst on holiday was not one I will be repeating! Suffice to say that I was pleased my mobile broadband provider had the good sense to email me when £50 of credit was expended—and that was the cost of one email session!

I had a rather more intense return to work than I had planned for after our return from France as the shell deliverable was required within a week of my return, and my client had not been able to find anyone else willing to write it over the summer. I remembered how little I enjoy weekend working as my children became urchins for a few days. I met the shell deliverable deadline and took a look at the draft patient data listings as soon as they became available. Within a short time, it became clear that the database was not entirely clean, or even approaching it. The statistician and I broke the news to the client that further work would be required to bring it up to the required standard. As a result, the reporting timeline began to stretch out.

That actually helped as another protocol synopsis management and protocol development project landed from the London-based group. That too stalled after the first review of the synopsis. This break enabled me to prepare the shell of another CSR for my northern England client whose project above had stalled. For once I felt ahead of myself, but only momentarily.

I remembered how little I enjoy weekend working as my children became urchins for a few days.

I now had time to chase up potential contributors for the issue of *TWS* which I was guest-editing for March 2009. I would need sufficient time to review and edit articles and write the editorial coming up to Christmas 2008 in order to meet the publisher's deadline. As some article topics naturally fitted in with the theme of the Ljubljana conference, a couple of contributors were approached by me and my fellow members of the Ljubljana Content Organising Sub-Committee to speak. The sub-committee was by now meeting monthly by teleconference and conference content was developing nicely.

I was invited to partner with a resource management group who were expanding from specialist placement into clinical project services. I had a productive meeting with the Group Operations Director and we agreed to move forward together. My first brief was to help with proposal writing for a large phase IV project they were bidding for and also to help craft their website text. Should the bid be successful, the reporting responsibility would be mine. Medium term goals such as my project managing their SOP writing and joining them as needed at bid defence meetings, were also discussed. I felt this was a potentially exciting partnership with an amiable group of people who seemed to share many of my own ideals.

Unbelievably, it was time to gather together documentation for my second year accounts.

Closing thoughts…

I feel privileged to have had such a happy and successful year. Freelancing is everything I hoped it could be and more. I love my work, work hard and sleep like a baby at night, probably because I feel a greater degree of control than when I was employed. I have so far managed to take as much time off as family commitments require—and for my lot, that isn't inconsiderable! I look forward to the year ahead and writing with new-found clarity in my uncluttered space, which is now mercifully free from 'gear'!

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Preceding articles in this series are available for reference at:
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Invoicing in Germany

Most freelancers have accountants, and your accountant should keep you informed about invoicing requirements. I summarise the requirements in Germany below with a few comments. It would be interesting hear from others about requirements in other countries.

- You are legally required to issue an invoice for any service provided.
- You are legally required to archive invoices for 10 years.
- The law also states that if you send an invoice as an electronic document you have to agree this in writing with the client in advance and that the invoice must be validated by an electronic signature or sent within a validated private electronic network.

  *I have three or four clients who require a signed invoice on paper, but so far no-one has bothered about verification with electronic signatures. 95% of the invoices I issue go out electronically without an electronic signature or a scanned signature. The client just prints out the email attachment as their paper copy. Sometimes they ask for a PDF file. Loads of freeware for conversion of *.doc files to PDF file is available on the web. You don't have to buy expensive programs.*

The following information must appear on all invoices issued in Germany:

- The complete name and complete address of the service provider and the recipient of the service.
- The service provider's tax number or VAT number for those liable for VAT.
- The service provider's and the recipient's VAT number, if the recipient is liable for VAT.

  I have only a few clients who ask for their VAT number to be included, and they are exclusively large pharmaceutical companies in Germany. CROs and other companies don't seem to be bothered about this, and it doesn't usually apply to physicians or others for whom I edit manuscripts. If VAT doesn't apply because the service is being provided for a client in a different EU country, however, they usually ask for their number to be included, and this is usually stated in the contract.

- The date of issue of the invoice.
- For invoices for more than € 150, a unique (alpha)numerical identifier (a simple serial number suffices).

  Germany has 'minimum requirements' for invoices of less than €150 including VAT. For example, they don't need a serial number or the name and address of the recipient. To make life easy, I just issue every invoice as if it were for more than €150 so I can use the same template. You must also maintain a separate 'job list' with the serial numbers. Again, it is easier to include all invoices, even those for less than €150. If you cancel an invoice, write 'cancelled' on it, or if you correct one, write 'corrected' on it, and archive it with your invoices so you can show an unbroken series of invoices if the tax inspector calls.

- A brief description of the service(s) provided.
- The month or range of months in which the service was provided.
- An itemised list of each service provided with the unit price (e.g. €65 per hour), the total amount for each service, and the grand total, or a fixed charge, without VAT.
- For a final invoice, all advance payments (for which invoices also have to be issued).
- The amount of VAT and the rate applied. If VAT does not apply (only for those liable for VAT), a simple statement explaining why.

