
The Write Stuff

The Journal of the European Medical Writers Association

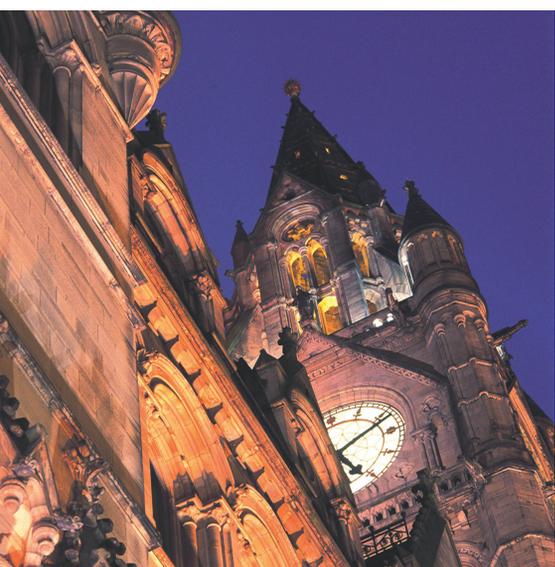
Greetings from Malta





7th Autumn Meeting

Radisson Edwardian Hotel, Manchester, UK.



Your Executive Committee has the pleasure of inviting you to the 7th autumn meeting in sunny Manchester on the 24th to the 26th of November 2005.

Originally founded in the 1st century by the Romans and named *Mamucium*, Manchester became a city of renown during the industrial revolution at which time it was considered the heart of the British Empire. As a thriving metropolis, which still produces more than half of Britain's manufactured goods and consumables, Manchester has acquired a mixed reputation. However, recent international events of some acclaim, such as the success of Manchester United, the 2002 Commonwealth Games and the soon to be held EMWA Autumn Conference are raising the profile of the city.

Our conference will be located at the Radisson Edwardian. A hotel ideally suited to combine the learning and networking opportunities available at the EMWA meetings with the cultural delights Manchester has to offer.

The programme of workshops will cover many aspects of medical writing, and will also include some of our new Advanced workshops. Keep an eye on our website (www.emwa.org) for regular updates and further details.

If you are looking for premier educational experiences for medical communicators the Manchester meeting holds great promise with the added attraction of discovering what the city has to offer.

I look forward to seeing you there.

Ian Metcalfe
Vice President, EMWA

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Journal insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued 3 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.

Articles or ideas should be submitted to the Editor-in-Chief (see back cover) or another member of the Editorial Board.

Subscriptions

Subscriptions are included in EMWA membership fees. 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 500 - 1500 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 electronically on computer diskette or by email as an MS Word file using Arial font (or equivalent), 11 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style).

Back issues

Subject to availability, previous issues of **The Write Stuff** can be obtained for the cost of mailing by contacting the EMWA Head Office (see back cover for address).

Advertising rates (in euros, €)

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Freelance members only

- Full page €200
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Cover picture

We thank Crispin Hodges for this photo from the 14th Annual EMWA Conference held in Malta on 17-21 May 2005.



From the editor's desk: Why the theme consent and plagiarism?

By Elise Langdon-Neuner

The answer is because both are beset with misconceptions.

Plagiarism misconceptions

I was flabbergasted¹ by the answer to a reader's question in the letters-to-the-editor section of a writer's magazine. The reader was told that he could use information from the Internet without qualms – or the author's permission for that matter – because the author by placing it on the Net had relinquished it to its fate in the public domain. This is a commonly held misconception. The fact is that probably all you can safely do is merely look at the Internet and identify a URL site or link it to another Internet site. The article in this issue of TWS by two lawyers who specialize in copyright puts this straight and provides an invaluable practical guide to copyright for writers.

Another important resource for medical writers is the ICMJE guidelines at <http://www.icmje.org/#copyright>. By-the-way like the increasing number of "open access" journals mentioned there TWS does not require authors to transfer copyright to the journal. The draft educational guide on avoiding plagiarism sponsored by the US's Office of Research Integrity (ORI) is also useful. It is an attempt to help students and professionals identify and prevent plagiarism and inappropriate writing practices as well as to develop an awareness of ethical writing [<http://facpub.stjohns.edu/~roigm/plagiarism>].

One such inappropriate practice is cutting and pasting from the Internet. Not only students but even the most well-meaning authors may not see the harm in using other people's words, or ideas behind their words, without attribution. Cultural viewpoints also play a part. Cheating in exams in Austria is for example considered canny, as long as you are not caught. Even then the consequences are mild. Another perspective is illustrated by an incidence at a diabetes journal I worked on. An author complained that a paragraph in a paper we had published was lifted from his work. We took this up with the author of our published paper. From his name I assume he was Chinese but his address was in the USA. He bitterly countered our enquiries by accusing us of discriminating against non-native speakers.

While authors might be relied upon to detect plagiarism of their work by others this is not the case where authors plagiarism themselves by reusing their own text without reference to their previous publication. In such self-plagiarism or duplicate publication the author might republish anything from the whole paper or passages of text with additional data, which is known as salami-slicing. I was asked lots of questions on the topic at our Malta conference. The question of how much material can be legitimately reused is not settled. Some journals have laid down a limit of 30%. Such limits do not help when it comes to 'intelligent plagiarism', which is where the content is similar to that published before but the words are different. An article published this May in *Nature*, 'Taking on the cheats' outlines publishers' concerns about duplicate publication and how they are starting to fight it [1].

1 See vital signs for glossary

From the editor's desk

Bandolier considered the problem on its site [<http://www.jr2.ox.ac.uk/bandolier/band123/b123-6.html>]. It refers to a *JAMA* study that found one in 12 papers to be a duplicate and of them one in 20 to have no cross-reference. Bandolier is a ferociously independent resource of what constitutes good scientific evidence, written with a touch of humour. Their discussion of the legitimate reasons why duplicate publication can occur includes for instance "if an important paper were originally written in Welsh, a translated version might be appreciated by the few of us who are not fluent in Welsh". Acceptable republication of your own work apart from translations, includes prior agreed electronic publication, previous presentation at a meeting or publication of an abstract, and of course referenced republished work.

Informed consent misconceptions

From the Incident Reports made to the US's Office for Human Research Protection between January 1990 and August 2000, 44% involved adverse events. Problems with informed consent constituted 34% [2]. Misconceptions about consent requirements are highlighted in an article on reporting of informed consent in anaesthesia journals [3]. Consent was only obtained in 66% of the 1,189 publications studied. Researches often do not understand that consent is required for standard treatments, case reports and even emergency situations, where retrospective approval should be sought.

A series of four articles in this issue tackle the practicalities of writing patient information leaflets, including those for children. You might think it is stating the obvious to say that all the required information has to be put into language that the patient will understand. Yet patient information leaflets are often incomprehensible. Adam Jacobs in his view from the ethics committee gives the need to rewrite the patient information leaflet as the most common reason for applications being sent back to investigators by his committee. This fate is unlikely to befall Simon Parsons whose EIDO Healthcare company is the first group to earn the Plain English Campaign's Crystal Mark for 150 separate patient information consent documents. Plain English have a glossary for translating medical terms into ordinary words at <http://www.plainenglish.co.uk/medicalguide.html>.

Wendy Kingdom ponders the difficulty medical writers face in becoming so infected with clinical report jargon as to be blithely unaware that other equally intelligent people might not be familiar with it. A patient's comment in an article about barriers in healthcare brings home the problem, "they talk to you like you don't know and understand as opposed to taking the time to make sure that they're speaking words that you could understand and could feel comfortable with" [4]. It could be called 'police talk' of the type coined by Richard Clark in his article in this issue on gobbledegook. But it is we who are in the dock on this one. We need to step back and put ourselves in the patient's shoes.

More plagiarism

Even as a child I saw medicine as closely connected with ghosts. A visit to the village doctor held more in store than merely being told that I had tonsillitis yet again. Our local GP had an all-engaging hobby. He cavorted with ghosts. He saw them on horseback riding down the railway line and gliding in long white dresses in the church. He took up battle with poltergeists. His stories were captivating. I still cannot resist ghost stories and there is one in this issue of TWS. Susanna Dodgson's *Over the pond* article argues that ghostwriting is a form of plagiarism. The question I have always asked about ghostwriting, be it an autobiography or scientific manuscript, is why an 'author' doesn't simply

admit that someone else has done the writing for him or her? I have yet to find an answer to this question that does not involve deliberate deceit and intent to mislead.

Mass media distortions

The value of a free press in rooting out misconceptions is a beacon in a free society (admittedly not always seen as a convenient one). Alas not all journalists reporting medical research in the mass media take up this gauntlet.

Nobody could accuse Roy Moynihan of being among the reticent when it comes to pointing this out to his fellow medical journalists. In 'Making medical journalism healthier' [5] he summarised evidence that mass media coverage looks more like industry promotion than journalism. One study found that manufacturer's press releases were cited twice as often as biomedical journal articles. Many stories overstate benefits of drugs and fail to mention adverse effects or study limitations. Moynihan speculated the reason for this is the deluge of promotions pharmaceutical companies shower on press offices, and prominent coverage of preliminary research presented at conferences. He suggested it would be more effective to produce questions for journalists to consider than write guidelines for them to follow.

