
The Write Stuff

The Journal of the European Medical Writers Association

Learning and Teaching



EMWA 14th Annual Conference



17-21 May 2005, Malta

The Executive Committee would like to remind members that EMWA's 14th annual conference will be held from 17 to 21 May 2005 at The Westin Dragonara Resort in the St Julian's region of Malta.

Further details are available on the website www.emwa.org.

This conference will see the launch of our advanced curriculum, so it's definitely not one to miss.

Looking forward to seeing you there!

Michelle Derbyshire
EMWA Vice President and Conference Manager

Learning and Teaching
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Sixth annual EMWA autumn meeting, 18–20 November 2004, Munich, Germany	41
Wolfgang Thielen A brand new EMWA member offers his observations of the recent autumn meeting in Bavaria, which was great fun even if we did just miss Oktoberfest.	
Training a team of medical writers with diverse backgrounds	42
Heather Bishop No one trains at university to be a medical writer, so exactly how do you train medical writers? In other words, find out how to make a silk purse from...many different types of silk.	
Foundation and advanced levels for the EMWA Professional Development Programme	45
Stephen de Looze and Beate Wieseler Everything you need to know about the changes and expansion in the EPDP.	
Medical journalism - a career move?	52
Jo Whelan Ever dreamed of writing about nanotechnology and the latest sex research rather than another study report on a me-eight drug? Find out what it is really all about.	
Programme for International Student Assessment (PISA) - learning for tomorrow's world?	55
Patricia Bünz Can we compare the success of the educational systems in different countries?	
From over the pond: cancer therapies	57
Susanna Dodgson A plea from a veteran medical writer - keep at it to help speed approval of drugs that deal with the scourge of disease.	
In the bookstores... medicines out of control? antidepressants and the conspiracy of goodwill	59
Liz Wager It is very popular these days to condemn the evil Pharmaceutical industry and some of the most infamous examples are involved with marketing antidepressants. Liz Wager, however, reports on a book that takes the "anthropological" viewpoint.	
Regular features	
▪ From the editor's desk	34
▪ Message from the President	36
▪ Meet the EMWA candidates . . . 2005	37
▪ Vital signs: the Gender Genie a misogynist?	61
▪ The lighter side: the importance of punctuation	62

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).

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- Half page €500

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The cover picture has been adapted from an image taken from Microsoft ClipArt.



From the editor's desk: Learning and teaching

by Barry Drees

What could be more central to the human experience than the theme for this issue: "Learning and Teaching"? The ability to learn, to pass on knowledge and to teach others allows knowledge to be accumulated and thus a civilization to be created. Civilization distinguishes the human species from all other forms of life and the ability to learn (and to pass on knowledge) is what ensures civilizations continue to develop and thrive. Although many animals use tools, share a language, or participate in culture, no other life form on this planet has developed civilization. Evolutionary biologists speculate that one of the reasons for the origin of civilization in the human species is the very long time relative to other animals that human infants are dependent on their mothers allowing them to learn from their mothers, their families and from society in general.

Those of you who have ever given EMWA workshops will know that the best way to learn and truly understand a subject is to teach it. If you are going to stand up in front of people, explain something, and answer questions on it, you have to really understand the subject. I found that when I started teaching the EMWA workshop on statistics, I realised that I hadn't understood statistics nearly as well as I had thought I had. I demonstrate this at the start of my workshop by asking the participants how many of them understand various statistical concepts. When I then ask whether any of them feel that they understand it well enough to explain it to the others, the number of people who claim to understand each concept drops dramatically. It is by teaching a subject that we come to learn it. So although teaching and learning might appear to be different aspects of this experience, they are very closely entwined.

One undisputable lesson learnt from studying the history of civilizations is that every society needs to encourage and promote learning amongst its citizens or risk being left behind and eventually dominated by neighbouring societies. But whilst personal learning can be measured and judged by the individual, how can a society measure its learning in order to determine the most successful ways of supporting it? Judging by what happens around the world, some form of standardised testing seems to be the method of choice. But how accurate are such tests and what exactly do they measure? Opinions vary widely, as can be imagined by anyone familiar with the controversy over the interpretation of IQ scores. I was at a party a few years ago when the results of such testing in different countries were announced. Everyone wanted to discuss why the German results were so poor rather than whether these tests actually measured anything relevant to real learning.

Many of you have probably heard of the infamous Programme for International Student Assessment (PISA) study, which attempted to compare the educational system and

***Tell me, I may forget,
Show me, then I may
remember,
But involve me and I'll
understand.
Chinese proverb***

From the editor's desk

actual learning achieved by students of different ages in developed countries. Those of us who have written pharmaceutical industry summary documentation are familiar with the difficulty of comparing clinical trials done in very different patient populations in terms of size, age, geographic location, etc. I noticed that the number of adverse reactions reported by patients to new drugs was often highest in the USA, followed by Europe and with Japan reporting the fewest. Colleagues who worked in Japan even told me that it was generally felt dishonourable there to report adverse events in clinical trials! How reasonable is it then to draw conclusions from comparisons of something like educational systems that are even more complex and culturally based.

Of course, the flagship article of this issue and the main reason for this theme of teaching and learning is to introduce EMWA's Advanced Curriculum Programme which is explained in detail in this issue. Personally I am thrilled to see the introduction of this programme, as it has been something that the EMWA Executive Committee (EC) has been discussing ever since EMWA's independence from AMWA. I also applaud the step that this represents in showing that learning never stops and that EMWA can support the training of both novice as well as more experienced medical writers.

This issue also introduces the 2005 EC candidates. This may seem unrelated to learning and teaching, but many members may not appreciate that another way that EMWA teaches and supports professional development outside of the EMWA Professional Development Programme is through member's participation on the EC and EMWA Professional Development Committee (EPDC). By volunteering to serve on the EC, members can learn from first-hand experience how to run an organization as well as obtain invaluable experience in leadership roles. This chance should not be underestimated, as ordinarily getting the chance to manage in the corporate sector without prior management experience can be very difficult. The only requirement for such a position in EMWA is enthusiasm, a willingness to work hard, and the flexibility to learn from the other EC members and the extremely competent professionals at our Head Office. Many EMWA members, myself included, acquired important experience on the EMWA EC that later proved invaluable in their professional careers.

Learning and teaching are vital for societies if they are to flourish and serve their citizens, as well as for individuals, for both personal satisfaction and professional development. Although we are presented with many opportunities for learning and teaching in life, the reason for the existence of EMWA is to support and encourage learning for medical writers. Opportunities, however, are passive, they need to be seized if one is truly to exploit them. EMWA offers countless opportunities for learning and teaching, whether in the official role of learner or teacher. To make the most of your EMWA membership, it is important to take advantage of those opportunities by attending workshops, being a workshop leader or serving on the EC or EPDC. Only then can you fully participate in the process of learning and teaching – indeed of what it means to be human.

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Message from the President

by Adam Jacobs

It's hard to believe that it's already time to write my last "Message from the President". Time goes so quickly when you're having fun. And what fun it has been! It has been a great privilege for me to spend a year at the helm of such a wonderful organisation as EMWA. Yes, it's been hard work, but EMWA is like so many other things in life, in that what you get out of it is in direct proportion to what you put in. Which brings me on nicely to the theme of my final presidential message: getting involved.

If your only involvement with EMWA is reading TWS—excellent journal though it is—then you are missing out on something. The best thing about EMWA, in my mind, is undoubtedly the conferences. As well as the excellent training on offer, EMWA conferences are a splendid place for networking. Through EMWA, I have not only made new friends, improved my medical writing skills, and found new clients, but also developed the network that made it possible to write the guidelines on the role of medical writers in peer-reviewed publications [1].

Even if you work for an Evil Boss who won't let you come to EMWA conferences, there are still plenty of ways to get involved. Articles for TWS are always welcome, and since presumably you are a professional writer, you should be well qualified to contribute one. Our website team have all sorts of plans to make the website an even better resource than it is, but they need volunteers to make them happen. If you can spare any time to help, our web editor would love to hear from you. And talking of the website, those of you who haven't visited it for a while may not be aware that the dialogue page has recently undergone an extensive makeover, and is now free of those annoying adverts. The dialogue page is an excellent medium for "virtual" networking with other medical writers, so if you ever want to discuss anything with the wider medical writing community, then please make use of it. If you have any other ideas for how you can contribute to EMWA, then please get in touch with any of the executive committee. Remember, the more you put into EMWA, the more you'll get out of it.