  You are liable to charge VAT in Germany if your income was higher than € 17,500 in the past year (this is the basic rule, but things can get very complex—this is why you need an accountant). This is considerably lower than in some other EU countries. Work done in Germany for recipients in other EU countries is not subject to VAT even if you are liable to pay VAT in Germany (this does not include training done abroad, as far as Germany is concerned; VAT at the German rate has to be charged). As I said above, under these circumstances, I am often requested to include the recipient's VAT number. I add the following statement at the bottom of the invoice to explain the absence of VAT because I am liable: 'Zero-rated VAT invoice for member state of the European Union'.

- The (grand) total including VAT.
- Any discount granted before VAT and the discount rate applied.

  This doesn't usually apply to our line of work, but if you grant discount, it must be described by this sort of statement: '2% discount is granted on invoices paid within 15 days of receipt'.

You should add something of this sort to each invoice: *Payable without discount within 30 days of receipt.* If this is in your contract, you don't need to add it. In come countries, 60 days is the standard, and you just have to accept it. By the time you have written emails and telephoned trying to persuade the client to do otherwise, you could probably have done a couple of hours of gainful work!

I was once advised (seriously) by a person in the UK with her own business to add 10% to every bill and add the statement: *10% discount is granted on invoices paid within 10 days of receipt.* I never went down that road, however! And I never explored how legally valid such a strategy might be.

Clients in Germany generally prefer separate invoices for services and expenses. For kilometres driven, the rate at present is €0.30, and you add VAT to the total sum from the kilometres driven. Because of the increase in oil prices, I have recently been charging €0.35, and no-one has objected yet.

A frequently asked question at EMWA Freelance Business Forums is: What do I do if a client doesn't pay within the set period?

It really does seem to be the exception in our business that clients don't pay, but they do sometimes take their time. Leave about one week after the set period, and drop the client a line (so you have written evidence) to remind them. The simplest thing is to forward them the email you originally sent with the invoice asking them to check whether it has been paid. Or resend it on paper if necessary. This usually does the trick. If they still don't pay, you send them an official reminder (with 'First reminder' as the subject line) on paper. If they still don't pay, remind them again ('Second reminder'). Make sure you can document the whole process on paper. After that, the next step is a solicitor's letter and legal advice, but discussions at the EMWA Freelance Business Forum have shown that this really appears to be the exception.

The longest I have waited in my 6 years as a freelancer was 4.5 months. This was from a German government organisation (with three official reminders). Otherwise it has rarely taken longer than 30 days, unless I knew it would probably take up to 60.

Alistair Reeves
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Ten questions for …

Lutz Gegenheimer

by Lutz Gegenheimer

In 100 words, what is your background and how did you become a freelancer?

After studying medicine and psychology, I worked for 4 years in a clinical CRO in different positions. During the subsequent 2 years, I was engaged in preclinical projects in a pharmaceutical company. I finally decided to become a professional medical writer because I had come to the conclusion that this was a suitable activity for me, and that there was sufficient demand for medical writing services. After carefully weighing everything up, I also decided to become a freelancer because I had come to the conclusion that—for me, at least—there would be more advantages than disadvantages working outside a company.

What is your most important piece of advice for people setting up a new business?

It is useful to have a couple of years of experience in a company so that you can build up personal contacts to potential clients. Of course, medical and statistical expertise, writing proficiency, and, very important too, the discipline and ability to work on your own form a favourable basis.

What do you like about being a freelancer?

Compared to my previous job as an employee, I have more flexibility to organize my time according to my own needs. Based on this flexibility, I have been able to optimise my working processes thereby increasing my productivity. I have never regretted giving up fixed working hours.

What do you dislike about being a freelancer?

As a freelancer in a one-person business, you have no direct opportunities to delegate certain activities. You may not have access to specialists who can rapidly help you solve certain problems. It is also easy to lose contact with other colleagues and to miss out on new developments.

What are your main sources of work?

For many years I have been working for a fairly small number of clients, mostly pharmaceutical companies.

What are the most rewarding projects to work on?

From both the point of view of motivation and income, I prefer to be involved in long-term development projects. It saves time if you are familiar with a compound. And there are considerable benefits due to transfer effects. I specialise in study reports, protocols and summary documents relevant for regulatory purposes. For some clients I work as a medical advisor.

What are the least rewarding projects to work on?

Personally, I dislike writing literature review articles. According to my experience, they are time-consuming and are often not well paid. Maybe I just don't have the skills required—but we can't all do everything!

Do you have a preferred type of client? If yes, why?

I prefer to work for long-term clients. Once a stable working relationship with a client is established, it makes it very much easier to meet the client's demands and solve problems that may arise during the working process. Of course, to prevent dependence, it is advisable to have more than one long-term client. One important thing is to meet the client personally, and I try to do this with all new clients.

What is the best way to say 'No' to clients?

It is indeed not always easy to reject a job. With the years, however, I have become more selective. If, based on previous experience, I'm in doubt that I'm qualified for a job, or if I suspect that a job may not be satisfactorily paid, I usually reject it due to 'timeline problems'. With potential new clients, high cost estimates can be a successful way to reject a job (see note from Alistair Reeves below).

Would you ever consider working for a company (again) as a fulltime employee? If yes, why?

After 13 years of freelance medical writing, I could never imagine returning to company employment. I would accept jobs that require a personal presence on the client's facility, but I would always prefer to remain independent.