The biggest ructions in recent medical journalism in the UK, the MMR (measles, mumps and rubella vaccination) controversy, was launched onto the media roller-coaster by Andrew Wakefield's comments at a press conference preceding his study's publication in the *Lancet*. His study suggested a link between the MMR and autism. He commented that parents should be able to choose single vaccines for their children rather than the combined MMR. The coaster came to rest when Brian Deer, working for *The Sunday Times*, asked questions and uncovered Wakefield's conflict of interest. Wakefield had been paid by the Legal Aid Board to investigate children who were allegedly damaged by the MMR vaccine. At the end of the day Richard Horton, editor of the *Lancet*, admitted that he had failed to manage media reaction sufficiently. He said medical journal editors have a duty to make sure that the context is responsible [6]. Context and the journalists' challenge to question rather than regurgitate information fed to them is taken up in this issue of TWS by the science journalist Paul Haines in his article 'Countering distortions'.

Elise Langdon-Neuner

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6. Joanna Lyall. Editor in the eye of a storm *BMJ* 2004 328; 528.



Message from the President

by Michelle Derbyshire

I am pleased to announce that our recent conference in Malta in May was a resounding success with a record number of attendees. The conference saw the successful launch of the advanced education programme, tailored to more experienced medical writers, thanks to all the hard work of our past education officer, Wendy Kingdom, and the education committee. Malta also saw the launch of a new concept of 'alternative events', such as discussion forums. This is a theme we hope to continue in our forthcoming conferences to expand what EMWA has to offer its members.

One other change that was successfully implemented was that, at the Annual General Meeting (AGM), the members voted into existence the new EMWA based in Switzerland. This change means that the work of the Head Office, also based in Switzerland, will be streamlined, making payments much easier and faster. The new constitution calls for many more decisions to be voted on by the members at the yearly AGMs. The members will consequently have much more say on any important decisions made within EMWA. After all EMWA is run by the members, for the members. This makes it more important than ever for you to attend the yearly AGMs or use your postal vote.

Looking to the future, EMWA is thriving and increasing its number of members every year. Suitable conference venues are however harder to identify for larger numbers so we are looking to book our conferences further in advance. Traditionally it was the job of the vice-president to identify and book the spring conference venue for the following year immediately after his or her election. But now with our advanced planning I am pleased to say that most of the groundwork has already been carried out for spring 2006. The venue in Lyon has been identified, and preparations are also underway to finalise the venue for autumn 2006 in Brussels. Planning further ahead means that we have more venues to choose from and can provide the best possible venues and value-for-money for future EMWA conferences.

I look forward to seeing many of you at the Autumn Meeting in Manchester.

Michelle Derbyshire

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The Executive Committee voted into office at the 14th Annual EMWA Conference held in Malta on 17-21 May 2005.

From left to right: Kari, Virginia, Wendy, Elise, Julia, Ian, Michelle, Adam, Marian and Kelly. Shanida Nataraja's delightful short report of the Malta conference is at www.emwa.org in the members' section.

Too many emails?

Apparently the Institute of Psychiatry (IoP) at Maudsley, Kings College, London have discovered that the distraction of emails and telephone calls cause an average IQ drop by 10 points. Does this mean that all those colleagues who constantly complain about receiving screens and screens of emails are the most stupid amongst us?

Of course sometimes it's our own fault. We pass on chain letters. If you receive an email with "Send this email to everybody you know" it is probably a hoax. More details of how to recognise a hoax, chain letters, urban myths and other bogus information on the Internet can be found on the Hoaxbusters website <http://hoaxbusters.ciac.org/HBHoaxInfo.html#identify>.

A calculation on this site shows if everybody on the Internet were to receive one hoax message and spend one minute reading and discarding it, the cost would be something like:
 $50,000,000 \text{ people} \times 1/60 \text{ hour} \times \$50/\text{hour} = \$41.7 \text{ million}$

The Webscout is taking time out for this issue but will be bouncing back in December. If you have any useful URLs please contact Joeyn Flauaus at joeyn@trilogywriting.com



Are you good at writing information for patients?

by Wendy Kingdom

A fundamental principle of informed consent is that the patient should be able to understand the language that is used to inform them about the study (ICH E6 4.8.6). In my opinion, we are not very good at this.

Patients do not have to understand how to do the study

Most of us spend our time writing documents that are to be read by colleagues, investigational site staff, ethics committees, regulatory authorities and anyone else who might be interested in pharmaceutical medicines or devices. We work to tight deadlines and it is often during the panic between protocol review and deadline for submission to the ethics committee that someone suddenly remembers that the patient information leaflet (PIL) and consent form must be attached to the protocol. Incidentally, if anyone can explain why a document that takes up a minimum of 6 pages is referred to as a patient information sheet (yes, sheet singular as in one sheet), please let me know.

To get back to the point, the PIL is often written in a hurry. This is the first reason, though not a good reason, why we are not very good at writing PILs. Before we start, we need to take some time getting into the mindset of the patient, which should be easy. Let us pretend that we are going to write a PIL for a study of a new treatment in patients with mild to moderate asthma. Start by pretending that you have gone to see your doctor because you have used up three inhalers of the sort that was prescribed for you last

Patients need to be told what the study involves for them

time but in the last few weeks you have been short of breath after walking up one flight of stairs. Your doctor says, "Ah yes. Now, I am conducting an interesting little study in a new treatment for asthma." What questions will you ask? If the first question you would ask is, "Who is sponsoring the study?" this isn't going to work. You are evidently too entrenched in the pharma industry. So, you need to step further back. Perhaps try imagining that it is not yourself who is unwell but a close relative or friend. What questions do you think they will ask? I believe the typical questions people ask are:

- How much time will it take?
- Will the treatment make me better?
- What are the side effects?
- Will the tests hurt?

Do you get the idea? Not many people will ask, "What is my percent of predicted FEV1?" or, "Please explain the impact that diurnal variation has on my spirometry data."

This illustrates the second reason why we are not very good at writing patient information; what is important to the patient is not necessarily important to us, and vice versa. When we come to write the section in the PIL on the study procedures we must bear in mind that the patient does not have to understand how to do the study. I'll say that again in a minute to emphasise the point. The patient has to turn up for visits and must allow the investigator to do tests. The patient has to take the medication as instructed. The patient has to answer questions, perhaps complete a questionnaire, maybe keep a diary. In other words, what the patient has to do in the study is not at all what the investigator has to do. Therefore, patients must be given information about the study that tells them what the study will involve for them. You cannot achieve this by copying the overview of study design section of the protocol into the PIL because this section of the protocol tells the investigator how to do the study. There are many differences between taking blood from someone and having blood taken from yourself. Which would you rather do (or have done) and why? The answers to these questions help to build up the picture of what the study means to the patient.

Once the writer understands that the patient is not the investigator and does not have to understand how to do the study, the rest starts to fall into place. A writer once asked me how I explain diastolic blood pressure in a PIL. I didn't know how to answer the question immediately because I couldn't work out why anyone would want to explain diastolic blood pressure to a patient. Where would it end? Do we need to draw a diagram of the heart and circulation system so that we can explain systole and diastole? Should we explain about how a sphygmomanometer works and how to recognise Korotkoff sounds? I doubt it. I have yet to see a PIL rejected by an ethics committee because a medical procedure wasn't explained adequately in medical and scientific terms. If you must mention it, "the lower of the two numbers" is probably sufficient, but perhaps of more relevance to the patient is that when the cuff is inflated, it is uncomfortably tight.

***We should not assume
all patients are idiots***

Choose one of the following: Carpal tunnel syndrome is A) when the protective sheaths around the tendons become inflamed, putting pressure on the medial nerve or B) pain in the hands and wrists. Now, I accept that B is not sufficient for a physician to make a diagnosis, but we are not writing a medical dictionary or a physicians' training manual on carpal tunnel syndrome. We are writing a PIL, and so we should be giving patients an idea of what side effects they might experience with this new treatment.

This is not to suggest that we should assume that all patients are idiots. The point is that the patient's education may be in another area and that they may not know the vocabulary. If we do our job well, the highly educated, intelligent patient will understand all of the information without feeling patronised, while the less well educated patient will understand enough about the study to make an informed decision, even if they can't place the information in a meaningful context.

Medical jargon is not the only area where we slip up. Some sections of PILs read as though they were written by company lawyers with the objective of protecting the company from being sued. We see language such as, "Your medical records may be subject to scrutiny by representatives of the competent authorities." If this were not real, it would be funny. If I was reading something and you wanted to read it when I had fin-

Patient information

ished with it, would you say to me, "I should like to subject that document to scrutiny when it becomes available?" I think not. I would expect something more like, "May I read that when you have finished with it?" In reality, you would probably say, "C'n I see that?" However, the word "clinical" has several meanings, including describing something as efficient, functional, clean. The patient must have confidence in their doctor and they must have confidence in the study, and this will not be achieved by using sloppy language or slang when we write.

The principles of Plain English include using short words and short sentences, though not so short as to be abrupt. More important than the length of a word is its familiarity. If you are unsure, read a couple of tabloid newspapers, or magazines. These are not brilliant examples because they do use slang, but they also provide a good guide to words in common use and sentence length.

Some PILs read like lawyers trying to protect companies from being sued

You should try and be concise with your language. Do not say "subject to scrutiny" when you can say "read" or "seen". If your PIL is too long, you must not make it look shorter by making the font smaller. This just excludes older patients from being able to read it. I would argue that this is unethical, because patients who do agree to

take part in a clinical trial probably just want to please their doctor and don't think it's worth the effort of trying to read the information. For you young things out there, Times New Roman 11 font might be legible when you're in your 20s and 30s, but it becomes progressively less legible with each decade thereafter. It is up to you to use your language well. It is not up to the patient to get a magnifying glass and a headache.