Finally, for those of you who were fans of the TV series "Grumpy old men", and share my sense of astonishment that I wasn't invited to contribute, allow me briefly to sound off on one of my pet hates: gratuitous capitalisation. Astute readers will notice that I capitalised the phrase "evil boss" in the preceding paragraph, which I did for dramatic effect. Apart from dramatic effect—which doesn't crop up very often in medical writing—capitals in English are only for proper nouns or the start of sentences. And yet if I had a pound for every time I read a protocol with phrases such as "the Investigator will notify the Sponsor of all Serious Adverse Events occurring in any Study Subject after the Screening Visit", I'd be a rich man. Well, OK, maybe not, but I'd certainly have enough for a round of drinks, perhaps even one of the enormous proportions that somehow found its way onto my bar bill at the EMWA conference in Munich. Maybe there are more important issues, but while I'm still figuring out how to end war, hunger, poverty, and disease, my campaign to rid the medical writing world of all gratuitous capitals will continue. Join me!

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1. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21:317-321. doi:10.1185/030079905X25578



Meet the EMWA Executive Committee candidates . . . 2005

If the new EMWA constitution is accepted, EMWA's legal entity will change and all positions on the Executive Committee (EC) have to be elected into that new entity. Candidates will be elected based on voting by members present at the Annual General Meeting in Malta on 19 May 2005. If you will not be present, you may also vote by proxy in advance, by sending your vote to Judith Westhoff and Adam Jacobs prior to 14 May 2005 (contact details on back cover).

For the position of Executive Secretary: Julia Cooper

The role of Secretary was originally created to ensure that EMWA fulfils its legal obligations as a registered company. In addition, the Secretary reviews the activities of Head Office and works with Head Office staff to improve our services. I have been a member of the EMWA EC since 1998. During my term as President, I worked together with Barbara Grossman to identify and appoint a new management company to replace the previous provider that EMWA had outgrown. Through my various roles on the EC and, in particular, the in-depth review that we carried out during the appointment of a new Head Office, I have gained wide experience of how EMWA works and where our strengths and weaknesses are. I would be pleased to carry on putting this experience to use for EMWA's benefit, by continuing as Secretary for a further term.

For the position of Immediate Past President: Adam Jacobs

I have greatly enjoyed the time I have spent as president of EMWA. In particular, I am very pleased to have been able to publish EMWA's guidelines for medical writers involved in publications, which has allowed EMWA to play an important part in shaping the great debate on "ghostwriting" in medical publications. I look forward to continuing this work in my capacity as Immediate Past President.

For the position of President: Michelle Derbyshire

The time I have spent as vice president of EMWA has been very enjoyable and I feel that I have contributed to the smooth running and growth of EMWA. I have enjoyed being part of the organisation of the conferences, from London in 2003 to more recently Munich and Malta, and with the broadening of EMWA's horizons with the introduction of the advanced curriculum and extra activities at the Malta conference. I hope to see many of you in May in Malta (both above and under the water - see the article on diving!) and look forward to continuing my work with EMWA in my capacity as president.

For the position of Education Officer: Virginia Watson

I have served as a member of the EMWA Professional Development Committee (EPDC) since it was formed in 1999 to develop an education programme for EMWA

members. During this time, the EMWA Professional Development Programme (EPDP) has become established, the number of workshop leaders and workshops offered have increased and, at this conference, we have launched the advanced level programme. Wendy wishes to stand down as Education Officer after completing her 2-year term and, having the support of the other members of the EPDC, I would like to stand for election as the next Education Officer.

I have been working full time in the world of medical writing for nearly 10 years, but behind that I have a wide range of experience gained from working in the pharmaceutical industry and in the public healthcare environment. This combined with many years of managing, training and mentoring staff has made me a firm believer in the importance of continuous professional development. My interest in training and development motivated me to join the EPDC and to become a workshop leader. It also led me, 5 years ago, to accept an invitation to become European Programme Chair for the medical writing track of the DIA. In this role I have been involved in the planning of 5 annual meetings and 4 medical writing meetings in the US and Europe.

With a growing membership in EMWA there is a continuing need for the foundation level programme, but we also now need to offer professional development at an advanced level. I would like this opportunity to represent the EPDC as Education Officer and to work with the EC, the workshop leaders and you, the members, in continuing to enhance our professional development programme for the benefit of all.

For the position of Treasurer: Wendy Kingdom

I first thought about volunteering for the post of treasurer several years ago but I didn't feel that I had the necessary experience at that time. Then came the period of transition when EMWA changed Head Office. Barbara, in partnership with Julia, managed this period with professional dedication. It was not the time for a new person to take over. Barbara has done a tremendous job as treasurer and she deserves our warmest thanks now that she is stepping down. Having been on the EPDC since it started, having served as Education Officer for 2 years, and having also successfully run my own business for 3 years, I now feel that I have more to offer EMWA. I enjoy organising funds, no matter who they belong to, and I would like to have the opportunity to manage EMWA's finances to ensure that our membership fees are allocated in the best way to serve us all.

For the position of Public Relations Officer: (1) Judi Proctor

Having been the Membership Officer for EMWA for the last 4 years I feel that I understand how the association works. As Public Relations Officer, I would like to be involved in working towards getting the name of EMWA known, not just to medical writers but all members of the pharmaceutical and medical communications industries. I would like to work towards the time when all people in our industries value the EMWA EPDC certification as much as we, as medical writers, do.

For the position of Public Relations Officer: (2) Kari Skinningsrud

I have been a member of EMWA since 2000 and have participated in most EMWA congresses since then. After speaking with enthusiastic and helpful freelancers at the congresses I was ready to start my own freelance business "Limwric" in Norway in January

Meet the candidates

2002. Before that I had worked in the pharmaceutical industry since 1983 with sales and marketing, but most of all with management of clinical studies and writing of the related documents. EMWA has been an extremely important forum for me. As an employee in the industry, the challenges were different from what they are for me as a freelancer, but help to define and gain respect for the medical writer role is definitely needed in both settings. Medical writing as a profession is unknown to most members of the medical community in Norway and I have had to think much about how to make it better known in order to sell my own services. Involving professional help to develop a brochure and a website for my company has been a valuable process. I believe medical writers possess competence that we should be proud to offer and that EMWA can do even more in spreading the good news. Since last year I have had the pleasure to be a workshop leader in EMWA and my workshop "Cross-Cultural Communication" will be offered at the Malta congress. I think coming from a country with weak traditions in medical writing and having experience with selling the profession there is a good background to have when joining the EC Committee as a Public Relations Officer.

For the position of Vice-President: Ian Metcalfe

Ladies and gentlemen, following the style of my last candidate statement, I'd like to try and hold your attention by providing you with more than "just my CV and dreams of grandeur" and hope to express my thoughts in terms of something close to my heart. The snow-capped peaks of the Alps offer many things to many people. To some they are a frightening prospect to be avoided at all costs, to others they are a daunting challenge to be surmounted and overcome, and yet others take them in their stride, although wary of hazards, their confidence in their abilities carry them through to the summit. On reflection, the world of medical writing is comparable, bear with me on this.

Take scaling the Matterhorn, Eiger or Jungfrau and think in terms of writing your first investigator brochure, trial report, or protocol. Initially the task may have seemed daunting, even impossible. But given time, and the necessary compliment of skills and experience, even the most overwhelming challenges can be met with success. In our world of data, templates and documents, much as in the world of ice, snow and rock, a helping hand is often required. Assistance in the form of Guides can provide the essential key, giving direction and indispensable information they can help you master the route and reach the summit. EMWA's Guides are those dedicated professionals who volunteer their time to share their knowledge and experiences - our workshop-leaders. They provide us with the skills and techniques that enable us to tackle some of the slipperiest slopes in medical writing. Once equipped with suitable Guides and provided with the tools of the trade, whether they are ice axes, crampons and rope, or templates, guidelines and regulations, there is another, vital piece of gear - the map.

In the early years of mountaineering the Alpine Club initiated the accurate cartography of the Alps. The club's meetings served as a forum for those intrepid few who dared scale into the unknown to express their opinions, share their experiences, and, most importantly, to build on what was already known and provide that information to others.

In much the same way, EMWA provides us with a map to medical writing. Without the contributions our members make, EMWA would no longer be able to provide an accurate map for others to follow.