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Note from Alistair Reeves: Beware! I recently tried this by saying that I would only do a training event on a weekend for double my usual fee—and the client accepted!

A sign of embarrassment

Do you know the difference between fewer and less? Tesco did not before The Plain English Campaign put them right about a sign they had placed at their fast-track checkouts. The sign read "10 items or less" rather than the correct wording of "10 items or fewer".

Source: http://news.bbc.co.uk/2/hi/business/7590440.stm

Gained in translation

Science at the multilingual crossroads

What was still a hazy idea in the wake of the 2008 EMWA conference in Barcelona dedicated to translation has come true: Here's the first chapter of our Medical Translation section in *TWS*.

Challenging as cross-cultural communication can be, content and nuances may occasionally fall by the wayside as facts, thoughts, and opinions are transferred from one language and culture into another. This is what is commonly referred to as being 'lost in translation'. (As a first-year translation student, I thought it referred to myself being lost in a maze of translation, so I guess the phrase has a dual meaning.)

But there's another, much brighter, side to the coin of translation that is less frequently looked at: With translation being a cross-cultural communication process that does not simply transpose words but, above all, the culture they rep-

resent, it requires us to take a very close look at both the source and target cultures and to attempt to be at home in one and in the other. There's a tremendous lot to be gained from looking at a 'foreign' culture so closely, from attempting to understand—or making ourselves understood to—a partner in dialogue who speaks a different language. The title 'gained in translation' is meant to highlight this side of the coin.

I hope for this section to be an information exchange for translators, a platform for readers and buyers of translation, a forum of multicultural science communication, and a place for debate. So—you're warmly invited to let yourselves be heard.

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English as the lingua franca of science: A translators view on what's lost–and what's gained–in translation

By Gabi Berghammer

There is no national science just as there is no national multiplication table; what is national is no longer science
Anton Chekhov

A few months back, I worked on writing a peer-reviewed publication for one of my clients, who, like me, is operating in a primarily German-speaking environment. The study to be reported was a survey conducted in a number of Central and Eastern European countries, with the investigators representing six European languages.

The question as to which language to write the manuscript in was therefore easily decided: To enable communication between all participating countries, we chose not to publish in German but in English. The website of the journal we had selected for submission, the official organ of an association representing German-speaking medical specialists, stated that both German and English manuscripts were acceptable.

What followed were a couple of joint sessions with the client during which we worked on the text, every time polishing our phrases and sentences to even more precisely express what needed to be said and sometimes even bargaining over nuances of terminology and style, particular-

ly when it came to the more political aspects of the publication. Ultimately, we submitted.

In due course, we received the final proofs of our manuscript. The satisfaction normally felt when faced with the almost published product of one's labour quickly gave way to astonishment: Was this really our paper? Well, yes, it was–but it had come in a German version instead of the English one we had submitted.

A few phone calls later we knew what had happened: the publisher had only recently taken over the journal. The editorial board had decided to turn the previously bilingual German-English journal into an exclusively German-language medium, but had forgotten to update their website accordingly. So they had our English publication translated into German. Also, rather than sending us the translation for review, they sent the proof for final approval.

Being a translator by training, I would have preferred to do the translation myself, particularly considering the time we had put into discussing and carefully wording specific text sections. I remained calm and canny in the face of this mishap, because I did not want to jeopardize the urgently awaited publication. Also, the editorial staff were very forthcoming and helpful.

English as the lingua franca of science...

Yet, this unexpected switch from English to German meant two things: first, publication would be delayed. Translation carries the potential for misinterpretation, requiring a thorough quality check on the part of the client or author. The final German version of the manuscript would then have to undergo an additional round of approval by all German-speaking authors. Second, ending up with a German publication instead of the originally planned English one meant that its international visibility would be reduced.

The manuscript has meanwhile been published and everyone is happy. Nevertheless, this rather unusual story provided me with some food for thought on the challenges of translation and of communicating science results in a multilingual world dominated by English as the lingua franca.

Lost in translation
We had invested a fair amount of time to carefully word the manuscript, and there we were receiving a translation for final approval we did not even know had been commissioned. Did the translator really get all the nuances right? The translation came without a single 'translator's note', something I always find rather suspicious. Can a translator really transpose a highly specialized text without having to at least comment on a single decision taken during translation?

In brief, the paper sought to obtain information on the profile of patients with inflammatory rheumatic diseases, their previous and current treatments, and the proportion of patients treated with conventional drugs but considered by their physicians to be eligible for treatment with a comparatively new class of drugs referred to as biologics.

Terminology
To be fair–the translation was not all bad, and most of the terminology was translated correctly. However, there were a number of terminological inaccuracies (Table 1).

Terminological inaccuracies
For example, the German text used *biologische Mittel* as a translation for the class of agents that were the focus of the survey, i.e., 'biological agents' or 'biologics'. Not only does the German word *Mittel* bring to mind some natural or herbal 'remedy' instead of a class of highly sophisticated drugs, *biologische Mittel* is simply not the technical term used for biologics, which is *Biologika*.