Without patients, there would be no clinical trials. Without clinical trials, there would not be any new medical treatments. Without new medical treatments, there wouldn't be a pharma industry and we would all be doing a different job. So we would like to invite patients to take part in our clinical study and we owe it to them to ask them politely, considerately, and in language that they can be expected to understand.

Wendy Kingdom

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Note from the Editor

Wendy Kingdom is the leader of a workshop entitled 'The Clinical Trial Patient Information Leaflet'. This workshop was not available at the EMWA conference in Malta in May 2005 because of lack of interest at previous conferences. Wendy is still battling to convince people, particularly native English speakers, that they can benefit from such a workshop.

For those of us who would never ask what their FEV1 is because, like me and the EMWA member who copyedited this article, they are not one of those people who write protocols mentioning a FEV1, the abbreviation means 'forced expiratory volume in one second'.



Patient information leaflets: Writing for children and adolescents

by Virginia Watson

Children and young people recruited into clinical trials need to be provided with information about the study and, if deemed old enough, will be required to assent to participation. Indeed, parents and physicians should not exclude children and adolescents from decision-making; all people involved in children's healthcare should listen to children [1].

The ICH E11 Guideline states that fully informed consent should be obtained from the parent or legal guardian but also states that "participants should be informed to the fullest extent possible about the study, in language and terms that they are able to understand". In 1995, the American Academy of Paediatrics issued a policy statement that "a patient's reluctance or refusal to assent should also carry considerable weight when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk". The Declaration of Helsinki also includes a statement on the need for the "minor's consent to be obtained in addition to that of the minor's legal guardian".

According to the ICH E11 age categories, children are aged 2 to 11 years and adolescents are aged 12 to 17 years. The age for assent is usually determined by the IRB/Ethics committee and local legal requirements, but in practice, for the purposes of providing written medical information to children for assent to a trial procedure, we are probably looking at those children aged six and upwards. This is a very broad age band and range of intellectual development. Often one Patient Information Sheet (PIS) is produced for children aged 6 to 11 years and one for the 12- to 16- or 18-year-olds. Nevertheless, if you think about it, what is written for a six-year-old is unlikely to be suitable for the average 11-year-old. Having said that, I have been told that when informed consent forms are written for both children and adults, many adults read and absorb the information from the children's PIS!

Children's understanding of illness and hospital is different from adults'

Are children old enough to give assent? Several surveys suggest that a young child will do what Mummy and Daddy think best; a 9-year-old will want to have a say but will leave the final decision to their parents; and young people of 12 and upwards want to have some degree of control and input into the decision.

So what should we as medical writers consider when producing patient information for children and adolescents? First and foremost it is important to think about the needs of the children we are writing for. What does the reader need to know and how should we present it?

Children's understanding of illness and hospital is very different from that of adults. In

1 article 12 of the UN Convention on the Rights of the Child

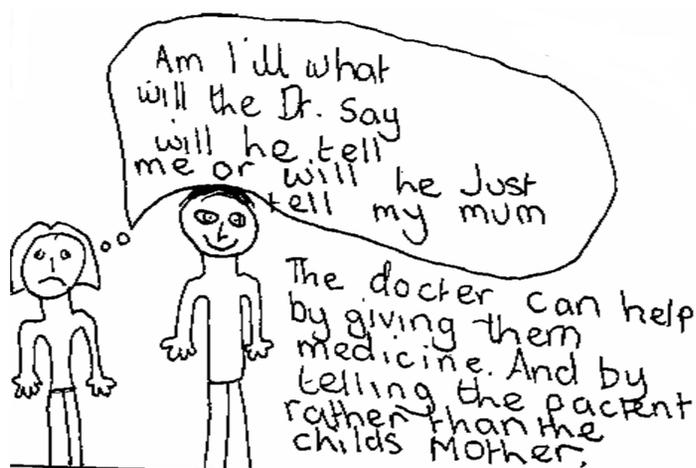
Patient information: children

1995, a project in 254 children was conducted in the UK by Action for Sick Children, a charity to improve the standards and quality of child healthcare. It emerged from this survey that the main concerns in children were

- What will they do to me and will it hurt?
- Will I get better?
- How long will it take?
- What will the doctor or nurse be like?
- Will the doctor talk to my mother/father – why not tell me what is going on?
- What am I missing: school, holidays, friends?
- Will it embarrass me?
- Will it help to cure others?

There is also a tendency for children to feel that it is their fault that they are ill: that, somehow, they are to blame.

The adult PIS contains all the GCP elements and so not all these points need to be covered in the children's assent information. Before starting to write, decide the age range for each of the information sheets you are writing.



Maybe you will decide on one for the 6- to 8-year-olds, one for those aged 9 to 11 years, another for 11 to 14 years and one for the 15- to 18-year-olds. Next, think about the information you need to impart and how to address the children's concerns, remembering also that some of the older participants may be smoking, drinking, abusing drugs and may be sexually active. Also, it is important to realise that a child's perception of time is different from that of an adult, so try to relate study visits to periods of time that mean something to them such as the school term, holidays, after school, etc.

Then, I would suggest you look at examples of material written for children/adolescents of that particular age group – comics, books, etc. Look at language used in TV programmes, videos and on websites. Use clear language. Think about the number of sentences per paragraph and page – these will vary according to the age you are writing for. For young children use short and simple words, for adolescents try to use words to which they can relate.

You don't have to use A4 paper; A5 is a better size for children to handle. Think also about the presentation style – don't use font size 12, go for 18 or 20 and Arial or Comic sans are more suitable font types. There is nothing to stop you using colour print. Although illustrations, cartoon characters and comic strip presentation may be an effective means of communicating medical information to children, I would not regard these as appropriate in the context of the PIS for a clinical trial. As with adults, consider any

cultural issues that you may need to cover and, most importantly, avoid information overload. Also, don't be patronising or talk down to them, whatever the age of the child.

Writing for children does mean adapting your style of writing and thinking very carefully about your reader. It certainly requires the ability to use Plain English. It does, however, add an interesting dimension to our work as medical writers.

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Note: The child's drawing pictured in this article is republished with permission from the book 'Pictures of Healthcare – a Child's Eye View' published in 1998 by Action for Sick Children. More information about this charity, which seeks your support, can be found at www.buy.at/a4sc.

CALL FOR WORKSHOP LEADERS

Would you like to contribute to EMWA by developing and running a workshop?

The EMWA Professional Development Committee (EPDC) would like to expand the range of workshops offered at the Annual Conference and November Meetings and are inviting proposals for foundation, advanced and short workshops.

All topics are welcome but we are also looking for workshop leaders for the following:

- Developing Research Materials into Articles
- Grant Writing
- Scriptwriting for Multimedia
- The Investigational Medicinal Product Dossier (IMPD)
- Writing About Health and Medicine for Magazines
- Writing Abstracts

If you would like to submit a proposal for a workshop, or are thinking about it, but would like to know more, please contact me or any member of the EPDC (www.emwa.org).

The Workshop Leaders' Handbook contains information on workshop format, workshop approval, templates, train-the-trainer training, expenses and other matters of interest to workshop leaders. A member of the EPDC will act as a mentor and provide support during the development of your workshop.

New ideas for workshops are welcome at any time, even if you do not wish to be a workshop leader yourself – you might also wish to suggest a leader.

Virginia Watson

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Informed consent for patients: The process

by Simon Parsons

Over recent years informed consent has changed dramatically. Previously the health profession used the paternalistic approach. The doctor made the decision on behalf of the patient and the patient seemed to have little say in the process and was merely asked to sign the form to agree to have the procedure performed upon them.

Experiences from Bristol Royal Infirmary and the enquiry that followed, have taught us that this paternalistic approach is no longer acceptable. The Department of Health's "Reference Guide to Consent for examination or treatment" makes this clear; it states that "acquiescence where the person does not know what the intervention entails is not consent".

Recent guidelines produced by the GMC, Department of Health and other governing bodies give succinct guidance that patients

- must be given sufficient information in a way that they can understand in order to enable them to exercise their right to make an informed decision about their care
- need up-to-date written information to support this process of consent, and they
- need sufficient time to make that decision.

In practice, the guidelines should ensure that patients receive information about the benefits and risks of the proposed treatment and alternatives to the proposed treatment. Discussion of complications is essential for the patient to make their own judgment on whether the procedure is right for them.

Empowering the patient

The healthcare profession is moving towards a partnership between the patient and health professional where there is an open and free provision of accurate and up-to-date information for the patient provided in a timely manner. This will facilitate an open and honest relationship between health professional and patient and will empower the patient, enabling them to choose the most appropriate treatment option whilst being guided and supported by the healthcare professionals.

The process of informed consent

The process of informed consent must begin much earlier in the patient pathway, so that patients are not suddenly presented with all the information on the day of treatment. Hospitals are moving towards beginning the consent process in the outpatient clinic with treatment-specific patient information being given to the patients when treatment is recommended. The patient is then put on the list for treatment; during the waiting time, there is opportunity to consider the information thoroughly and perhaps to discuss it with family, friends and perhaps the GP.

The patients will then return to the pre-assessment clinic and this is an ideal time for the health professional trained in consent (usually the person carrying out the procedure) to go through the patient information and confirm the consent with a signature on the new Department of Health consent forms.

Thus when the patient is admitted for their treatment, the consent has already been taken and this need not delay the various processes that have to take place on the day of treatment.

From the medico-legal viewpoint, it is essential the information given to the patient is documented in the clinical notes. Just as importantly, the patient information must support the clinical consultation, improving the efficiency of that consultation and the health professional's relationship with the patient.