I may not be a Hillary, Whympers or Coolidge. It is unlikely that I will be the first to summit some previously un-trodden peak. However, I have enthusiasm, commitment and creativity. I want to contribute to an organisation that can provide real, tangible knowledge and skills. I would like to help others reach that sometimes-illusive summit, and to share the medical writer's equivalent to a dawn panorama above 4000 m. As your Vice-President I will concentrate on the service EMWA offers its members, on the retention and recruitment of the best Guides and, perhaps most importantly, on maintaining EMWA as the unparalleled medical writing cartographer available.

For the position of Membership Officer: (1) Kelly Goodwin

I suppose I should tell you a bit about myself before launching into all the reasons why I would make a great Membership Officer for EMWA. After earning degrees in mechanical engineering and biomechanics, I was itching for some adventure and started looking for a job in Europe. Now jump ahead 5 years and ask how true love can turn a mechanical engineer into a medical writer in 3 easy steps. Step 1: marry a handsome Swiss man and move to Switzerland. Step 2: look for any job they will give to a non-Swiss, non-EU citizen. Step 3: land a sweet deal working as a medical writer. And the rest, as they say, is history. I have been working as a medical writer for almost 2 years now and I love my new career. Even though I started with limited experience, I was quickly able to take on many writing responsibilities due in a very large part to my participation in EMWA. I attended my first conference 2 months after starting my job, and since then everything I have learned through the workshops or simply by talking to other members has been a tremendous help to me.

So, why do I want to take on the role of Membership Officer? First of all, I have benefited enormously from EMWA and I would like to give something back to the organisation. As a relatively new member, I know how intimidating it may be to attend your first conference. I am fortunate enough to work with another EMWA member who gave me the low-down on the organisation and introduced me to many people, but I realize many new members may not have this luxury. One of my ideas would be to pair up first-timers with an experienced EMWA member who could act as a mentor during a conference, introducing them to other members, answering questions, and generally helping them feel at ease. As Membership Officer, I would work to ensure that your ideas are heard and that EMWA is truly run for and by its members.

For the position of Membership Officer: (2) Alison McIntosh

I joined EMWA after becoming a freelance medical writer in 2000. Since then I have supported the activities of the association by developing workshops for the EPDP, contributing articles to *The Write Stuff* and assisting with the Freelance Forum. For the future of the society, I believe it is important to ensure that the needs of the membership are being satisfied, and that the number of medical writers joining EMWA should continue to grow. I would like to serve the membership by being elected as Membership Officer. In this capacity I would develop and implement a strategy to ensure that the views of the membership are heard, and in conjunction with the PR Officer, work on a plan for growing the membership. I have found EMWA to be a welcoming and dynamic association for medical writers and hope to give back to it by representing the members on the EC.



Sixth annual EMWA autumn meeting, 18–20 November 2004, Munich, Germany

by Wolfgang Thielen

As a brand-new EMWA member (and one relatively green behind his medical writer's ears), I was eager to experience what had been the talk at our office for weeks. Let me say upfront that my first EMWA meeting exceeded my expectations, that it was easily the most worthwhile conference I have attended and an enjoyable initiation to EMWA at that. The meeting was held at Munich's Le Meridien hotel, close to the central railway station. Although its five-star status was not apparent from the outside, the hotel turned out to be a superb and well-equipped venue with a pleasant atmosphere for work and play (and with a confusingly varied breakfast buffet).

On Thursday evening, Susan Bhatti and Geoff Hall kicked off the meeting with their plenary lecture on the changes effected by the new European directives and the repercussions for us as medical writers. They did not fail to point out – with an unmistakably sarcastic tone at times – the difficulties of implementing these directives. The subsequent conference-warming reception was the first opportunity to mingle with the "friendly bunch" and to meet the other new members (the blue dot on the name badge proved a helpful identifier). Also, it was interesting to see that people came to medical writing from various backgrounds (some through the backdoor, like myself) and engaged in a broad range of medical writing and consulting activities apart from the canon of regulatory documentation. The first day ended (officially at least) with an informal dinner where a jolly EMWA crowd occupied an entire wing of the restaurant, as it were, and kept the waiter busy serving (some more, some less traditional) German/Bavarian specialties.

On Friday it was workshop time, and I found the first tentative steps in the professional development program very rewarding. With 9 workshops to choose from and 3 workshop sessions in total, there was a lot going on and a lot to be learnt. In addition, the workshop leaders came across not only as knowledgeable and enthusiastic, but also as very approachable inside and outside the seminar rooms. After the second round of workshops on Friday, it was time to put on hats and gloves and brave the weather on a bracing walk to the *Green Goose* where we indulged in hearty Bavarian fare (for the carnivore in each of us) and a fun social evening in the vaulted cellar of the restaurant. On Saturday morning, more meat (i.e., the last set of workshops) was served, rounding off a short 2½ days in Munich.

It was great to have the opportunity to attend and experience a friendly and encouraging welcome to EMWA. I am sure we have every reason to look forward to this year's main conference on a small Mediterranean island known as Malta – this must be the first time in the 7000 years of Maltese history that the place is teeming with medical writers. Hope to meet you there (again) – Pfuati Munich, Mer ħba Malta!

Wolfgang Thielen

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Training a team of medical writers with diverse backgrounds

(Making a silk purse from...many different types of silk)

by Heather Bishop

A recent internet search produced the following statement, "No one grows up declaring a wish to be a medical writer...". Although we might feel a little defensive at this sentiment, there is a truth at the heart of it. A truth demonstrated by the large number of medical writers who come to this profession via another.

Our medical writing group, established 5 years ago, is no exception to this. Nine of our 10 medical writers began their working life doing something else. Our group includes a former nurse, a pharmacist, a pharmacokineticist, an analytical chemist, a research scientist, a scientific journalist and a project manager. Between us we have 78 years of clinical research experience and 55 years of medical writing experience.

Such a breadth of previous experience is a hugely useful resource and we draw on each other's knowledge on a daily basis. Our diversity of backgrounds means that, as a group, we have experience in many aspects of the clinical research process and there are few medical writing situations that at least one of us hasn't experienced previously.

On the whole, our diversity is a strength. However, the same diversity presents a challenge in terms of ensuring that the team delivers a consistent product, regardless of the individual team members involved. This is particularly important when our final product takes many different forms: a protocol, an informed consent, a case report form, a clinical study report or a clinical overview. The answer to this challenge is training.

Basic training

The backbone of our basic training is a programme of core clinical modules run by Inveresk designed to give new staff an overall awareness of the clinical research process, whatever their previous experience. The hour-long modules relevant for medical writers include study design, adverse event and concomitant medication coding, product safety, Good Clinical Practice and the Clinical Trials Directive. Core courses are augmented by specialist courses, which include statistics and pharmacokinetics. These specialist courses can be adapted to suit the needs of the individual medical writer or a specific project. Additional training is provided through supplementary skills courses such as time management, negotiation skills and assertiveness training, considered by most medical writers to be vital rather than supplemental! A list of mandatory and optional core, specialist and supplementary courses for medical writers has been devised. This list includes target times by which individual courses should be completed, usually within 6 months of joining the company for the majority of the core clinical courses and one year for the specialist courses.

Training medical writers

All medical writers receive training on Inveresk's standard operating procedures (SOPs), style guide and guidelines (e.g. review of statistical analysis plans and a quality control [QC] checklist). SOP training is now conducted using an electronic system of multiple choice tests with automated scoring and recording of results.

The requirement for information technology (IT) training has risen sharply over the last 5 years. The increasing use of electronic publishing systems and ever more sophisticated sponsor-specific templates shows no sign of slowing. Basic IT training currently focuses on standard software and the Inveresk templates. However, external training courses are being used to provide advanced training in areas including desktop publishing software and electronic publishing systems. We expect the quantity and variety of IT training (both in-house and external) to grow over the next few years to ensure the team can continue to meet sponsor requirements.

A more recent innovation at Inveresk has been the introduction of therapeutic area teams (TATs) specialising in oncology, cardiovascular diseases, respiratory diseases, infectious diseases and ophthalmology, with more indications to follow. The primary function of these specialist teams is to provide continuous expertise throughout the clinical research process. The teams also provide staff with ongoing training to maintain cutting-edge expertise. TAT training generally takes the form of lunchtime web-based seminars that are accessible from all Inveresk sites. One or more of the medical writing team is present at every TAT training seminar and feedback is provided to the team.

On-the-job training

During their initial training, junior staff perform QC and review of a wide variety of documents in parallel with a more experienced member of the medical writing team. The resulting comments are then compared and discussed. Only when a member of staff is considered to be competent, are they allowed to perform their own independent QC or reviews. All junior staff are mentored to ensure that advice, assistance and reassurance are available when required.