Also, the text talked about contraindications to prescribing biologics, one of which is 'a history of or current malignancy'. This was translated into German as *eine überstandene oder aktuelle Malignität*. Even a cursory look through the Summary of Product Characteristics would have shown that what was meant was *eine überstandene oder aktuell bestehende Tumorerkrankung*. Although both 'malignancy' and *Malignität* can refer to any disease tending to become progressively worse and resulting in death, the meaning of the German *Malignität* appears to be more general still, referring to anything from cancer to epileptic seizures or catatonia.

With our manuscript originating in Austria, translating 'specialized clinic' as *Spezialsprechstunde* was not quite fitting because this word is not used in Austria. Why translate 'clinic' with *Sprechstunde* instead of the more straightforward *Ambulanz*, which would have resulted in *Spezialambulanz*, a term used in both language areas.

Leaving source-language terms in the translation
Leaving English source-language terms in the translation often simply is an easy way out for those who do not take an effort to think about a fitting term in the target language. There are numerous English terms that have entered medical parlance in German, such as *Compliance, First-pass-Effekt*, or *Intent-to-treat*, and have become accepted technical terms. Generally, however, why not attempt to find a target-language equivalent for a source-language term? For example, why use *Score* in German when there are good words to use instead, such as *Wert* or *Index*? Why translate 'Cox-2 inhibitors' as *Cox-2-Inhibitoren* and not as *Cox-2-Hemmer*?

Phraseology
In terms of phraseology–in my opinion the more challenging aspect of any medical translation–the translation had some noteworthy shortcomings. For example, the translation contained a number of unusual collocations and unidiomatic translations.

Unusual collocations
A 'mild disease course' was translated as *milder Krankheitsverlauf*, an Anglicism which should more appropriately have been translated as *leichter Verlauf*.

Throughout the text, the German translation used *leiden unter* instead of *leiden an*, the former meaning to 'suffer under' and the latter to 'suffer from'. Whereas 'suffering from' a disease is an objective statement, 'suffering under' refers to anything causing subjective suffering, such as pain. Patients may have a disease they 'suffer from' but they may not necessarily also 'suffer under'.

Unidiomatic translations
One of the major temptations to resist when translating is to translate word by word, more often than not resulting in unidiomatic text smacking of translation. Translators must dissociate themselves from the source language–free themselves of the grip of the source text–and find adequate and idiomatic means of expression in the target language.

For example, the phrase *800 Patienten wurden als geeignet für die Therapie mit Biologika eingestuft* reflects the word order of the English source text and should more appropriately have read something like *800 Patienten kamen nach Auffassung ihres behandelnden Arztes für eine Therapie mit Biologika in Frage*.

At other times, sticking more closely to the source text may be just fine. For example, why translate 'median disease

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duration' as *Medianwert der Krankheitsdauer* instead of the verbatim *mediane Krankheitsdauer*?

The same goes for the phrase 'a score of 10 indicates very severe symptoms', which was translated as *eine Punktzahl von 10 besagt, dass der Patient unter sehr schweren Symptomen leidet*. Choosing a translation closer to the source text, such as *ein Wert von 10 steht für sehr schwere Symptomatik* would have resulted in a more idiomatic and 50% shorter phrase.

Nuances lost in translation

Finally, some nuances of the source text were not adequately transposed into the target language. For example, the phrase 'one limitation of our study' was translated as *die Aussagekraft unserer Studie ist insofern eingeschränkt*, suggesting that the entire study did not allow reliable conclusions to be drawn. What was meant, obviously, was that there was one specific aspect of the study that could not be sufficiently answered.

To translate 'the results of our study reflect' with *unsere Studie belegt* is again overstating the point. The original did not say 'proves', a word hardly ever used in reporting research results, knowing that no single study ever 'proves' anything. The simple word *zeigen* would have done the job.

Inaccuracies such as those presented above may appear negligible when looked at individually, but taken together, they can seriously distort the character or even message of a text. Our text was easily identifiable as a translation.