Primary care in the process of informed consent

As many diagnoses are made in primary care, it would be optimal if information about treatment options for a particular condition were provided to the patient by the GP. The patient would then have time to read the information prior to their visit to hospital or treatment centre and move seamlessly into secondary care with consistent and appropriate information being given at each stage.

This depends on two factors: firstly that the diagnosis is correct and secondly that all the health professionals agree the information (ideally produced centrally but adapted to the local setting).

Ideal information for consent

So what information represents the ideal patient information to support the consent process? Recommendations from the GMC, Department of Health and Bristol enquiry have made it clear that there needs to be an explanation of:

- the problem or condition
- the treatment options available, including the alternatives to the proposed treatment
- what the proposed treatment involves, including diagrams
- the risks and complications
- the benefits
- post-operative expectations

Information must be easy to read and understand. In the UK and other English-speaking countries, achieving the Plain English Campaign's Crystal Mark status on each information document is a good indicator that the information can be understood by most people at first read.

Information must be evidence-based with the evidence regularly reviewed and the information updated accordingly. There are a number of very good sources of high quality evidence-bases such as the Cochrane Library. It is best for research-trained clinicians who communicate regularly with patients in clinics (as opposed to research methodologists who often have minimal, if any, patient interaction) to review the evidence and decided what to include in patient information documents.

Information must be updated regularly and be date-stamped to indicate when the infor-

Informed consent process

mation 'expires'. It is often surprising how quickly treatment options and technical aspects of treatments adjust.

The patient should also be provided with local contact details should they have any questions or concerns before and after their treatment. They should also be aware of specialist services (for example, services for impaired sight or hearing). Furthermore, it is beneficial for patients to have pointers to sources of further information such as validated Internet sites and organizations that provide support for their condition.

The role of the medical writer

Medical writers have a role but their role should be considered carefully. It is often inefficient for the medical writer to develop informed consent patient information 'from scratch'. Their role should be focused on structural editing, subediting and proofing. In all the development stages, the development co-ordinator should involve the expert clinician on a regular basis to ensure the technical integrity of the information is maintained. This may be a different approach to 'normal' medical writing but bear in mind that the end product in the context of informed consent will be used as a risk management tool by hospitals. Any responsible provider of medical care will want evidence of professional indemnity insurance which will, in turn, demand technical expert involvement and sign off.

Involving patients

Patients should be consulted and their needs addressed. It is worth noting that the rigorous guidelines mentioned in his article have for the most part been developed following intensive research into patients' information needs, such as the research work done by Dr Angela Coulter at the King's Fund. However, on a regular basis, patient representative organizations, patient charities and individual patients should be asked to review and comment on patient information documents to ensure their needs, in the context of the consent process, are fully met.

Conclusion

Regulatory guidelines and medico-legal pressures are providing the impetus to patient empowerment. At the centre is the informed consent process that relies on the provision of high-quality treatment-specific patient information.

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EIDO [www.eidohealthcare.com] specialises in products and solutions that improve the doctor-patient relationship, reduce the risk of litigation and increase patient satisfaction.

Acknowledgement: Owain Tudor, Director and Head of Product Development, EIDO Healthcare contributed to the article.



Patient information leaflets: The ethics committee view

by Adam Jacobs

I have been a member of a research ethics committee for about two years now, and while this does not make me an expert on medical ethics, it has given me a pretty good idea of what makes the difference between a good ethics application that will sail through the committee at the first attempt, and a poor application that will be sent back to the investigators for extensive changes, or worse, rejected completely.

There are of course many factors that distinguish the good from the bad, but there is no doubt whatever in my mind what the single most important factor is. Contrary to popular belief, it is not whether the research is ethical. Most clinical investigators understand what is ethical and what isn't, and are usually at least as keen as the ethics committee to avoid exposing their patients to unjustifiably risky trial procedures.

No, the single most common reason why we send applications back to investigators is because they need to re-write the patient information leaflet (PIL). Everything Wendy says in her article elsewhere in this issue is true. Many PILs are extremely badly written, and include far too much medical jargon. Not only that, but often the risks of a study are not explained at all. All research has risks, and only a fool would pretend that he or she is running a risk-free trial. The important thing is that the risks be proportionate to the expected benefits, and the even more important thing is that the risks be explained honestly to the patient. Patients cannot give informed consent if they have not been informed about the possible risks. This doesn't mean you have to scare patients with a long list of rare side effects, but it does mean you have to be honest. Guidance for writing PILs is available from the COREC website (www.corec.org.uk).

One thing that has surprised me, is that PILs in industry-sponsored studies appear to be far worse than those in investigator-led studies. Before I joined the ethics committee, I had assumed that pharmaceutical companies would be able to afford to pay medical writers to write their PILs and that they would therefore be wonderful, but this doesn't seem to be true. Maybe the companies are showing off just how much money they have to spend on the PILs by getting lawyers to write them, who are of course much more expensive than medical writers, but, as Wendy so perceptively points out, write lousy PILs. Or maybe the PILs are written by medical writers who spend most of their time writing protocols, clinical study reports, or similar, and have not developed the necessary skills in writing for patients.

So, let me end with some practical advice. First, keep your legal department well away from any PILs. Second, if it is your job to write the PILs, ask yourself whether your skills in writing for patients could use some improvement, and find yourself a suitable training course if you need it.

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Copyright: the writer's guide

by Steve Holmes and Lizzie Jones



The minute you lift pen from paper or fingers from a keyboard, copyright arises in any original words that you have just written. Copyright arises automatically in the UK with no need for any registration, and it protects the expression of an idea. So long as you have put some effort into creation of the work, copyright will arise in new music, poetry, books, articles and advertisements. It has even been held to arise in a list of British railway stations.

Copyright is one of the oldest intellectual property rights and was first protected by law in England in 1708. It was designed to encourage creativity and to enable people to profit from the artistic and written work they create, and this is its continued purpose. In most instances, copyright lasts for the life of the author of the work plus the seventy years after their death. Like other property, copyright can be sold, given away, or passed on in a will, or permission can be granted for another person to use the copyright.

Copyright in the work you create

Have you considered who owns the copyright in any work you create? While the general rule is that you will own the copyright in any work that you create, if you are an employee then your employer will automatically own the copyright in your work. Even if you are not an employee, you may be contractually obliged to transfer copyright in your work to whoever may be funding you. For example, many academics have a clause in their contracts giving their university copyright in the work they create. While universities frequently choose not to exercise this right, in future they may consider this to be a useful revenue stream.

While it is not strictly necessary in the UK, copyright holders will often protect their work by marking it with the copyright symbol © followed by their name and the date of creation. This serves as a reminder to people looking at your work of your rights, which is particularly useful if the work is posted on the Internet (a space in which copyright is often ignored).

Copyright in other people's work

If you decide to publish someone else's work or include an excerpt from someone else's work in an article that you are publishing, you need to ensure that you do not infringe their copyright. The first thing to consider is who may own the copyright. The owner may be the original author of the work, or they may have sold or transferred their ownership of the copyright. If they have died, it will have been passed on through their estate. The copyright holder could also be the author's employer or a "collective licensing society" that has been asked to collect fees on behalf of the copyright holder. One of the most famous examples of transferring copyright is J. M. Barrie transferring the rights in Peter Pan to Great Ormond Street Hospital in order for them to benefit from the

royalties. Copyright in Peter Pan expires in 2007 so Great Ormond Street recently chose Geraldine McCaughrean to write a sequel, "Captain Pan", to hopefully provide a future source of income for the hospital.

As copyright arises automatically in the UK, there is no register listing copyright ownership and there is no official copyright body to provide information on copyright holders. However, the following methods could be used to identify the copyright holder:

- Try contacting the author of the work at their last known address or check authors' directories such as the Gale Research publication 'Contemporary Authors' that can be found in the reference section of most academic libraries. 'Contemporary Authors' consists of hundreds of volumes and in order to locate the relevant one a search can be conducted on the following website:
<http://www.galenet.com/servlet/LitIndex;jsessionid=29C88468D6703285CC7122D9FD25C6B6>
- Contact the publisher of the book or journal.
- Check the notes or acknowledgements of published works by the author.
- If the author is famous, biographers or academics who have researched the author may be able to help.
- Contact authors' societies that may hold information. The main UK societies are the Society of Authors (<http://www.societyofauthors.net/index.php4>); the Writers' Guild of Great Britain (<http://cgi.writersguild.force9.co.uk/>) and the Authors' Licensing and Collecting Society (<http://www.alcs.co.uk/>).
- Contact other major collecting societies such as the Copyright Licensing Agency (CLA) (<http://www.cla.co.uk/>), Newspaper Licensing Agency (<http://www.nla.co.uk/>) or the Design and Artists Copyright Society (<http://www.dacs.org.uk/>).
- If you're using primary sources or manuscripts, ask the library or collector who owns the documents for details on the copyright holder.
- Carry out Internet searches on Google, Yahoo! or copernic.
- A useful website is <http://tyler.hrc.utexas.edu/uk.cfm> the WATCH file (Writers, Artists, and Their Copyright Holders). This website allows you to insert the name of the author of the work and produces the name of the copyright holder or the collective licensing society to contact. In some instances, it provides the address and details in full.