A particularly popular part of our on-the-job training is a day spent on a monitoring visit with a clinical research associate (CRA). This in-the-field experience has proved invaluable for those team members whose previous clinical research experience is data rather than field based.

We make good use of our medical writing team's experience by inviting members to present short courses. An especially useful example of this is a presentation on laboratory data given by our former analytical chemist.

Since the earliest days of our group we have held weekly team meetings mainly for scheduling purposes. However, they are also used as a training forum for sharing feedback from the medical writing team, from other departments within Inveresk and from sponsors.

External training

External training is a vital component of our training programme, allowing us to gain access to fresh ideas and new innovations, not only from the trainers but often from other training course participants.

The EMWA Professional Development Programme (EPDP) forms the core of our external training for new medical writers (and some not so new ones). This decision was made based on the positive feedback on the conferences from those who had attended and we have also had requests from sponsors who were keen to see industry-recognised training and accreditation. EMWA's system of parallel workshops allows training to be tailored to the needs of each medical writer and provides training that is excellent value for money. Specialist external courses are also used to provide additional training on subjects such as statistics and advanced training on various software packages.

Training records and review

Training is currently documented using paper-based training records, supplemented by electronic records of SOP training. The records hold full details of all training, dates and competencies. Training records are reviewed at least annually and new training requirements identified. However, training needs can be identified at any time based on the requirements or interests of the individual medical writer.

Why and where now?

Commitment to a progressive training programme is good for our company, for the individual medical writer and for our customers. In a large team such as ours, training is vital to ensure that the diverse skills that we have are applied consistently.

Future training plans at Inveresk include a move away from paper-based internal training and training records, expansion of our use of the EPDP to all new medical writers and more frequent and specialised IT training to keep ahead of increasingly complex templates and electronic publishing systems. We are also watching the new EMWA advanced level Professional Development Programme with interest.

The diversity of backgrounds within our medical writing group is an asset that we increasingly rely on as studies become more complex and reporting more rigorous. We value this diversity, and plan that our training programmes will support and encourage this, whilst allowing the team to continue to deliver products of a consistent high quality.

Heather Bishop is a medical writer within the European Medical Writing group at Inveresk, a Charles River Company. Inveresk is one of the largest contract research organisations in the world. The European Medical Writing group is managed by Karen Manson.

Foundation and advanced levels for the EMWA Professional Development Programme

**by Stephen de Looze and Beate Wieseler
for the EMWA Professional Development Committee**

New training and certificate opportunities for medical writers

It may come as a surprise to new EMWA members to learn that the EMWA Professional Development Programme (EPDP), such a backbone of our annual spring and autumn conferences, was introduced as recently as 2000, at the ninth annual EMWA meeting in Dublin. With the aim of providing training for medical writers by medical writers through workshops and homework assignments, it provides one of the few opportunities of attaining a formal certificate in Medical Writing.

Since its inception, the EPDP has grown rapidly, from 18 workshops in 2000 to around 40 workshops at the spring conferences in 2003 and 2004. Various workshop types and formats have been introduced to keep pace with the growth of the EPDP, including short workshops, double workshops, "soft skills" and special interest workshops. EMWA's own steady growth means that experienced writers increasingly number amongst our membership. The EMWA Professional Development Committee (EPDC) has responded to our changing membership needs by developing the advanced level curriculum programme, with corresponding certification, that will be launched at the forthcoming spring conference 2005 in Malta.

The "new look" EMWA professional development programme

When the EPDP was initially introduced, workshops were assigned to one of four options, namely Foundation, Editing and Writing, Pharmaceutical, and Public Relations and Marketing (later renamed Communication). All of the options included workshops of mixed levels; some were intended for new medical writers while others were aimed at people with some experience. To attain an EPDP certificate, members were required to obtain credit in four foundation option workshops and any other four workshops. If these four workshops were all selected from the same option, a specialised certificate in that option was awarded; otherwise a multidisciplinary certificate was awarded. Additional specialised certificates could be obtained by obtaining credit in four more workshops from a different option.

The present EPDP structure has outlived its usefulness because of the growth and diversification in the workshops now offered at EMWA conferences. The balance of workshops assigned to each option has become increasingly uneven, and some workshops do not easily fit into any option. A thorough review of all workshops revealed that a couple of workshops that had even been assigned to the foundation option were actually more suited to experienced writers.

The EPDC has therefore decided to redesign the entire programme so that it provides a robust framework now and in the future for both the foundation level and the new advanced level curricula.

The Write Stuff

Foundation and advanced levels for EPDP

All credit workshops have been re-assigned to one of five options, each of which is offered at two levels – foundation and advanced. The five new options are:

- Language and Writing
- Professional Techniques
- Medical Science
- Drug Development
- Medical Communication

All of the workshops that were previously in the foundation option have been assigned to one of the above five options, and the word "foundation" now applies to the certificate that is aimed at new or relatively inexperienced writers.

As in the past, EMWA conferences will offer short workshops, "soft skills" and other special interest workshops that are not for credit, as well as events such as discussion forums that are not part of the EPDP.

The diagram below summarizes the training opportunities now offered by EMWA:

EMWA MEDICAL WRITER TRAINING					
FORUMS SOFT SKILLS & SPECIAL INTEREST WORKSHOPS	EPDP WORKSHOPS				
	Language and Writing	Professional Techniques	Medical Science	Drug Development	Medical Communication
	Advanced Level Workshops				
	Full-length	Full-length	Full-length	Full-length	Full-length
	Short	Short	Short	Short	Short
	Foundation Level Workshops				
	Full-length	Full-length	Full-length	Full-length	Full-length
	Short	Short	Short	Short	Short

Full-length	Full-length workshops (8 required to complete a foundation or advanced certificate)
Short	Short workshops (not for credit towards a certificate)
Soft skills and special interest	Full-length or short workshops (not for credit towards a certificate)
Forums	Open discussion groups on forum-specific topics

Foundation and advanced levels for EPDP

Content and format of the foundation and advanced level workshops

The content of the foundation level workshops will be aimed at new or relatively inexperienced writers. The format of the foundation level workshops remains the same as under the old scheme: each workshop will be three or three-and-a-half hours long, with a maximum of 28 participants, with pre- and post-workshop assignments that should generally take on average no more than five hours in total.

Advanced level workshops will cover topics that are likely to be of greater interest and benefit to more experienced writers, or will take foundation level subject matter and deal with it at greater depth. The advanced level workshops will also be three or three-and-a-half hours long, but with a maximum of 15 participants. Pre- and post-workshop assignments will be required, and should take experienced medical writers on average no more than five hours in total to complete. The lower number of participants will enable workshop leaders to develop a more intense and interactive training session, and provide more detailed feedback on the workshop assignments.

Inevitably, there can be no sharp dividing line between foundation and advanced topics and we know from experience that new medical writers sometimes find themselves performing "advanced" assignments (e.g., preparing clinical submission documents). The EPDC will therefore decide on a case-by-case basis whether a new workshop is more suited to the advanced level rather than the foundation level curriculum.

Certification at foundation and advanced levels

An EPDP specialised or multidisciplinary certificate at foundation level may be awarded to candidates enrolled in the EPDP at foundation level who have obtained credit in eight approved foundation workshops as follows:

- At least five workshops in a single option to qualify for a specialised certificate in that option.
- Workshops in at least two options but no more than four workshops per option for a multidisciplinary certificate.

As in the past, candidates may obtain a multidisciplinary foundation certificate and more than one specialised foundation certificate. The type of foundation certificate is not registered in advance, but can be chosen when the required credits have been attained. However, each new foundation certificate will require eight new credits. This is a change from the past arrangements, when only four new credits from a different option were sufficient for a further specialised certificate.

An EPDP certificate at advanced level may be awarded to candidates enrolled in the EPDP at advanced level who have obtained credit in any eight approved advanced workshops. Advanced certificates (which do not come in different varieties) will be limited to one per candidate.

There are no formal prerequisites to enrol at advanced level. However, in order to obtain maximum benefit from the workshop and minimize the risk of failing a workshop, participants are strongly advised to select each workshop according to their educational needs and experience in that particular area. Workshop leaders of advanced workshops will keep the focus of the workshop at an advanced level and will not spend time responding to the needs of inexperienced participants – not least because this would be unfair to experienced participants.

Questions and answers

Q: May I be enrolled at both the foundation level and advanced level at the same time?