Table 1   Translation decisions

Source text	Original translation	Suggested translation
Terminological inaccuracies		
Numerous recent reports have convincingly demonstrated the efficacy and tolerability of *biological agents* in the symptomatic treatment of rheumatic diseases.	Viele aktuelle Berichte belegen die Wirksamkeit und Verträglichkeit von *biologischen Mitteln* zur symptomatischen Behandlung rheumatischer Erkrankungen überzeugend.	Die Wirksamkeit und gute Verträglichkeit der *Biologika* in der symptomatischen Behandlung rheumatischer Erkrankungen ist durch zahlreiche Studien überzeugend belegt.
Other reasons given included a history of tuberculosis, good efficacy of current therapy, a history of or current *malignancy*, or the desire of the patient to get pregnant.	Andere angegebene Gründe waren Tuberkulose in der Vorgeschichte, gute Wirksamkeit der jetzigen Therapie, eine überstandene oder aktuelle *Malignität* oder Kinderwunsch.	Weitere Gründe waren Tuberkulose in der Krankengeschichte, gute Wirksamkeit der aktuellen Therapie, eine überstandene oder aktuell bestehende *Tumorerkrankung* oder Kinderwunsch.
1200 patients had consulted *specialized clinics*.	1200 Patienten hatten *Spezialsprechstunden besucht*.	1200 Patienten hatten *Spezialambulanzen* aufgesucht.
Leaving source-language terms		
A *score* of 10 indicates very severe symptoms.	Ein *Score* von 10 steht für schwere Symptome.	Ein *Wert* von 10 steht für sehr schwere Symptomatik.
Unusual collocations		
The course of the disease may range from *mild* to severe.	Die Krankheit kann *mild* bis schwer verlaufen.	Die Krankheit kann einen *leichten* bis schweren Verlauf nehmen.
Overall, 600 patients had *suffered* or were suffering *from* enthesopathies.	Insgesamt *litten* 600 Patienten *unter* Enthesiopathien oder hatten früher unter ihnen gelitten.	Insgesamt *litten* 600 Patienten früher oder aktuell *an* Enthesiopathien.
Unidiomatic translations		
A total of 800 patients surveyed were *considered eligible for treatment*.	Insgesamt 800 Patienten *wurden als geeignet für die Therapie eingestuft*.	Insgesamt kamen 800 Patienten *nach Auffassung ihres behandelnden Arztes für eine Therapie mit Biologika in Frage*.
An *important criterion for considering* the use of biologics is...	Ein *wichtiges Kriterium für die Entscheidung für* die Therapie mit biologischen Mitteln ist...	Ein *wichtiges Entscheidungskriterium für* eine Biologika-Behandlung ist...
Median disease duration ranged from 5 to 10 years.	Der *Medianwert der Krankheitsdauer* schwankte zwischen 5 und 10 Jahren.	Die *mediane Krankheitsdauer* lag zwischen 5 und 10 Jahren.
A score of 0 signifies no symptoms and a score of 10 indicates very severe symptoms.	Ein Score von 0 steht für keine Symptome, *während eine Punktzahl von 10 besagt, dass der Patient unter sehr schweren Symptomen leidet.*	Ein Wert von 0 steht für keine, *ein Wert von 10 für sehr schwere Symptomatik.*
Nuances lost in translation		
One *limitation of our study* is that…	Die *Aussagekraft unserer Studie ist insofern eingeschränkt*, als…	Eine *Einschränkung unserer Studie* liegt darin, dass…
Overall, the results of our study *reflect* the willingness of physicians to prescribe biologicals in a high proportion of their patients.	Insgesamt *belegt* unsere Studie die Bereitschaft der Ärzte, einem hohen Anteil ihrer Patienten eine Biologika-Therapie zu verschreiben.	Insgesamt *zeigt* unsere Studie die grundsätzliche Bereitschaft der befragten Ärzte, einem hohen Anteil ihrer Patienten eine Biologika-Therapie zu verschreiben.

English as the lingua franca of science...

One of the obvious conclusions to be drawn is that every outsourced translation needs to undergo careful revision, particularly when working with translators one does not (yet) know. To yield the best results, every translation should be considered a cooperative effort [1] between the translator and the client or author and, ideally, between a linguist and a subject-matter expert.

Also, selecting a professional translator with a sound linguistic, procedural, and medical background who is capable of reading between the lines to not only translate words but implied meaning is essential. Being among the first critical readers of the source text, a well-versed translator will often spot inconsistencies or point out missing links, providing additional value.

However, I found the unintended switch from English to German remarkable in yet another way.

English–the lingua franca of science

It highlighted many of the challenges non-English-speaking authors face when entering the international scientific arena. For scientists whose native language is not English, one of the first questions is "What language will I publish in?"

In our case, having to publish in German instead of English meant two things: First, it made the paper inaccessible to those co-authors who had no command of German. Second, dissemination of a German paper is limited to a comparatively small language area.

Since the end of World War II, there has been a consistent increase in the proportion of scientific papers written in English, paralleled by a decrease in the use of other languages. What about the role of German in scientific reporting? Isn't the commitment of a journal to publish in a particular national language a step in the right direction towards maintaining multilingualism?

Loss of cultural diversity?

The hegemony of English is an indisputable but oft-deplored fact.

With language and culture so intricately intertwined, many are concerned that the supremacy of English will lead to a loss of cultural diversity. Complex systems are more adaptable to change [2]. Diversity enables society to draw on a large pool of different views, strategies, and behaviours, unleashing society's creative potential and leading to innovation [3]. Losing this diversity may compromise the 'health of human society' [2].

On a socio-political note one might argue that, as vernacular languages cease to function as languages of science, one of the main achievements of the era of enlightenment, that of replacing Latin as the prevailing language of science with the language of the people to enable them to participate in public discourse may be reversed and science may again become elitist [4, 5].

Also, increasing and uncritical internationalization may lead to terms for new concepts simply being unavailable in national languages, degrading our mother tongues to regional dialects used only to fulfil general daily functions, but not in learned speech [4].

While these arguments are most certainly true and relevant, the advantages of one common language of science are obvious.

Lingua franca–not a novel concept

Science has always been dominated by one or few languages. The first centres of learning were located in Greece, and Greek dominated the medical writing of the time. When Greece was absorbed by the Roman Empire in the second century AD, the centres of learning moved to Egypt, and medical texts were translated primarily into Arabic. However, Greek continued to dominate teaching and research for centuries. Between 1000 and 1800, Latin was the main medium of teaching and learning. By 1800, Latin had been replaced almost entirely by local languages. However, having retained a strong Greco-Latin terminological core [6] with a smattering of Arabic, all Western languages of medicine still reflect all of these historical influences.

