EMWA European Medical Writers Association

The Write Stuff

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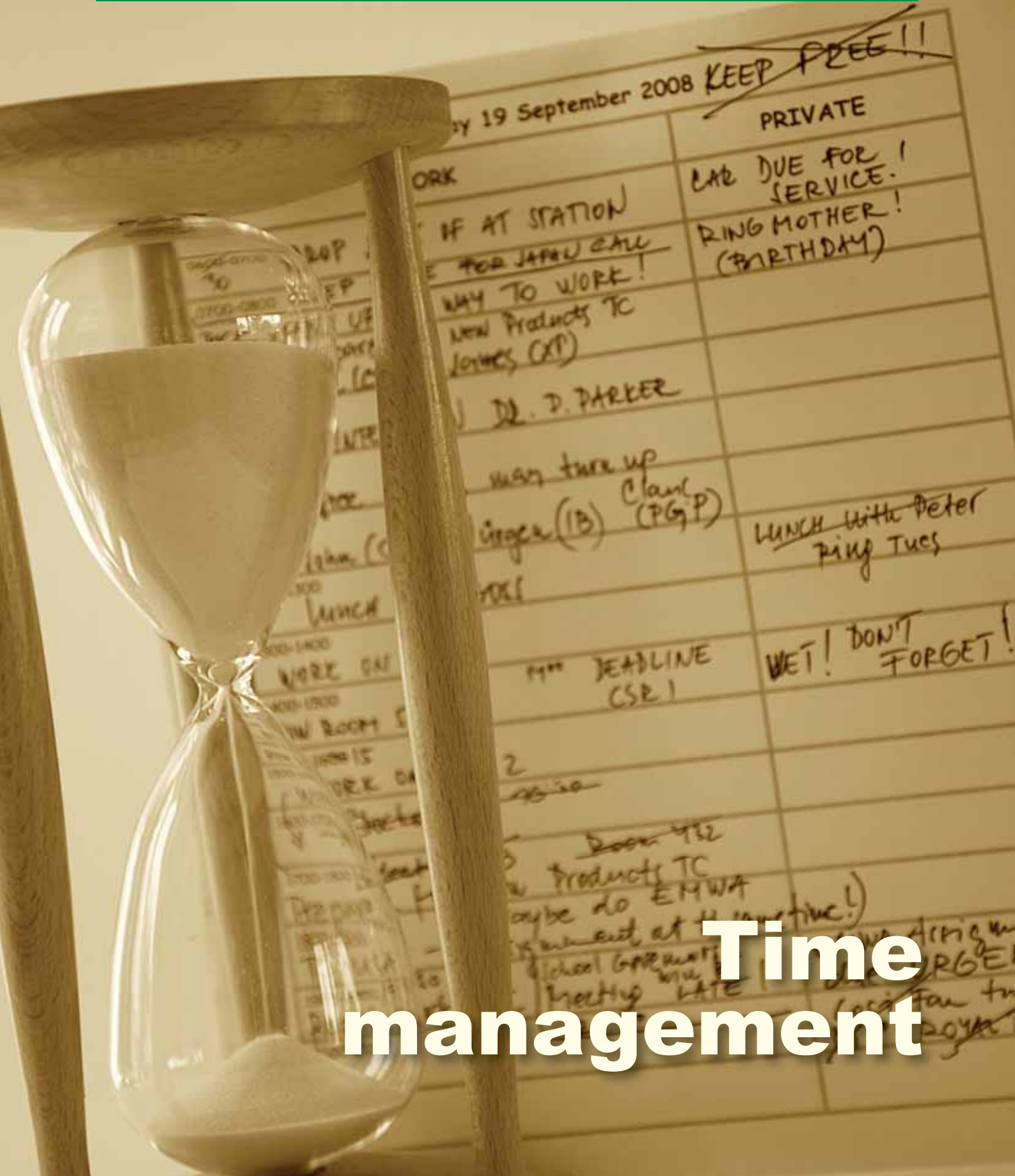

Time management

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Journal insights

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

Subscriptions

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

- €35 within Europe
- €50 outside Europe

Instructions for contributors

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

Timelines

Month distributed	Deadline for receipt of articles	Deadline for receipt of adverts
March	1st January	15th February
June	1st April	15th May
September	1st July	15th August
December	1st October	15th November

Advertising rates (in euros, €)

Corporate		Private / Freelance members only	
• Full page	**€1000**	• Full page	**€200**
• Half page	**€500**	• Half page	**€100**

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Cover picture

Cover photograph from Nadja Meister (nadja.meister@inode.at). Cover motif inspired by Franz Meister.