Once you have established the identity of the copyright holder, you need to contact them to request a licence to use the material. A licence is a contract between you and the copyright holder on terms and conditions negotiated between you. The licence will set out exactly how the material can be used. Your use of the material may be quite limited. If you require use that falls outside the terms of your licence, a further licence is essential. An independent adjudication from the Copyright Tribunal (<http://www.patent.gov.uk/copy/tribunal/>) on the terms and conditions set by a collective licensing body such as the CLA may be available if you consider the terms set to be unfair.

Publishing without permission

A full record of your efforts to discover the identity of the copyright holder should be kept, plus a sum could be set aside in a bank account as a potential licence fee for the copyright holder. As a final resort, publishing a notice in *The Times* requesting details on the

Copyright for writers

copyright holder is a good option to demonstrate every effort has been made to establish their identity.

If you go ahead and publish without the consent of the copyright holder, they may approach you at a later date to request a licence fee or they could decide to sue you for infringing their copyright. In either of these circumstances, the steps mentioned above show to them and a court that you acted in good faith and made reasonable efforts to track down the copyright holder. The copyright holder could sue you for infringing their copyright, and a court may award the copyright holder damages or grant them an injunction to prevent further publication of your work that infringes their copyright. However, due to the significant expense of going to court, the likely consequence of publishing without consent is that the copyright holder will contact you to notify you of the infringement and request payment of a licence fee.

Exceptions

There are a limited range of circumstances in which copyright works may be used without needing a copyright licence. For instance, if you are reviewing or critiquing a work, this may fall under one of the "Fair Dealing" exceptions. Using short excerpts from the work you are reviewing does not require permission provided an acknowledgement to the author is included and the work reviewed is currently in the public domain. Other "Fair Dealing" exceptions include using material for non-commercial research or private study, for teaching in an educational establishment, for the purposes of reporting current affairs, or for judicial proceedings. However, if you are copying large amounts of materials or making multiple copies, you may still require permission.

International copyright

Copyright is inherently a territorial right – a German or Japanese copyright does not exist outside those countries. However, copyright is protected by international treaties, such as the Berne Convention (http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html), which allow copyright holders to effectively protect their works throughout the world. Therefore, before using foreign copyright works, you still need to identify the copyright holder and obtain a licence. Although it may be more difficult to discover a copyright holder of a foreign work, the approaches listed above should be used. In the USA, there is an official register of copyright that can be searched. However, as registration of copyright is not a legal requirement for copyright to exist, it is not completely reliable. Nevertheless, the register can make identifying the copyright holder easier (see <http://www.copyright.gov/>).

Copyright on the Internet

Material on the Internet is protected by copyright in the same way as material in newspapers, books and journals. If you intend to use work published on the Internet, then the steps mentioned above should be taken to find the copyright holder and obtain a licence from them. There may be information about copyright on the website, such as whether any general licence exists for others to use the work. You should also bear in mind that the material on the Internet may have been placed there illegally without the permission of the copyright holder so downloading the work or even printing off a copy is in further breach of the copyright holder's rights.

The future of copyright?

Copyright is an extensive and long-lasting right that enables copyright holders to have a very tight hold on their own work that severely limits others' use of the work. More recently, the view that society in general would benefit from copyright works being more freely available has become more popular. This is reflected in the "Creative Commons" movement, which was set up in the United States in 2001 to enable copyright holders to license their work for free in certain circumstances (such as for non-commercial use). Creative Commons achieves this by providing standard copyright licences to help copyright holders inform people that their work can be used for free on certain conditions. This enables the copyright holder to disseminate their ideas more widely and allows the ideas to be developed and improved, without the need for specifically licensing every user. Creative Commons recently launched their licence for use in England and Wales. More information on using Creative Commons licences is available from their website at www.creativecommons.org.uk.

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How can copy editors spot plagiarism?

As long ago as the last century (1998 or 1999 I think it was) John Barrie, a doctoral student in neurophysiology at the University of California suspected that students were taking material from online companies that provide articles over the Internet such as Schoolsucks.com and Cheater.com. He was instrumental in setting up Plagiarism.org. A system was developed that produces a printout of the examined document on which the plagiarised material is highlighted. This is done by linking these parts to their sources. In one instance when students had been warned at the beginning of their semester at Berkley that their work would be checked 15% of the students were found nevertheless to have plagiarised material (Nature 1999 vol 402 page 222).

As part of their remit copy editors often need to check articles for plagiarism. Software is available on the web for automatically searching key phrases to establish whether these have been lifted from previous publications (<http://www.turnitin.com>, <http://invention.swmed.edu/etblast/index.shtml> and <http://www.google.com/alerts>)

A useful editorial about figure manipulation was published by the *Journal of Cell Biology* and can be found at <http://www.jcb.org/cgi/content/full/158/7/1151>



From over the pond: Plagiarism in the pharmaceutical industry

by Susanna J Dodgson

After I was offered my appointment as Professor and Director of the MS Program in Biomedical Writing at the University of Sciences in Philadelphia (USP) last Spring, I wrote an "Over the pond" article on how to become a medical writer. Because I mentioned the Biomedical Writing Program, I sent a draft of my article for comment to my predecessor, Jennifer J Connor. Jennifer was not pleased that I wrote the most important skill of any medical writer was cutting and pasting. She told me that since the widespread use of the Internet, plagiarism had become such a problem on university campuses that I needed to make quite sure I was not endorsing it in any way. I modified the article and promised to write a follow-up article on plagiarism. This was to let the world know that under no circumstances is plagiarism endorsed by USP, which was founded in 1821 as the first US College of Pharmacy.

We take plagiarism very seriously at USP; seriously enough to have a policy of expulsion from the Program if a student is caught appropriating another person's work. According to the University Student Handbook:

'Ghost authors' are plagiarised by 'guest authors'

"... ideas are highly valued, and so is the language that expresses those ideas. In both a legal and moral sense, words and ideas are the property of their authors. Plagiarism is the theft of that property. When you plagiarize, you are presenting someone else's words and/or ideas as if they are your own. This situation applies to all printed material as well as to words and ideas found through electronic sources. Plagiarism may be intentional or unintentional. In either case, the penalty for plagiarism can be... expulsion from the institution." (www.usip.edu/writing/plagrsn.shtml).

According to the USP definition, a student lifting a paper from the Internet and submitting it for a grade without quoting the source is a plagiarist. Our MS Program in Biomedical Writing first enrolled students in August 1997. Since then 182 students have enrolled in courses. We have expelled a single student from both the Program and the university for submitting course papers with lifted content. This student fought our accusations, claiming to have only taken blocks of text from government websites, and that everyone on the planet has the right to pass off this work as their own because government websites are not copyright. The University's argument is that we do not care who copyrights what, any document submitted for credit or publication needs to have been written by the person for whom credit is given.

I take the argument further. I have come to the conclusion that the use of medical writers, who have been called "ghost authors" to prepare papers is also plagiarism by those who have been called "guest authors". These are the persons whose names appear on papers they did not write, and who may also take money for lending their name to the paper. My reasoning for identifying these people as plagiarists follows.

The International Committee of Medical Journal Editors (ICMJE) have been concerned about who writes papers since 1979 when they started publishing the first of evolving sets of guidelines. These define what constitutes authorship. In 2004 and 2005 their main concern was the data included in papers describing clinical trial results. From July 1st 2005 these papers may only be written on data deposited in the publicly accessible Clinical Trials Registry. This development has arisen from the distrust of these data, specifically, because editors had no way of knowing whether favourable results in a paper had been observed for a part or the whole duration of a clinical trial, how long a clinical trial lasted or the negative effects of the drug. Part of the ICMJE Statement on Clinical Trial Registration published in March 2005 states:

Only when the manuscript had all the company signatures was it sent to the selected author

"Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making."

The ICMJE published their October 2004 guidelines, like the March 2005 Statement on Clinical Trial Registration, in several medical journals, including the *New England Journal of Medicine* and the *Journal of the American Medical Association*. In these guidelines, the rules for being the named author are:

"..... biomedical authorship continues to have important academic, social, and financial implications.Authorship credit should be based on

- 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- 2) drafting the article or revising it critically for important intellectual content; and
- 3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3..... Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship."

All authors declared they had done all the work

As a working medical writer, I have seen flagrant non-compliance with these rules in American and European medical communications companies, whose work is entirely funded by pharmaceutical companies.

In one medical communications company, now defunct in the US, manuscripts describing issues in HIV/AIDS, gastroesophageal reflux disease, cardiovascular disease, and hepatitis B therapies were outlined by medical writers. After the outlines were approved by the pharmaceutical sponsors (four of the world's largest pharmaceutical companies) the medical writer wrote the manuscripts. Most manuscripts were reviews, although some were clinical papers describing patients seen in healthcare offices. The finished review manuscripts were reviewed by the committees permanently employed by the sponsor, and when the manuscripts were acceptable, then and only then were pharmaceutical company-selected authors (PCSAs) sought. The clinical manuscripts about patients resulted from the pharmaceutical representatives out in the field identifying

From over the pond

A contract research company was acknowledged for 'some help with the data collection'

healthcare professionals with interesting patients or clusters of patients, whose illness and reaction to treatment were in line with that predicted for one of their marketed therapies. By telephone, the medical writer talked to the healthcare professional about the observations, and prepared a complete paper around this information. When the manuscript had all the signatures from the pharmaceutical company and medical communications company, the files of the manuscript and cover letter with the names of the PCSA was sent to the PCSA chosen to be named first. The PCSA then signed the letter saying it was all his or her own work, and e-mailed or posted the package from his or her own address. As far as the journal editors knew, the manuscript came from the local post-office or e-mail server of the PCSA, who had done all the work and fulfilled all requirements of authorship.