Throughout history, therefore, dominance in a particular aspect of culture has had direct repercussions on language. In the late 19th and early 20th centuries, German was still a prerequisite language of the scientific community, not least because of the outstanding achievements of scientists like Koch, Billroth, or Röntgen. Medical journals such as *Acta Medica Scandinavica* published articles in German, and the *Deutsche Medizinische Wochenschrift* enjoyed a wide readership in Japan [7].

World War II changed this picture fundamentally, resulting not only in the emigration of much of the German-speaking scientific community, among them Carl Djerassi, Albert Einstein, or Eric Kandel, to name only a selected few. Also, the post-war period was characterized by strong anti-German sentiments and a lack of economic prospects.
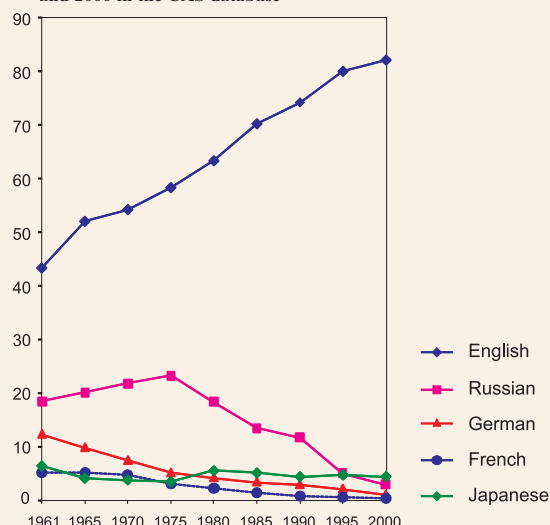
As a result of the rise of the USA to the position of a world power after 1945 and its dominant role in science, favoured, as we have seen, by the political developments in Europe in the first half of the century, publishing research results in English today is the only way to gain wide visibility and to actively participate in international scientific discourse [8].

Increase in scientific papers written in English

One bibliometric study based on information retrieved from the Chemical Abstract Service (CAS) database showed that the proportion of English publications in the area of chemistry increased from 54% in 1970 to 82% in 2000 [9]. At the same time, the proportion of publications in other languages decreased (Figure 1).

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Figure 1 Proportion of major languages in journal papers between 1961 and 2000 in the CAS database

Adapted with permission from Table 1 in [9].

Between 1970 and 2000, the proportion of English publications originating in non-English-speaking countries increased from 31% to 58%. The study also looked at the proportions of English papers originating in a given country. For example, the share of English papers written by French scientists increased from 16% in 1970 to 93% in 2000.

Advantages of a unifying language of science

For readers, the advantages of this development, which is likely to be generalisable to other areas of scientific research, are that more than 80% of publications are accessible to readers with a command of English. As a result, non-English speaking scientists have to learn but one foreign language instead of many, facilitating faster distribution of knowledge and preventing duplication of work [9].

For authors, the use of English means that their research will be available to a much wider audience. The international discussion and exchange this fosters is likely to be a motivating factor stimulating further research [9]. Also, the use of a common language is one prerequisite for international peer-review to function.

Similar figures come from a report by the information scientist Eugene Garfield. In the late 1990s, the Pasteur Institute in Paris decided to no longer publish its *Annales de l'Institut Pasteur* in French, but to switch to English. Whereas in 1973 about 15% of manuscripts had been submitted in English, close to 100% of articles in 1987 were English. What followed was an uproar among both the French media and politicians, with *Le Monde* even proposing that this change sounded "the death-knell for French-language science" [8, 10].

In Germany, Austria, the Netherlands, Belgium, and Scandinavia, decisions in favour of English as the prime language of scientific reporting have also been taken. In Germany, concerned voices have talked about the *Preisgabe eines Stücks nationaler Identität* [11] or 'surrendering part of our national identity' and more recently about the *geistige Selbstkolonialisierung unserer Gesellschaft* [12], the 'intellectual self-colonization of our society'.

In my opinion, the use of a common language of science, one of the few truly universal human undertakings, does not necessarily affect the use of our native tongues.

Science–one of the few truly universal human activities

Fortunately, language does not only play a role in scientific reporting. There are multiple other areas where language is used. Practicing clinicians communicate with their patients in their mother tongue. Clinicians talk to each other in their native language–an environment in which linguistic preciseness is a key prerequisite [7].
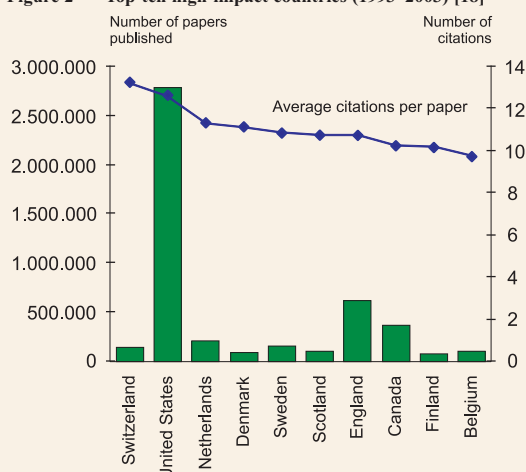
Equally important, vernacular language is–and should remain–the primary medium of education, teaching, and training [7]. Journalism likewise has an important role in communicating science to the general public and translating research into terms the public will understand.