A: Yes. Members may be new to some areas of medical writing, such as pharmaceutical writing, but be more experienced in others, such as editing. Because there are no formal prerequisites for enrolment, it would even be possible for members to enrol first at the advanced level and later at the foundation level. The responsibility for making best use of EMWA's training opportunities lies with the individual member. As in the past, members may attend workshops without being enrolled in the EPDP at all, but in such cases, no credit will be awarded.

Q: How do I know if I am experienced enough to benefit from the advanced level curriculum?

A: Each workshop is advertised with a "participant profile" as a guide to the required level of experience. As a rule of thumb, completion of an EPDP foundation certificate (or similar), or about four years of on-the-job experience in a particular area should be sufficient.

Q: What about enrolment and workshops fees?

A: As in the past, fees are due both for enrolment in the EPDP (good for five years) in order to attain credit, and for participation in individual workshops. Enrolment in the EPDP at foundation level and at advanced level will each incur a separate fee. Individual registration fees for advanced workshops will be somewhat higher than for foundation workshops due to the lower number of participants. Details of the fees will be provided on the registration form for the Malta conference.

Q: When does enrolment under the "new look" EPDP begin?

A: Members can enrol for the foundation and advanced level programmes when they register for the spring 2005 meeting in Malta. Credit workshops at each level will be available during the Malta conference.

Q: I am already enrolled into the "old" EPDP and have acquired some credits. What happens now?

A: All members will have their enrolment fee and credits transferred towards a foundation level certificate. Members intending to complete a multidisciplinary certificate, or specialised certificate under the new scheme, can continue to accumulate credits from the new foundation level workshops as described above. **Anyone who was intending to complete a specialised certificate under one of the old options must contact the Education Officer or EMWA Head Office before the Malta conference and register their intention.** For these members, the old arrangements and old workshop option allocations will be applicable up to and including the spring conference 2006. After that time, only certification under the new scheme will be possible. Members should also be aware that any new workshops added to the EPDP from 2005 onwards will not be allocated to the old options and hence will not count towards a specialised certificate under the old scheme.

Foundation and advanced levels for EPDP

Q: Where can I see the new workshop allocations?

A: A complete list of workshops in the programme showing their old and new allocations is given in the following section. This list also includes short workshops, which were not previously assigned to an option. The EPDC feels that this will provide a useful guide to members interested in taking a short workshop. If the short workshop is developed into a full-length credit workshop, the option allocation will remain the same. The Malta conference brochure will give details of 22 foundation level workshops and five advanced level workshops that will be held during the conference.

Q: I have credit for a workshop that has now been assigned to the advanced level curriculum. Will this count towards an advanced level certificate if I now enrol in the advanced level curriculum?

A: No. Credits towards an advanced level certificate can only be attained after enrolment into the advanced level curriculum. As in the past, retrospective allocation of workshop credits is not possible. Furthermore, as described above, the format of the advanced workshops has changed, and in some cases, the workshop leader will adjust the content to suit the advanced participant profile. So if a member wishes to attain an advanced credit for a workshop they have already taken under the "old" scheme, they must enrol in the advanced level curriculum and take the workshop once more. The credit they have previously attained will of course count towards a foundation certificate.

Re-allocation of EPDP workshops

In the lists below, each option is divided into foundation level workshops and advanced level workshops, each sorted alphabetically by workshop title. The previous EPDP option assignments are given next to the workshop name and are denoted as follows:

- EW, Editing and Writing
- F, Foundation
- P, Pharmaceutical
- C, Communication

Note the following:

- An asterisk (*) denotes workshops currently under assessment.
- The short workshops (not for credit) were not previously assigned to an option but now appear in the new categories.

Language and writing option

Foundation Level

Developing Patient Education Handouts	EW
Essentials of Editing and Proofreading	EW
Grammar Flaws: Taxonomy and Revision	EW
Improving Comprehension: Theories and Research Findings	F
Medical and Pharmaceutical English for Non-Native Speakers	F
Paragraphing	F
Punctuation	F
Syntax flaws: Taxonomy and Revision	EW
Syntax, Meaning and Word Order	F
Word Usage Flaws: Taxonomy and Revision	EW

Advanced Level

Medical Writing for the Multilingual Audience: How to Enhance
Cross-Cultural Comprehensibility and Translatability (short workshop)

Professional Techniques Option

Foundation Level

Advanced Word Processing	F
Data Presentation I	F
Ethics for Biomedical Writers and Editors	EW
Information Sources for Medical Writers	F
Introduction to Macros in Microsoft Word	F
Maximising Presentation Performance	F
Medical Writing and Quality Control	F
Using Statistics in Medical Writing	F
Web Page Design*	
Cross-Cultural Communication	

Advanced Level

Association, Correlation and Regression Analyses	F
Data Presentation II	F
Do More With Less Faster: Project Management for Biomedical Communications	P
Managing Medical Writers (short workshop)	
Recruitment and Selection (short workshop)	
Statistical Thinking for Medical Writers	F
Strategies for Improving Document Quality	EW

Medical Science Option

Foundation Level

Pharmacology for Medical Writers Part 1: The Basics	P
Pharmacology for Medical Writers Part 2: Drugs acting on Peripheral body systems - Cardiovascular, Hormones, Inflammation, Gastrointestinal	P
Basics of Epidemiology for Medical Communicators	P
Understanding Homeopathy (short workshop)	

Advanced Level

No workshops presently available in this option

Drug Development Option

Foundation Level

Drug Safety for Medical Writers	P
European Regulatory Procedures for Medical Writers	P
From Protocol to Study Report: What's In Between?	P
Introduction to Health Economics	P
Introduction to Pharmacokinetics	P
Introduction to Quality of Life	P
Plain English: The Clinical Trial Patient Information Leaflet	EW
The Clinical Study Protocol	P
The Investigator's Brochure	P
The Package Leaflet	P
Understanding Research Ethics Committees	P
Writing Clinical Study Reports Using ICH E3	P

Foundation and advanced levels for EPDP

Drug Development Option (continued)

Advanced Level

Clinical Study Design	P
Medical Writing Between Dossier Submission and Drug Approval	P
Serving Two Masters: Comparing and Contrasting US and EU Regulatory Submissions and Processes	P
The Clinical Development Plan and its Relevance to Medical Writers (short workshop)	
The CTD Clinical Overview*	P
Writing Global Clinical Submission Dossiers Using the Common Technical Document	P

Medical Communication Option

Foundation Level

Crafting a Press Release: The Principles of Writing for the Press	C
Marketing Your Manuscripts and Dealing with Biomedical Journals	EW
Publication Planning (formerly Publication Strategy and Planning)	EW
So You Want to Write Promotional Pharmaceutical Copy	C
Targeting Your Audience	F
The Biomedical Paper	EW
Writing a Manuscript for Publication	EW

Advanced Level

Publication Strategy (formerly Publication Strategy and Planning)	EW
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Soft Skills and Special Interest (not for credit)

- Good Publication Practice for Pharmaceutical Companies
- Interpersonal Skills for Medical Writers
- Literature and Medicine
- Speaking in Public (double workshop)
- Starting up and Running a Freelance Company (short workshop)

FOOD FOR THOUGHT

"By three methods we may learn wisdom: First, by reflection, which is noblest; Second, by imitation, which is easiest; and Third, by experience, which is the bitterest."

Confucius, philosopher and teacher (c. 551-478 BCE)



Medical journalism – a career move?

by Jo Whelan

Bored with writing protocols or scientific papers? Fancy seeing your name in print? Then maybe you've thought about moving into medical and scientific journalism. There is continuing demand for good writers who can understand scientific stories and convey them in an interesting way. So what opportunities are out there, what skills do you need, and how easy is it for medical writers to move across into journalism?

What do we mean by journalism? At one end of the spectrum is the investigative journalist, who looks behind the public face of companies, products or policies to dig out stories that would otherwise remain hidden. Then there are news reporters, covering stories as they break and often writing or broadcasting on their feet – or by the seat of their pants – to make that day's issue or bulletin. For some, these are the only true journalists. According to Michael Kenward, an ex-editor of *New Scientist*, "Science writing is about explaining complex ideas that nobody wants to keep secret; science journalism is about explaining things that everyone can understand but that some might prefer to keep buried."¹ By this definition, much of what most science writers in the media do is just that – science writing. Even so, they are expected to maintain a critical approach. At the other end of the spectrum is public relations (PR). PR writers supply stories to the media as part of their client's communications strategy. At their best these articles can be informative and scientifically correct, but by their nature they lack independence. For the purposes of this article I will use the term "medical journalism" to describe journalism and science writing – but not PR – covering the life sciences.