This medical communications company was not unique. This is how manuscripts are written for pharmaceutical companies. The problem with authorship is that the sponsoring drug companies and marketers make decisions about the qualifications of an expert who they want as the public face of their drugs. These experts seldom have any skills in statistics, researching their own area of expertise, or writing and preparing manuscripts for publication. I have been told by other medical writers that the worst thing that

In reality the research company had done all the work

can happen to a manuscript is have the PCSA make changes to the manuscript. The sponsor is happiest when the PCSA cashes the cheque and signs his or her name on the letter submitting the article to the journal.

Manuscripts written breathlessly describing the results of human testing of promising drugs in clinical trials are a whole industry in themselves. I was once asked to prepare a paper from clinical trial data for an upstanding pharmaceutical company, which has a code of ethics. I have been told this requires that all papers with their employees given as authors have to be written and prepared entirely by these professionals. That may be partly or even entirely true for pre-clinical studies; certainly I wrote part or all of several pre-clinical papers on research I did for this company when I was an academic bench scientist. However, clinical trials are expensive procedures. They involve safe administration of drugs to healthy and sick volunteers, teams of statisticians, medical writers, clinical research associates and project managers. Paradoxically, appointing PCSAs for these manuscripts is much easier than appointing PCSAs for other manuscripts because the healthcare professionals needed as signatories on the clinical trial protocols have been seen as natural PCSAs.

The ICMJE has done its best to ensure all parties are being honest

I was startled to read a manuscript in a premier US medical journal in November last year, that had been written on the results of a large post-marketing clinical trial with data-lock in August. The journal editors required statements from each author in line with the IJCME guidelines. Each PCSA earnestly declared that he or she had done all the work, including all the statistical analysis and written every word in the paper. I looked carefully through the paper. Right at the end of the acknowledgments I saw a contract research organization thanked for "some help with data collection". In reality this contract research organization had done all the work, including conceive and

write the protocol and collect and analyze data for 5 years. What really interested me was that one of the PCSAs, who had cheerfully taken the role as one of the two public faces in the study, was one of the most vocal critics of the FDA and the drug company, whose non-steroidal anti-inflammatory drug was recently voluntarily removed from the market. Even more startling were the conclusions of the study: healthy people with no risks for the investigated disease need to take drugs. Reading the data carefully with my students in my NDA submissions documentation class, we found that the conclusions were not supported by the data.

The ICMJE no longer believes professionals tell the truth

The inability of drug companies and healthcare professionals to understand the complexity and skill needed to research and write a review, or a paper from a clinical study report has led to healthcare professionals plagiarizing the work of medical writers. Until this practice is recognized as plagiarism and not disguised with the plagiarizer called the "guest author" and the medical writer called the "ghost author", the profession of medical writing will never be given the respect it deserves.

The International Committee for Medical Journal Editors has done its best to ensure that all parties are being honest in the journals that agree to abide by their guidelines. Their guidelines calling for posting data on all clinical trials relating to therapies from which publications are generated indicates that the ICMJE no longer believes that professionals submitting papers for publication tell the truth. For the first time ever, the data in clinical papers must be verified. This guideline does not apply to data generated by life or physical scientists, only for healthcare professionals making claims about clinical trials. I have to ask why, and I find I can answer my own question immediately. Reports of bench science findings have always been verified, or discredited, by other scientists in other laboratories. This self-regulation is not possible in clinical trials because of their expense. Once a therapy is approved for marketing and has been taken by patients with the approved indication, its ineffectiveness can be blamed on the patient not taking the pills in the right quantity at the right time.

From 1 July papers describing clinical trials can only be written on data deposited in a public registry

I had been thinking about composing this article for several months, and had started writing when I read a post on the US Medwriters list serve in April. The writer, Adriane J Fugh-Berman, MD, is an Adjunct Associate Professor of Physiology at the University of Georgetown, and a bona fide expert in the field of complementary medicine. She wrote that she had recently written two articles, one in the Guardian (<http://education.guardian.co.uk>, April 21, 2005) and one in the *Journal of General Internal Medicine* (2005; 20), on her reaction to an invitation to be a PCSA on a completed article on complementary medicine. Adriane is the first potential PCSA to write about PCSA solicitation, which she has done with some disdain. My admiration for her writing the articles is huge; she is one of the few healthcare professionals to report the practice of pharmaceutical company-sponsored plagiarism. I thank her for reading this manuscript and for her warm encouragement.

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Countering distortions

by Paul Haines

Earlier this year, the editors of *Scientific American* made an extraordinary confession. In the editorial of the April issue, they admitted that the magazine's past coverage of evolution had been "hideously one-sided", and they declared a new-found admiration for the "superior scientific theory" of intelligent design [1].

The article, entitled "Okay, We Give Up", went on: "We owe it to our readers to present everybody's ideas equally and not to ignore or discredit theories simply because they lack scientifically credible arguments or facts" Also: "If politicians or special-interest groups say things that seem untrue or misleading, our duty as journalists is to quote them without comment or contradiction. To do otherwise would be elitist and wrong."

The editorial was an April Fool's Day spoof, of course. It not only exposed intelligent design as the scientifically impotent idea that it is, but also got to the heart of an important issue in science reporting today – the ease with which scientific principles or findings can be distorted, deliberately or not, by groups or individuals with vested interests or by journalists themselves. If we as writers can't recognise and eliminate distortions, what hope is there for clear, effective science communication?

Recognise and challenge

To have any kind of useful and informed discussion, there needs to be an agreed upon body of facts. If someone wants to derail a discussion, they deny, question, or distort those facts. The current Bush administration in the USA excels at this in order to justify ideology-fuelled policy (see climate change, stem-cell research, needle exchange, abstinence-only education, abortion) but it would be foolish to think that it doesn't happen elsewhere, or indeed everywhere to some degree.

Most specialist science/medical writers should be able to recognise distortion. But it's not always easy or practical in terms of the time involved in getting familiar with the subject in question. It obviously also requires a certain level of scientific knowledge to be able to assess the quality of studies and weigh up the evidence, and to keep up-to-date, so it doesn't help that, thanks to financial pressures and downsizing, many general print and web publications either do not have any specialist science or medical reporters (so nonspecialist reporters will research and write a story), or they have fewer full-time ones than they used to have (so reporters may have less time to devote to any single story). This all increases the chances that distortions will go unrecognised and be passed on uncritically to the reader.

As journalists, our next step after recognising a problem must be to challenge those responsible for it, on behalf of our readers. This goes back to the *Scientific American* editorial: unfortunately there are too many journalists who will quote politicians or spe-

cial-interest groups without comment or contradiction. A case in point: late last year a report from the US House of Representatives' Committee on Government Reform (Minority Staff) concluded that most federally funded abstinence-only education programmes contained "false, misleading, or distorted information about reproductive health" [2]. According to the fully referenced report, millions of children were (and still are) being taught, for example, that pregnancy occurs one in every seven times that a couple uses a condom, that 5-10 percent of women who have a legal abortion will become sterile, and that a 43-day-old foetus is a "thinking person".

The two-paragraph official statement from the government department responsible – the Office of Public Health and Science at the Department of Health and Human Services (HHS) – said these issues "have been raised before and discredited" and the report was dismissed as taking information out of context "for purely political reasons" [3]. The second paragraph re-asserted abstinence as "best so [children] can grow up to be healthy thriving adults." In this way, the report and any controversy it raised was framed as solely political – just partisan politics, their word against ours. A search in the LexisNexis database at the time showed that most news coverage followed this line, burying the science, playing up the politics, and usually repeating some or all of the official statement. I found only one news report, actually the transcript of a CNN discussion programme, that directly addressed the misuse of science and why we are telling lies to children.

The body of facts at the centre of this issue was, in the main, successfully obscured by the smokescreen formed from the official statement casting the controversy as political rather than scientific, and by the reluctance or inability of journalists to deviate from this view. There are two postscripts to this tale. One is that I covered this story for a medical journal and found that getting any detailed response from the HHS was very difficult, and very, very time consuming – we are talking weeks, not days. If that experience is typical, it could explain the reliance on the clearly deficient official statement in many news reports. The other postscript is that in January this year the authors of the original report sent a formal letter to the HHS asking, among other things, *where* the issues had been "raised before and discredited" [4]. The HHS silence has been deafening in the months since then. As for the education programmes, nothing has changed.

This is just one example of how those who misuse science aren't being held sufficiently to account by the media. Wherever we write, and whatever the target audience might be, we have a responsibility to use our scientific knowledge and journalistic training to peer through any smokescreens in order to see the facts at the issue's core.

Context cures coffee confusion

Of course, journalists are by no means perfect. We can add distortions of our own, intentionally or unintentionally, of which the worst is probably lack of context. Science and medicine are all about incremental gains, building on what has gone before, and it is important to put new information in the context of what we already know (or think we know). The *BMJ*'s current requirement for authors of original research papers to include a box describing "What is already known on this topic" and "What this study adds" is, in my view, an admirable development helping to clarify context and improve communication, and could easily be adopted by many more journals.

Countering distortions

Without context there is the potential for much confusion. Search the online archives of any news outlet, and you have a good chance of quickly finding apparently conflicting headlines, such as "One cup of coffee a day 'risky'" and "Coffee is health drink, says Italian" (from BBC News online in 2004, seven months apart). Similarly, figures and risks need to be placed in context. Just last week I saw a television news item reporting a 1% rise in teenage pregnancies in the UK in 2003 but giving no further factual information. A 1% rise on its own is meaningless – I'm sure that the viewers, whatever their level of scientific literacy, could have coped with, at the very least, two more numbers, to show the number of teenage pregnancies had risen from X in 2002 to Y in 2003. Viewers would then have a better idea of the scale of the problem. Context is king, and key to responsible communication.