Finally, not all science is dominated by English [13]. Rather, the sciences can be grouped into those relying on English as their lingua franca, such as chemistry, physics, and specific areas of medicine, those that are influenced by English, such as the applied natural sciences, clinical medicine, economics, sociology, and philosophy, and those that are still primarily based on national languages, such as law, theology, literature, or philology [13, 14]. Thus, national languages appear to play a dominant role in those areas of learning that are permeated with culturally determined terms and concepts that escape exact classification and are not easily translatable.

Are English-speaking scientists at a competitive advantage?

Another main argument of the critics of English as the language of science is that native speakers of English are at a clear competitive advantage over those who first have to acquire sufficient skills to report their findings in a language not their own. As a result, non-English-speaking countries carry a disproportionate burden of language training and translation costs, and this is considered unfair [15, 16]. However, are researchers from non-English-speaking countries really at that huge of a disadvantage? For example, based on papers indexed by Thomson ISI [17] between 1993 and 2003, the country ranking highest in terms of average citations per paper is Switzerland (Figure 2) [18]. Even though the US ranks second, it is closely followed by the Netherlands, Denmark, and Sweden.

Figure 2   **Top-ten high-impact countries (1993–2003) [18]**

Adapted from In-cites.com by Thomson Reuters [18]

Admittedly, the hurdle non-native-speakers of English face towards participation in scientific discourse is higher than for people whose first language is English. Yet, as one commentator put it, "science should not be primarily concerned about fairness" [19], which is a political issue. "Science is about achieving the best and fastest results for the lowest cost. So what if some people have it a little easier? [...] You have to bring the disenfranchised up and make sure they have assistance and opportunity" [19].

Increase awareness of the Anglophone world

A number of ways have been proposed to make this happen. One is to increase the awareness of the Anglophone world, including journal reviewers and editors, of the added effort non-native speakers have to undertake to publish in English [16, 20, 21]. The incident I described above bears proof of how complicated it can be to get one's research published when languages other than English come into play.

Wim Crusio, a Dutch scientist who has lived and worked in Germany and France, had to learn German and French to be able not only to get a plumber or do his shopping, but also to teach and participate in scientific discourse. And, he added, "of course I had to learn English in order to survive as a scientist. My occupation [...] has taken me on a fascinating trip to different places and countries and has immensely enriched my life. Still, the casual way with which some native English speakers brush away my 30-year efforts to master their language is sometimes galling" [22].

Increase funding for translation

Yet another way of supporting non-native speakers of English that has been proposed is to increase funding for science translation [19, 20]. Indeed, being cross-cultural communicators, translators are well poised to support authors in getting their messages across cultural and linguistic borders.

English as the lingua franca of science...

As linguistic experts, translators can also take their share in preserving the integrity of the language(s) they work in. They should constantly be on the lookout for the most fitting target-language term or phrase for a particular source-language concept or even coin new terms for new concepts, not giving in to the temptation of uncritically using English terms in translation.

Another responsibility, I believe, translators should take is to adhere to the highest linguistic standards at every level of text production. To fulfil these functions, translators have to constantly challenge themselves to maintain a high level of linguistic competence, to stay abreast of the latest developments in their fields of specialization, and to be firmly rooted both in the source and the target language cultures.

English as a 'relais' language

Even though increased funding for translation will sound like a great idea to all translators, translation is not a cure-all for the challenges of multilingualism. Translation is a relatively slow and costly process. A perfect example is the European Union, founded to bring European countries closer together again in the wake of a war that had shown some of the uglier faces of 'cultural diversity'.

The EU, dedicated to the grand and laudable goal of preserving cultural pluralism and each of its 23 mother tongues, appears to be seriously hampered by its commitment to multilingualism. Today, some 15% of EU staff are dedicated to translating or interpreting, and more than one third of the administrative budget of the EU goes into language mediation. In what is most likely the world's largest translation agency, the backlog of texts that should–but perhaps never will–be converted into each of the 23 EU mother tongues is increasing [23, 24]. And every newly added language makes this process more tedious and costly [25].

An additional challenge is to find translators in some of the rarer language pairs, such as Finnish-Greek or Lithuanian-Italian. One way of solving the language pair problem is the use of English (or French) as a 'relais' language, with some of the 'smaller' EU languages first translated into English and then into other 'small' languages [11].

This concept brings us right back to the importance of a lingua franca in a multilingual world.

What's the cost?

Yes, transposing words, concepts, meaning, and thoughts between languages and cultures–no matter whether through translation proper or, more generally, by people with different mother tongues simply wanting to talk to and understand each other–takes both time and extra effort. But in today's 'global village', this challenge is here to stay.

Bilingualism–having a sound and solid command of one's mother tongue and a good command of English–does not appear to complicate but to simplify matters.

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It has been commented that "the fundamental unfairness of the system seems surprisingly acceptable to the international community" [21], suggesting that this may be because non-native English speakers have themselves already invested considerably in the learning and use of English and do not want to surrender this advantage [21]. I would like to attempt a different explanation.