A huge quantity of medical and scientific journalism is churned out each week by the various media. The scientific and medical press, consumer magazines, newspapers, radio and television, online news services and medical/scientific websites – all require writers, reporters and editors. Encouragingly for anyone wanting to break in to the area, many editors say good people are hard to find. So what are they looking for? PhDs and research experience can be a plus with the specialist scientific media, but elsewhere will score no more highly than a basic science degree. Curiosity, good general knowledge and the ability to pick up new concepts quickly are more important than in-depth expertise, especially when writing for a non-specialist audience.

You must, of course, be able to write well. The core writing and analytical skills needed by medical writers apply equally to journalism, but the emphasis is different. A dry summary of some clinical trial results is not a news report and would make a pretty turgid feature. Journalists must engage the reader's attention from the first paragraph, and keep it until the last. You are telling a story, not just setting down facts. It is interesting to take something you rate as a good piece of journalism and analyse why you found it interesting and how the writer kept you wanting to read on. Essential to this is knowing how to write for your market, a skill that some medical writers will already be practiced in. The

Medical journalism

same story needs to be told very differently depending on whether the audience are doctors, business managers, readers of the quality press or buyers of a weekly glossy.

So medical writing skills are a useful foundation for journalism. But moving between the two activities requires a definite change of mindset. It is a fact of life that as medical writers we write about the companies and products that pay our wages, and our quite legitimate aim is to further their interests (within ethical and regulatory guidelines, naturally). Journalism shouldn't be romanticised, but the ideal is to give the reader a balanced and objective view. This requires a questioning attitude and a healthy dose of scepticism. It is essential to look both behind and around the "facts" you are reporting. So, you see a press release from Kuritech Magiceuticals Inc. This young company has made a potential breakthrough in the fight against cancer, it reads. Its new compound, KM007, can completely eliminate tumours in mice. It's in a new class called wotsitase inhibitors, and extremely promising. Wow, you think, this is news. You ring the head of R&D at Kuritech. He explains about KM007 very persuasively and at great length. Your tape recorder runs out of memory and your head is going round. Nevertheless, you think you've got a story so you rephrase the press release, add some quotes from your interview and call the piece "New class of cancer drug cures mice".

You are about to send it to your editor when you stumble across the same story on a rival journal's website. It is entitled "Last chance for wotsitase inhibitors". It seems that several have worked in mice but all have left human tumours untouched. It cites a paper called "Possible reasons for the lack of wotsitase inhibitor efficacy in humans." Curiously, the Kuritech guy never mentioned it (he had a counter argument, but to his surprise you never asked.) The article also quotes an expert from Cancer Research UK, who says she'd be very surprised if KM007 could overcome the problems inherent to its class. Finally, it mentions that if the drug fails then Kuritech will go bust. You come over cold and start to feel sick. Shakily, you retrieve your article from the outbox and begin to rewrite it.

The near-disaster above would have been averted by observing a few basic rules:

- never take press releases, corporate publications or newspaper/magazine articles at face value;
- get the background on your story;
- ask searching questions when you interview people;
- always get an independent expert to comment;
- be aware of people's motivations, agendas, conflicting interests and possible prejudices;
- don't report statements as fact. Use qualifying phrases like "according to Kuritech", or "says Dr X".

These rules (not to mention the one about getting your facts right) are routinely ignored by sections of the British media. Bad science journalism (usually by non-specialists) is depressingly common. And you will often find your carefully expressed nuances and qualifiers obliterated by an over-zealous sub-editor. The mangling has occasionally been so bad that I've wanted to disown the end result.

Getting started

How do you move into medical journalism? The specialist press and its online counterparts are the easiest to break into if you have the right scientific background. Getting

into consumer magazines is more difficult, and getting a break in broadcasting or the national press is very tough indeed. For an excellent guide to starting a career in science journalism, visit the website of the Association of British Science Writers [1].

A course in journalism may help. Don't waste money on those heavily advertised correspondence courses: they are generally acknowledged to be useless. Read a good journalism textbook instead. Freelancing is a good way in. Study the market to see who is using freelance contributors. You could then ask if they are looking for new writers. Better still, suggest a specific story that you think might interest them – having carefully studied the publication or website first. Some publish guidelines for contributors. If it's a feature idea, give a synopsis. If it's news, say where you heard it and who you plan to interview. For consumer magazines and the national press, the only hope for unpublished writers is probably to send in the entire article on spec, unless you have a very hot piece of news indeed. Never offer something to more than one publication at once.

Freelance journalism is fun, but it's tough to make it pay the bills on its own. While some markets pay well (the best ones matching the average daily rates paid for medical writing), most do not. Many have held their word rates static for the last 10 years or so. The scientific and medical press generally pay better than the general and consumer media, unless you can make it into the colour supplements. A first staff job in the media will almost certainly pay less than medical writing.

Editors want evidence of writing ability, and a background in medical writing provides that. Your close links with the pharmaceutical industry could be seen as positive – giving you an inside view; or as negative – too uncritical and unable to see things from a non-pharma perspective. Many medical journalists are suspicious of the industry, particularly of its PR activities. However, it is possible to combine medical writing and journalism, providing you are seen to understand the different requirements of each discipline.

Jo Whelan

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FOOD FOR THOUGHT

"No mistake is more common and more fatuous than appealing to logic in cases which are beyond her jurisdiction."

Samuel Butler, writer (1835-1902)



Programme for International Student Assessment (PISA) - learning for tomorrow's world?

by Patricia Bünz

Recently a discussion has been going on in Germany about the Programme for International Student Assessment (PISA), an Organization for Economic Cooperation and Development (OECD) programme. The PISA results shook the belief of Germans and other countries that their education system was one of the best in the world. PISA 2003 seemed to confirm that the quality of the German education system is only average. But what exactly is PISA and can we learn anything from it?

PISA is an international standardised assessment of 15-year-olds, which takes place in 3-yearly cycles in industrial countries. The domains of reading, mathematical and science literacy are assessed in all cycles. However, the emphasis differs from cycle to cycle. In 2000, the main focus was on reading literacy, in 2003 on mathematical literacy and problem solving, while the emphasis will be on scientific literacy in 2006. The survey was implemented in 43 countries for the first assessment, and 41 countries participated in 2003. Tests were administered to between 4500 and 10,000 students per country. PISA was developed to find out what kind of knowledge and skills students have acquired, and how well prepared they are for tomorrow's world near the end of their education. In addition, results should enable countries to monitor their progress in meeting key learning objectives. Sounds wonderful, but is this survey really useful?

Most of my teacher friends criticise the survey as a generalisation, which does not consider the differences and diversity amongst students or national education systems. However, PISA *did* evaluate differences in schools, gender and socio-economic background. In addition, school policies and practices, resources invested in schools, the

In contrast to reading, which showed an overall gender difference in favour of girls, there were no pronounced overall gender differences in mathematics or problem solving.

organisational structure, and the student approach to learning were assessed. However, these factors were not considered for the determination of overall scores.

In contrast to reading, which showed an overall gender difference in favour of girls, there were no pronounced overall gender differences in mathematics or problem solving.

ing. In most countries, gender differences were larger within schools than overall and depended on the evaluated area of mathematics. PISA also showed that there is a link between mathematics performance and school differentiation (use of different institutions or programmes to group students) or students background (e.g. parents' education level, students' immigration status, and language spoken at home) in favour of students with a more advantaged home life. These differences were more pronounced in Germany than in Finland, the top ranking country. In addition, school resources appear to reinforce rather than moderate socio-economic differences in Germany.

Parents complain that less and less money is invested in education. One friend of mine once said that life was wonderful as long as her children were at kindergarten but life is unpredictable for parents with children at school. She never knows when her children leave for school or are coming back home because classes were dropped due to teacher shortages at school. Teacher shortages appears to be of concern in a number of countries according to PISA 2003.

"You cannot teach a man anything, you can only help him to find it for himself".

Galileo Galilei

Recently, two 16-year-olds provided their opinion on PISA 2003 in a German newspaper. They assumed that the German outcome is linked to their observation that most of their fellow German students do not even speak their own language in a grammatically correct way. I agree that nowadays some parents shift responsibilities like learning discipline or German to the school. Thus, teachers are hindered in their instruction capacity by dealing with these kind of problems. School should not only motivate students, show them their own abilities and teach them how to adopt effective learning strategies, but should also show them the relevance of lifetime learning.