The past few years have seen the launch of online initiatives assessing what medical reporters on certain papers have written, including Media Doctor ("Improving the accuracy of medical news reporting") in Australia, and the Hitting The Headlines project in the UK [5,6]. These should be welcomed for encouraging accurate reporting, although Media Doctor in particular is sometimes unrealistic in what it expects reporters to include in news stories. As discussed above, we as medical writers also need to be more effective at identifying and holding to account those who distort science, whoever they are and for whatever reason they do it. Let's make it part of good practice.

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Policing English: Gobbledegook on trial

by Richard Clark

Whilst listening to a sports commentator how many times do we hear something such as "That was a virtually faultless performance!" Those, like me, who are pedantic about the English language will mutter that a performance is either faultless or it is not, and cannot be watered down by inserting an 'almost', 'nearly' or 'virtually'. Sadly for us this practice is now common in medical writing. I would go as far as saying that most (I've resisted writing 'almost all' or 'nearly all!') medical writers have indulged in this practice at some point. To be honest this is merely an irritation and doesn't compromise the readers' understanding of the text, and so is not really a serious offence, so maybe I should move on to more serious matters.

The main purpose of a medical writer is to communicate, so clear, concise and readable writing should be the ultimate objective in our profession. So, when we transgress and start to dress-up our prose with flowery language this is – to me at least – a serious offence. This can take many forms, but one we should particularly guard against is what I call 'Police speak'. This is analogous to a policeman giving evidence in court, who, consulting his notebook says:

Sometimes I can almost hear the rustle of the policeman's notebook

"I was proceeding in a northwesterly direction when I observed the accused in the vicinity of the King's Arms public house."

This sort of statement is far from normal spoken English, is clumsy and less understandable. Sometimes when reading an article I can almost hear the rustle of the policeman's notebook pages:

"A survey encapsulating the results of recent trials verified that the administration of paracetamol elicited an enhanced response."

My own least-favoured phrase is 'negative(ly) impact'. For example:

"The administration of aspirin negatively impacted on patient mortality."

Sometimes I wish, rather uncharitably, that writers using this phrase would experience a painful 'positive impact'!

It is probably more common for a scientist or medic than a medical writer to use Police speak, but why do they do it? Possibly to make their work sound more complicated, thus inferring that they are rather clever. Sometimes language is used to distance themselves from a distasteful act such as killing an experimental animal ("The rats were sacrificed"), maybe elevating their experiment to the status of a religious ritual and themselves as a sort of high priest of science? I can understand why this sort of language is used in methods sections of

My least-favoured phrase is 'negative impact'

The Write Stuff

Policing English

traditional peer-reviewed journals as it has become the accepted writing style, but we as professional medical writers should be able to communicate more effectively.

A second (and mercifully less common) form of flowery language is the use of idioms in a misplaced belief that this will make 'Police speak' more understandable, or appear more friendly and accessible. The results are even more amusing than the usual straightforward gobbledegook. For example:

"In order to be considered as part of cardiologists' armamentarium, new therapies will have to pass the acid test of a large-scale, randomised double-blind trial."

Most good medical writers wouldn't open this can of worms and use idioms – not even for all the tea in China! As the words forming an idiom together have a meaning that is different from the definitions of the individual words, idioms are particularly unsuitable for an international readership. Idioms are also rather close to cliché territory.

Find a balance between plain and flowery writing style

Please do not think that I advocate a dull and unimaginative writing style; there is always a balance to be found between plain and flowery writing styles, and this balance point will shift depending on the likely readership of the article. One final thought is that whatever I'm writing I try to ensure that people don't have to read sentences more than once to understand them, which can be quite a challenge when explaining a complex situation. Thus, we are rather like journalists in this quotation:

"Literature is the art of writing something that will be read twice; journalism what will be read once." [*Enemies of Promise*, Cyril Connolly (1938)].

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Hey it's only my opinion: new local lingo

Diana Epstein was not able to contribute her opinion to this issue because she is flitting¹ from Germany to Scotland.

Lang may yer lum reek², Diane!

(¹ translation of Glaswegian = moving house, ² long may your chimney smoke)



My return to medical writing

by Clair Firth

When I was asked to write something for TWS, I was surprised to say the least. My next thought was, what on Earth can I write about? Having only been a medical writer for a couple of years and having fallen into this profession by living abroad and not being able to find work in my chosen field, I thought I was the last person who would be able to contribute to the journal. But then again, many (most?) of us have come to this area by accident, very few of us follow an exact career plan with the aim of being a medical writer.

Anyway, back to my conundrum of what to write. I'm sure we could all write about the daily problems medical writers face, so I've decided to write about what happens when you're out of the office for a while. I have just returned to work after an 18-month absence. I am lucky enough to live in Central Europe where maternity leave of up to two years is the norm. Although I have kept in touch with my colleagues, I severely underestimated the changes that have arisen in my absence. Not only has my 3.1-kg baby girl grown to a huge 14-kg toddler, and not only have I managed to complete my MSc (after a long 5-year slog on a distance learning programme), but my office environment and working day has changed completely.

First of all, there were three medical writers (myself included) based in our European office before I left work; now there are four full-time and two part-time medical writers in Europe and four full-time writers and one editor in the USA. When I first came back to work, I had worked with just one of the medical writers prior to maternity leave, and she was in the process of leaving the company. So I was left working with three medical writers in our office with whom I had never previously collaborated – not an easy prospect. The first few weeks were therefore quite frustrating, e.g. I had people explaining studies to me for which I had written the CSR. Of course, all the study numbers were new and, as our department had quite dramatically increased its scope, we were now writing reports on all kinds of therapeutic products, rather than just vaccines as it had been before. On a more negative note, for some apparently unknown reason, we now use a CSR template with the dreaded "1. TITLE PAGE" printed above the actual study title because we have to follow the 'guideline' ICH-E3 to the letter.

Another big shock was that the CTD is now a real document, rather than just the subject of numerous courses and training sessions. I lost count of the number of courses I was sent me on in 2002, but now the CTD was being written by my new colleagues and I had no idea where to begin. Unsurprisingly it seems that the aim of the CTD to be fully acceptable internationally has not quite paid off, given that our American colleagues write one version for the FDA and my office another version for European submissions, but that was to be expected (at least it was always inferred at the courses I attended).

I am now working part-time, just 14 hours a week, and this has also limited my ability to work on specific projects. To be home relatively early, I start work at 8 am. Most of my

Return to medical writing

colleagues come in after 9.30 am as they are likely to be here until late if working with the American office. Obviously it is not easy for me to be involved in teleconferences, which start at 6 pm, so it is hard for me to always be "out of the loop" (as the Americans would say). However, the short hours allow me to help my colleagues with a variety of projects rather than being solely responsible for an individual report and working on it for weeks. I am enjoying the variety of new documents and therapeutic areas, especially after two years of working on relatively monotonous vaccine studies, which was my only medical writing experience prior to maternity leave.

In spite of all these challenges, I am glad to be back in a scientific (and adult) environment, although I do still enjoy the finger-painting and Play-doh of my office-free days!

Clair Firth

Medical Writer

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Announcement and Call for Participation

Mediterranean Editors' and Translators' Meeting 2005

Interdisciplinary Collaboration
—International Communication

4-5 November 2005, Barcelona, Spain

Mediterranean Editors' and Translators' Meetings (METM) is a new southern European and Mediterranean network of English language consultants of many types—editors, translators/interpreters, communication coaches, technical writers and educators in English for specific purposes. The association will be launched at the group's first meeting in Barcelona on 4-5 November 2005 at the start of Science Week.

METM aims to provide a meeting place for consultants who work with oral, written and multimedia texts—and with their authors—in areas where English language mediators are needed. The plan is to share expertise and channel information between local language consultants and larger organizations like the European Association of Science Editors, the Council of Science Editors, the European (and American) Medical Writers' Association(s) and the IEEE Professional Communication Society. While the main focus will be on editing, translation, coaching and other communication services for academics and professionals in scientific disciplines, the needs of other groups in finance, culture, politics, business and non-governmental organizations will also fall within our scope.

The first meeting—METM 05—will feature two plenary speakers. Joy Burrough-Boenisch, founding member of SENSE, a model self-help organization of English editors in the Netherlands, will speak on the "sense" of editors' associations. She will also give a workshop on how to train editors and translators to work with the texts of non-native English speakers. The second speaker is Ana Marusic, former president of the World Association of Medical Editors and editor-in-chief of the *Croatian Medical Journal*. In that capacity Dr. Marusic has been instrumental in implementing an approach to peer review that also serves to mentor young scientists, helping to create a critical mass of publishing researchers in her region.



Are you my Mommy?

by Ursula Schoenberg

When I quit my agency job and began freelancing last year, I decided I wanted to join some sort of professional organisation. Little did I realize that this simple decision would lead to some heavy-duty soul-searching and almost to an identity crisis. I assume for many of you this sounds like an easy task: I am an X, so I join the X Organisation, right? My problem lay in defining the X.

I am a biologist and worked in communications agencies for many years. At the moment, I offer copy writing/editing, translation and strategic communications solutions for clients from science, technology, environment and healthcare. A good amount of my work is for pharmaceutical and/or medical clients, but not exclusively.

Was I some sort of woolly sow that lays eggs and gives milk?