What's to gain?

Most non-English-speaking scientists publishing in English may not see learning and using English (or any other language) as a disadvantage, but as something that enriches their professional and personal lives. The European Union puts it this way: "The ability to understand and communicate in more than one language—already a daily reality for the majority of people across the globe—is a desirable life-skill for all European citizens. It encourages us to become more open to other people's cultures and outlooks, improves cognitive skills and strengthens learners' mother tongue skills" [26].

This also brings to mind a more than 20-year-old quote by Eugene Garfield: "... the French language is not threatened by French scientists who publish in English or any other language. It is the complacently monolingual English-speaking world that needs to worry. By not learning foreign languages, it risks being left out of the conversation in an increasingly global and multilingual business community" [8].

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Out of office reply

All official road signs in Wales are bilingual. The Swansea local authority was keen to stop heavy goods vehicle using a road near a supermarket. They decided to erect a sign which would state in English, "No entry for heavy goods vehicles. Residential site only". The in-house translator was asked to produce a translation. The request was sent to him by email. Naturally when the authority received a reply to the email they assumed this was the translation they needed, so they had the bilingual sign made and erected. It had not been standing long before someone pointed out that the Welsh read "I am not in the office at the moment. Please send any work to be translated."

Bad translations from English into Welsh are apparently quite common. A Welsh magazine Golwg collects examples which have included a road sign for cyclists telling them they had problems with an 'inflamed bladder' and one for pedestrians in Cardiff which read 'Look Right' in English and 'Look Left' in Welsh.

The managing editor of Golwg thought that one of the problems is that everything is first written in English and then translated, whereas a better approach would be to create the signs in both languages separately.

Source: http://news.bbc.co.uk/2/hi/uk_news/wales/7702913.stm

How optimal can you get?

I have always questioned the words *optimum* and *optimal* where *best* will do the job just as well, and have come to live with the fact that many prefer the polysyllabic solution. The following, however, went too far:

Such adjudication is almost certainly more accurate than reliance on administrative healthcare databases, although a combination of both techniques is probably more optimal than either technique used alone.

Optimal is the adjective formed from the word *optimum* and means 'best or most favourable' [1]. So this author had actually written *is probably more best than*.

This is a clear case where *better* was better than *more best*.

Alistair Reeves
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Reference:
1. Pearsall J, Trumble B. *The Oxford English Reference Dictionary*. Oxford: OUP, 1996.

Say no more!

So far, this receives my Worst Sentence of 2008 Award (others may yet supersede this one!):

Finally (imagine what came before!–AR)*, the 'correlate' model between level of HI antibody in serum and protection of a population, while indirect, seems not to be so appropriate in older adults and immunocompromised populations; consequently, it is not surprising that some authors relying on comparative antibody measures and low performance of the HI test compared to others and a recently updated literature review on the difficulty of interpreting serological responses in the elderly concluded that it may not be relevant to use HI serological outcomes as a surrogate measure for clinical protection in the elderly.*

Here is a close second:

Table 35 summarises respectively the worst-ever grades of all adverse events reported at any time during the entire study.

Both came from 'native speakers'.

Alistair Reeves
a.reeves@ascribe.de

The event was treated with cortisone ointment

And I hope the event recovered—but what about the patient? 'English as she is spoke' interfered here: it is certainly not how 'she' should be 'wrote'.

Alistair Reeves
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Would anyone notice if you died at your desk?

I did not feel particularly privileged to be among the more than 100,000 recipients of an email containing the tale of George Turklebaum. Friends and colleagues are aware of my interest in medical writing. The email reported that George was proofreading a medical textbook when he died at his desk. At the time he had been employed at a New York publishing company for more than 30 years. He died aged 51 years of a heart attack on a Monday but the surprising thing was that none of his work colleagues noticed that he had died until 5 days later on Saturday morning when an office worker asked him why he was working at the weekend. Elliot Wachiaski, his boss, said of George that he "was always the first guy in each morning and the last to leave at night, so no one found it unusual that he was in the same position all that time and didn't say anything. He was always absorbed in his work and kept much to himself". The report I was sent ended "The moral of the story: Don't work too hard. Nobody notices anyway."

This incidence was reported in such reputable organs as the *Daily Mail* and the *Guardian*, where it was published on 17 December 2000. However, the original report seems to have been on 5 December 2000 in *Weekly World News*, which according to David Emery writing on About.com Urban Legends [1] is a supermarket tabloid renowned in the USA for such scoops as human females being impregnated by aliens. Emery does not believe a word of the story and points out that the corpse would have given off a strong aroma after 5 days. This is not to mention that nobody by the name of Turklebaum is listed in the New York City white pages. Nevertheless the tale plays on the fear they we are ignored and unappreciated at work and it's interesting that a medical proofreader was chosen to exemplify this scenario, isn't it? There was a subsequent report in the BBC that a tax office official who died at his desk in Finland was not found by his colleagues for 2 days [2].

1. http://urbanlegends.about.com/cs/horrors/a/turklebaum.htm
2. http://news.bbc.co.uk/2/hi/europe/3410547.stm

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