Politicians use PISA to justify their wish for global changes in the German education system but their recommendations are not really new and are mainly made for political reasons. A teacher said that 30 years ago another international survey on education resulted in even worse results for Germany. I assume that this survey assessed the knowledge and skills of some of the German politicians. Interestingly, Germany showed an improvement in 2003 in science performance and in some areas of mathematics performance since 2000. Thus, it would be more interesting to investigate the reasons for the overall average German outcome before implementing global changes in the education system.

Obviously there are very different opinions about PISA. But what kind of questions were really asked in this survey? I would like to provide you with one example of the mathematics tasks which students had to solve. A figure was shown to the students illustrating a staircase with 14 steps and providing additional information like a total height of 252 cm. The total depth of the staircase was added as redundant information to confuse the poor student. The question "What is the height of each of the 14 steps" should have been answered. According to PISA, the correct answer is a simple division (252 cm divided by 14). But is this true? No! They should have asked for the mean height of each step! Thus, the correct answer would have been a counter-question to be able to measure each step on site.

So what can we learn from PISA? How about that learning never ends, not even for people who develop these surveys!

Last, but not least, I would like to say "goodbye" to the editorial board of TWS. After 3 years working as Linguistic Diversity Editor, I decided to resign from this position. It was always a pleasure working on the editorial board and I hope that someone else will have as much fun in this position as I had.

Patricia Bünz

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From over the pond: cancer therapies

by Susanna J Dodgson

The first time I saw anyone die from cancer was the first time I saw someone die, the first time I saw someone dead, and the first time I was asked to help clean and lay out a corpse. Mr Berk had been a farmer in New South Wales, and during the month before Christmas he was far away from his horses and his land, taking nothing but beef broth, getting thinner and thinner and turning greyer and greyer. By the time the lead nurse was joking with the undertaker about Mr Berk not needing Christmas dinner, Mr Berk weighed less than 100 lb. I had just finished my second year of science at the University of New South Wales, the year I fell in love with Biochemistry, particularly with amino acids and simple sugars. My goal in life had become defined: to save lives remotely, by brilliant research with molecules no-one could see, or better yet, discovered, and here I was working in what was known as a convalescent hospital, face-to-face with a dead man. I cleaned and laid out the late Mr Berk the best I could and that evening sang Christmas carols about soft snow falls and winter quiet with other young persons afire with religion in the subtropical summer humid heat. I remember we were all sweating and I remember thinking how quietly Mr Berk died and how glad I was that my career goals precluded me from making a habit of looking at the human face of death.

In the years since, cancer has insinuated itself quietly into my life in many ways, taking first a girl named Karen Baker, who was 15. I was 22 when she died and I had known her since she was 6. She had beautiful green eyes and red hair, used long words effectively and was the eldest child of a pathologist colleague of my father who had moved from Manchester to Sydney by way of Kenya, rather than New Zealand as we had. After Karen's death, which followed a hind-quarter amputation to stop the spread of malignant melanoma from the sole of her foot, deaths by cancer sprung up everywhere, taking my father, a mother-in-law, a neighbour with 2 teenagers, a neighbour with 2 young children, an old neighbour, colleagues and a score of friends with whom I had expected to grow old.

Sometimes cancer has been diagnosed, medicine has been taken, no hair has fallen out, no body parts have been irradiated or lost and my medical writing colleague shrugs and continues teaching aerobic exercises and invests money in her retirement account. Sometimes cancer has been diagnosed, drugs have been injected and radiation has been endured and my daughter's cello teacher survives for 10 years with the loss of favoured, but not essential, body parts. Sometimes every approved and experimental medicine and procedure has been infused, applied and surgically completed but the cancer does not retreat, nor does it suck life away any slower than when no tubes are inserted and no therapies tried. The question I ask is why? Why is diagnosis of cancer an inconvenience in some and the signal of rapid progression towards premature death in others? Why can an early aggressive cancer not be distinguished from one that grows slowly or spontaneously goes away? How can cures that are totally effective in rats and mice be so sparingly effective in humans? The answer is we don't know, but we do know that researchers all over the world will try to find out until the last dog dies.

The despair and optimism that go hand-in-hand in any discussion of cancer are seen in the protocols which define clinical trials and in the medical writer's interpretation of demographic, efficacy and safety data in cancer trials.

Returning home from the Lisbon EMWA conference in Spring 2003, I answered an e-mail in Schiphol Airport in Amsterdam, telling a recruiter that I was available for a four-days-a-week, long-term assignment to work on New Drug Application (NDA) for a new cancer drug. Two weeks later I checked into a motel in Piscataway and for the next six months spent Tuesdays to Fridays working onsite 80 miles north of my house, 10 miles from New York City, in a gorgeous marble, steel and glass building that was part of Bell Telephone back when Bell was one company and they spent lavishly. I was on the top, fourth floor; one wall of my cubicle was a picture window through which I watched cars passing on a highway, and beyond that, deer grazing in the fields and forests. When I needed a break I walked onto one of the many balconies and looked out over the trees in the national forests nearby.

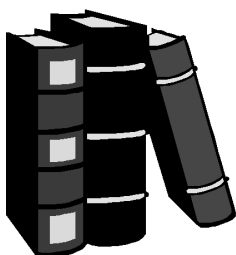
My task, to help put together NDA documents, involved slogging through more than 10 clinical trials in which our drug had been tested on terminally ill patients, some with an expectation of three months more life, some with six months, none with any real expectation of surviving four seasons. I was checking databases to plug gaps in case narratives in clinical trials, writing ongoing trials documents, bits of clinical study reports, bits of labeling documents, bits of NDA summary documents, bits of clinical study report shells, bits of protocol shells. Mostly bits, because that is the way NDA documents are written when drug companies are racing to get to market and databases are being locked three months before filing.

The fact that I was working in a drop-dead gorgeous place with dedicated, friendly regulatory affairs and regulatory writing colleagues was largely responsible for my being able to work on such a grim topic for so long. I was hired with 14 other contract writers by a perpetually cheerful woman who always looked and dressed like a fashion model, and worked harder than anyone I have ever known. I remember her giving me a big smile and telling me that she was going home early, at 9:00 PM, so she would like me to hand her a document that she needed to finalise before then so she would have it to read when she started work again at 4:00 AM. We all adored her and worked together as a team into the winter snows, and then the drug company filed for US marketing authorisation.

The week before Christmas I left North Jersey to work as Editor-in-Chief of the American Journal of Diabetes, relieved to be working with a disease that was chronic, and waited to see what happened with the NDA. Well, unfortunately, the cancer drug was not recommended for approval and so the drug company withdrew its application and started working again feverishly to prepare a new application. The company has good results in some patient trials, they have the best director of medical writing in New Jersey, patients have a desperate need, and so I watch eagerly and try to push them on, blowing in the direction of North Jersey, sending wishes and prayers: keep at it! Keep believing! For Karen.

Susanna J. Dodgson

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In the bookstores... medicines out of control? antidepressants and the conspiracy of goodwill

by Liz Wager

*Charles Medawar and Anita Hardon, Aksant Academic Publishers, The Netherlands.
ISBN 90 5260 134 8. Copies available from www.socialaudit.org.uk*

I started reading this book with the feeling that it was probably something that I ought to read but not expecting to like it. I was afraid it would be a one-sided rant against all that is wicked in the pharmaceutical industry which would leave me feeling both disheartened and irritated. I felt that I ought to read it because I am the first to admit that the behaviour of some drug companies falls far short of perfection, but I expected to be irritated because so many critics misunderstand the workings of drug companies and impute the worst of motives for all their actions. But this book is different.

While the subject is not cheering, and the side-effects of antidepressants may not be a revelation to many EMWA members, Medawar and Hardon have a refreshingly balanced approach. Charles Medawar describes himself as a "layman" specialising in "medicines policy and drug safety issues with a particular interest in corporate, governmental and professional accountability" whilst Anita Hardon is Professor in the Anthropology of Care and Health at the University of Amsterdam. Approaching the subject from an anthropological viewpoint instead of seeking to apportion blame, these

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authors try to understand why individuals and organisations act in the way they do. They also note that "the question mark in this book title is emphatic" and indicates that the book represents "an invitation to make up your own mind".

The book takes the form of an extended case history using the example of antidepressants, in particular fluoxetine (Prozac) and paroxetine (Seroxat), to highlight problems with the regulation and promotion of medicines. The authors central tenet is that everybody wants to believe that new drugs work and that they are safe. This is the "conspiracy" of goodwill of the title. What makes this analysis unusual is the authors' insistence that all players, including patients, regulators and prescribers, are simply swept along by this "conspiracy" rather than manipulated by the drug companies.