Taking my virtual surfboard and launching out into the Internet, I soon stumbled on the EMWA. Did they tally with my X? Well, sort of. Am I a medical writer?

Yes, I write for the medical and pharmaceutical industries. But no, I don't write study and grant reports etc. Oh dear, I thought. So I foraged off in other directions. There is a German organisation for advertising copy writers, but that didn't really fit, because I rarely write ad copy. The German public relations organisations didn't appeal to me because they don't have a strong freelance base, and besides, I wanted something European.

I was becoming depressed. Having spent some time and effort in deciding what I was going to offer the market, it seemed I fitted into no niche. Was I some sort of exotic "Eierlegendewollmilchsau", as the Germans say, not always approvingly (this roughly translates as "a woolly sow that lays eggs and gives milk")?

I returned to the EMWA website. And I thought "What the heck!"

Now, I should be used to this "displaced" feeling, because I grew up in two countries and have been

fielding questions like "Well, do you feel more American or more German?" for several decades. Still, I felt a bit like the baby bird in the story I was just reading my 3-year-old daughter, that falls out of its nest and runs around asking cats, dogs and cows "Are you my Mommy?". The final twist being that it is scooped up by a bulldozer and dumped back in its nest, where its Mommy is waiting for it. I know it's ridiculous to be wanting your Mommy (professionally speaking) when you are rapidly nearing your mid-life crisis, but there it is.

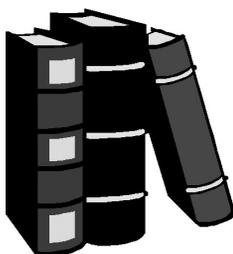
Having exhausted many other options, I returned to the EMWA website. And I thought "What the heck!". Some of what I do fits their profile. And most of what they do sounds pretty interesting and might be a challenging area to explore when my own responsibilities as a Mommy have waned a bit more. So here I am, in the EMWA "nest" and looking forward to what the future may bring!

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In the Bookstores... History of Science Made Fun

by Karen Shashok

Neal Stephenson. Quicksilver (Volume One of the Baroque Cycle). London: Arrow Books (Random House Group), 2003. ISBN 0 09 941068 0 (Paperback)

Since so many of us have crossed more than one cultural border on our way toward our chosen profession, it is probably safe to say we are comfortable working with more than one language, and in more than one area of knowledge. The profession, in fact, seems to contain a larger number of us than even we tend to assume who started out specializing in some area of the human or social sciences and ended up transposing our skills into scientific-technical-medical (STM) writing, whether out of necessity or out of curiosity about the so-called harder sciences.

A queer amalgam of historical and biographical fact and fiction

But regardless of whether your academic background is in experimental, exact, human or social sciences, this opus, a sometimes queer amalgam of historical and biographical fact and fiction, has something to delight everybody. Although some of you will have already heard more than you want to know about the acclaimed Baroque Cycle, be assured that this is just the sort of stuff that STM communication professionals (who tend to be curious about lots of other things besides the topics we handle in daily practice) are likely to enjoy. There is endless diversion for historians of science and technology, geographers, economists, ethicists and alchemists (I know you're out there!)

For readers who enjoy delving into the psychological relationships between characters, there are well-developed threads that show Stephenson to be an excellent contemporary novelist no matter how sceptical you may feel after all the hoop-la in the literary supplements. Particularly enthralling is the portrayal of the intimate personal and professional relationship between the brilliant but irascible and jealous Isaac Newton and the novel's fictitious protagonist Daniel Waterhouse, Puritan and pioneer in proto-computer programming. For fans of postmodernism there are blatant anachronisms, abrupt intrusions of contemporary English idiom and slang into otherwise carefully rendered 17th century speech, and romps through time that happily stomp all over our notions of continuity. I know; postmodernism can look like sloppiness disguised as art to those of us who were taught in school about good writing and critical reading, and there are times when I thought to myself "If I see that pedantic 'phant'sy' just one more time, I'll scream." But postmodernism as style is probably just a passing fad that will not do permanent damage to good written English expression, so try to ignore these minor, fashion-driven irritations and enjoy the story.

What I found best about Quicksilver was the way it documented the origins of the Royal

Society by bringing its founding members to life in a believable way. The alliances, rivalries, quirks and personal biases Stephenson uses to animate eminent historical figures make their behaviour so like that of their contemporary scientific offspring that Wilkins, Wren, Boyle, Hooke, Newton and Oldenburg become human beings, as magnificent in their personal failings as they are in their historical achievements, rather than hallowed icons with unknowable and hence presumably impeccable ethics. (The great Newton vs. Leibniz controversy over who invented The Calculus is another part of the story, and yes, Leibniz himself makes an appearance, but you'll have to read the third volume of the cycle for that.) The mix of religion, politics, science and intrigue in England (and to a lesser extent, in France, Germany, and Russia) during the end of the 17th century and beginning of the 18th century is rendered not only understandable but also a pleasurable read for those of us who always wished we had time to learn more about the history of science (or just history, period).

Best is how the founding members of the Royal Society are brought to life

The Baroque Cycle has been classified in the big chain stores—rather inappropriately—as science fiction, probably because the author initially achieved fame as a cyberfiction writer. The full three volumes of the trilogy total about 2600 pages in paperback, but once it gets into your blood you can't stop turning the pages. The historical erudition is impressive, and the author duly acknowledges the very considerable assistance he received with the research and fact-checking. The characters and events are epic on a scale readers haven't seen since *The Odyssey*. At the deepest level, the Baroque Cycle is a thesis on how Western thought evolved during the bumpy transition from the Stuart dynasty to the Hanoverian dynasty in Britain, but if you're looking for an updated and greatly expanded Restoration comedy that's well written and makes the history of science fun, the 900-odd unputdownable pages of *Quicksilver*—the first of the three volumes comprising the full Baroque Cycle—will not disappoint you.

More information and further reading

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The Wikipedia entry for The Baroque Cycle is at http://en.wikipedia.org/wiki/Baroque_Cycle . (Beware; Wikipedia entries can be habit-forming.)

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**Vital signs....
So you think you know
English revisited**

Dear TWS,

Bookkeeper is the only word in English with three consecutive letters

Geoff Hall

Geoffreyhall@aol.co

Dear TWS,

I would like to contribute the Minidrama 'Sorry' by Flann O'Brien, although I am not sure where it would fit in. It is not quite the "So you think you know English" section. Maybe you can find some space – if you find it as funny as I do.

Sorry

Waiter, what was in that glass?

Arsenic, sir.

Arsenic. I asked you to bring me absinthe.

I thought you said arsenic. I beg your pardon, sir.

Do you realise what you've done, you clumsy fool? I'm dying.

I am extremely sorry, sir.

I DISTINCTLY SAID ABSINTHE.

I realise that I owe you an apology, sir. I am extremely sorry.

Anne Bartz

Anne-bartz@freenet.de

Dear TWS,

Worth a look, from the Annual Neologism Contest

Flabbergasted (adj): appalled over how much weight you have gained.

Willy-nilly (adj): impotent.

Lymph (v): to walk with a lisp.

Gargoyle (n): olive-flavoured mouthwash.

Balderdash (n): a rapidly receding hairline.

Testicle (n): a humorous question in an exam.

Negligent (adj): describes a condition in which you absentmindedly answer the door in your nightgown.

Paul Woolley

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Dear TWS,

How do I recognize 'an 'armchair biologist'? I have read academics are warning that the current generation of students write brilliant essays (*from the Internet?*) about species they would not recognize if they tripped over them.

Wayne Whitby

(email withheld)

Postscript: The ghost of the Gender Genie

Gender Genie (<http://www.booklog.net/gender/genie.html>) which analyses whether an author is male or female, was mentioned in the first 2005 TWS issue (vol14 No. 1 page 18). Some readers took up the challenge of testing their own writing. Confusion abounded when the ladies amongst us underwent a sex change. This requires some explanation.

Women's writing has been postulated to be more emotive and personal with more compliments, self-derogatory statements and apologies compared with the opinions and insults that typify men's writing. Studies of students' academic writing found that male students write more dynamically, mention more quantities and use more judgmental adjectives than female students who use more hedges, and write more dependent clauses and longer sentences.

Genie is based on research on fictional and non-fictional text. This research identified words most frequently used by men and those most frequently used by women. Differential weighting was allocated to the words according to their relative frequency within the text tested. This establish 'feminine' and 'masculine' words [examples of feminine words and their weighting are with (52), should (7), and (4); and masculine words are around (42), a (6), said (5)]. The Genie counts the masculine and feminine words in a piece of text. Then it multiplies the number of occurrences of each word in the text by the word's established differential weighting and pronounces the writer male or female based on the total score.

A review of recent studies by Hartley [1] found with fiction text Genie was better at identifying female than male authors and with academic text it was better at identifying male authors. This suggests that genre differences rather than sex differences are at play, i.e. within fiction or academic writing men and women write in the same way. Why then does academic style turn out to be masculine? Hartley suggests that the standards to which all academics aspire are masculine ones because universities are still bastions of male activity. Perhaps then the decline in the success rate claimed by Genie from 80% in September 2003 to 62.5% by July 2004 indicates that a feminine touch is creeping in.

In any event one variable seems to have been missed by the studies; the wicked ghost-writers—umps—professional medical writers. Most are women. What are they doing to these masculine papers? I for one edit out judgemental adjectives.

Just by way of a post-postscript Hartley also points to evidence that journalism is becoming less of a male stronghold with female journalists now sourcing their articles and writing them differently from male journalists.

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