Their story starts with the earliest attempts to treat mental illness, noting that "between the 1860s and 1960s, doctors treated mental distress by prescribing alcohol and opium, then morphine, heroin and cocaine. Later came chloral, bromides, barbiturates and many similar drugs. Bar alcohol, each of these drugs was also used to treat addiction – and later found to cause it too." The "historical" evidence, much of which will seem frighteningly bizarre to modern readers, gradually leads into the current story of the selective

serotonin reuptake inhibitors (SSRIs). Medawar and Hardon never neglect the fact that antidepressants have helped many people, but they also demonstrate how (and why) patients' reports of adverse experiences have been systematically overlooked or underplayed.

The roles of doctors, governments, journal editors and drug companies are all scrutinised, yet the authors avoid demonising anybody and are generous in crediting good behaviour even within a catalogue of weaknesses. The problem with SSRIs, the authors conclude, lies in the complex relationships "between the professional, business and governmental organisations involved – and between individuals and organisations." They offer no simple solutions, but it is refreshing to see the players described as "collaborations of essentially decent, honest, intelligent people".

I urge EMWA members, especially those who write up drug studies for pharmaceutical companies, to read this book. In addition to the thought-provoking analysis of the development and promotion of antidepressants it contains interesting insights about the use of language, especially about the description of adverse events. This book also shows that it is possible to write about complex scientific issues in a highly readable style without sacrificing detail or clarity, and that it is even possible to make the seemingly dull topic of drug regulation enjoyable.

Having expected to be irritated by errors I must admit that I did find a few, and, yes they did annoy me. There is a rather sweeping condemnation of ghost writing which is described in the context of "unsavoury marketing practice," but don't worry, I have already sent the authors a copy of the EMWA guidelines!. There is also a very curious statement that "most journals have no system of peer-review". I hope these annoyances can be corrected in later editions but also believe Medawar and Hardon's message is sufficiently important that EMWA members should not use the weaknesses as an excuse to ignore this thought-provoking work.

Liz Wager

liz@sideview.demon.co.uk

Assistant or Associate Professor Biomedical Writing

The University of Sciences in Philadelphia is seeking a faculty member for a 12-month appointment to the College of Graduate Studies MS Program in Biomedical Writing as Assistant or Associate Professors, depending on academic achievement and experience. The successful candidate will start on July 1, 2005 and will report to the Director of the MS Program in Biomedical Writing.

The successful candidate will have an earned and accredited doctorate in the Life Sciences with at least 5 years experience writing FDA regulatory documentation, at least 5 years experience teaching in universities, experience mentoring research students and have a record of publishing in the biomedical literature.

Successful candidates are expected to teach elements of biomedical writing to graduate students, including but not limited to, documentation procedures for marketing approval submissions, publication strategies, CME writing, grant proposals, scholarly manuscripts and is encouraged to initiate or continue an active research program in Biomedical Writing. The successful candidate is also expected to participate in the nurturing of the MS Program in Biomedical Writing by increasing its visibility: on campus, by participating in University committees and search committees and attending University-sponsored seminars and meetings; and off-campus, by participating in professional and scholarly conferences and collaborating with scholars in other institutions. This position requires working onsite daily, being available for student and faculty conferences and teaching onsite and online.

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Vital signs . . . The Gender Genie a misogynist?

Dear TWS,

I was intrigued by the description of the Gender Genie in the last issue of TWS. Can a piece of computer software really tell whether the author of an article is male or female? Well, the scientist in me couldn't resist doing the experiment, so I tried feeding the Genie all the articles from the last issue of TWS to see how well it did. It thought the author of every single one, including our esteemed Editor-in-chief, was male. From my admittedly limited sample size, I conclude that the Gender Genie has 100% sensitivity for identifying a male author of a piece of writing, but that the specificity may need a little work. Either that, or there is some unacknowledged ghostwriting going on behind the scenes, which would of course be thoroughly unethical! I think we should be told.

Dr Adam Jacobs

www.dianthus.co.uk

Dear TWS,

I enjoyed the recent issue of The Write Stuff very much – congratulations on pulling together so much of interest.

I was intrigued by the note about Gender Genie and thought I'd feed it some samples from my book (due out in May) – they came out resoundingly masculine. I purposely didn't try it on clinical papers, as these are usually written in collaboration with doctors who are usually men, but it did make me wonder. The only section which sounded female was the preface, in which I use the first person and refer to myself quite a lot. This made me wonder if this would form the basis for a light-hearted survey of other EMWA members.

With good wishes,

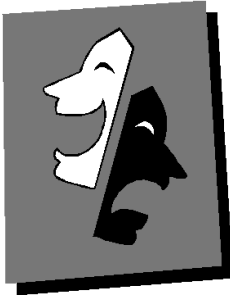
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The Lighter Side . . . The Importance of Punctuation

So you think that punctuation is annoying and unimportant? Take a look at the following two letters which have the identical text in terms of words and differ only in punctuation and see if you think there is any difference. Which one would you rather receive?

Dear John:

I want a man who knows what love is all about. You are generous, kind, thoughtful. People who are not like you admit to being useless and inferior. You have ruined me for other men. I yearn for you. I have no feelings whatsoever when we're apart. I can be forever happy—will you let me be yours?

Jane

Dear John:

I want a man who knows what love is. All about you are generous, kind, thoughtful people, who are not like you. Admit to being useless and inferior. You have ruined me. For other men, I yearn; for you, I have no feelings whatsoever. When we're apart, I can be forever happy. Will you let me be?

Yours,
Jane

The Last Word

I have always wished that my computer would be as easy to use as my telephone. My wish has come true. I no longer know how to use my telephone.

Bjarne Stroustrup, computer science professor,
designer of C++ programming language (1950-)



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Control to Goal Journalist Awards - SPRING INTO ACTION

Information for healthcare journalists

The *Control to Goal* Journalist Awards are a new international initiative of the *Global Partnership for Effective Diabetes Management* to recognize journalists who increase awareness of the importance of appropriate diabetes management, including getting people with type 2 diabetes to recommended goals for blood glucose control.

Control to Goal Journalist Awards will be given in September 2005 to journalists who have published an outstanding article on the importance of effective diabetes management.

Winners of the *Control to Goal* Journalist Awards will receive sponsorship to the 41st European Association for the Study of Diabetes Meeting 2005 in Athens (10-15 September, 2005) and runners-up will receive sponsorship to a national diabetes conference.

The *Control to Goal* Journalist Awards are open to print and on-line media journalists worldwide, excluding the USA.

To find out more details on the *Control to Goal* Journalist Awards including submission criteria, and to receive an entry form, please visit www.diabetespressoffice.com or contact the Award Secretariat at controltogoal@porternovelli.co.uk. Articles must be received by 30 June 2005.

The *Control to Goal* Journalist Awards are sponsored by GlaxoSmithKline

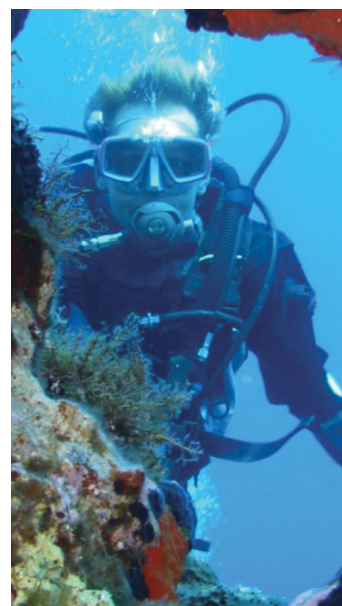


Fancy a Dip in Malta?

Malta has a reputation for many things, not least of which is a diverse marine environment full of interesting fauna, flora and sunken treasures – soon to include EMWA members. In order not to compromise the important business of conference attendance, proposed dates for an organised sub-aqua sojourn are Tuesday the 17th and Saturday the 21st (afternoon) of May. I have been assured that the facilities can cater for divers of any level, from first time snorkellers to dive masters.

Anyone interested in exploring the underwater world of the deliciously warm Mediterranean is invited to email me at ian.metcalf@bernabiotech.com, with the Subject "Diving in Malta". It is important that I know in advance the number of participants in order to establish a good discount for all.

Please note, diving with pressurised air should NOT be undertaken within 12 hours prior to flying and underwater pens are not included. See you in Malta.



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