EMWA European Medical Writers Association

Upcoming EMWA Conferences

27th EMWA Conference,

20–22 November 2008, London, England

The next EMWA Conference is just around the corner and will be held at the Holiday Inn London, Kensington Forum, 97 Cromwell Road, London, UK (www.hikensingtonforumhotel.com). Registration for this event will begin this month and online registration will be available for the first time.

The programme offers 20 training workshops and a freelance forum for freelance writers to exchange ideas and experience. In addition, new to the programme this year is a seminar providing GCP training for medical writers. Login to www.emwa.org for further details and to register for this event.

28th EMWA Conference,

26–30 May 2009, Ljubljana, Slovenia

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

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

These will be great opportunities to expand your medical writing horizons. So mark these dates in your calendars and plan on joining your colleagues from across Europe at these events.

From the guest editor's desk:

Time management—Who manages YOUR time?

by Alistair Reeves

A telephone conference about 10 years ago with my group around me: I am the head of a productive and committed publishing team in one of the world's largest pharmaceutical companies, responsible for the 'European dossier' on an international project. Things are going well. After a merger, management has moved the central development department outside Germany, as they apparently felt that this would make the company more productive, although no clear reasons have been given. All members of my publishing group—all specialists in their fields—are working at full capacity, as usual. My boss abroad at the other end of the line says, for all to hear: "Higher management wants to go for 'stretch goals' on this project". 'Stretch goals' are a mystery to me, but they immediately smack of 'le citron bien pressé', so I 'innocently' ask: "What do you mean by stretch goals?" The answer is: "That means we set successive goals and then knock off about 20% of the time required for each because everybody has to be prepared to go that extra mile for the good of the project". My team had already chalked up so many extra miles that they should have been languishing on a beach on a Pacific island with no need to return. Dare I ask the question? I did: "So what you actually mean are *unrealistic* goals?" I bite my lip nervously in anticipation of the response. Silence from overseas. Visible thumbs up all around in my group. I am thankful this is not a videoconference. As you might imagine, this did not endear me to management, and certainly contributed to my becoming a freelance writer and editor in 2002. But being a freelancer did not help me to plan better at first, because I mistakenly thought it would be so much easier being my own boss.

I started working on documentation for clinical trials in the pharmaceutical industry in 1976. In the ensuing 32 years, I have worked on only one project that stayed on the schedule planned 18 months in advance: the above project. It was the first centralised procedure in Europe at my company. The reason that it remained on schedule was not because we subscribed to the dubious policy of 'stretch goals'. No. We had planned everything well in advance, built in buffers, and had an exceptionally responsive management in Europe who realised that we were all committed and knew what we were talking about when we said how long things would take. We did have a couple of setbacks, but we actually finished early in Europe (by 19 days, if I remember correctly), and maintained a humane schedule for all concerned. Our colleagues abroad were 6 weeks late.

"Where can we squeeze out another couple of (half-) days?" This was always the statement I dreaded in meetings. What it really meant was: how can we push the workforce harder? How do you answer this when your workforce is at full capacity anyway, and your scanning specialist is just as stressed as your top medical writer or publisher? And we all know: we are in October, we are talking about 'squeezing out' days next January, but by the time November comes, things will probably look very different (because of unresolved questions about those nasal tumours in rats, for example), so why are we wasting time with this sort of question now? Everything—almost always—slips, anyway.

Whether you are a freelancer or a salaried employee, you always have to ask: "What are the timelines on this?", and you are always asked: "By when can you have it ready?" So you have to be a good planner and have a good idea of how long things take. Why does everyone always want everything yesterday? And how often have we broken our back to complete a job, only to find that it laid around in a drawer (20 years ago), or on a hard disk (10 years ago), or on a memory stick (nowadays) for a couple of weeks after you worked until 22:00 several nights running to complete it? The important elements in good planning are honesty with yourself about what you can do, honesty with your staff if you are a manager, being able to represent your staff's interests when higher management has unrealistic expectations, the confidence that your client is being honest with you, and—moreso if you are a freelancer—the ability (and the confidence again) to say no, despite that nagging worry that the client may not come back.

I have been a freelance editor and writer for 6 years now. When I started, I had the luxury of a partner in full employment, my children had almost finished university, and the house was nearly paid off, so the end of large financial commitments was in sight. But that still didn't stop me taking on far too much work for the first few years and working 12-hour days and on weekends, public holidays, and even on 'holiday', trying to please everyone. Four years in, I was completely exhausted and decided I had to do something about it, so I took 2 months off and did no work (I realise this is a luxury a lot of people cannot afford, and I had to wait 3 months before my 2 months off could be accommodated in my calendar). *Plagued* by guilt in the first couple of weeks, I literally did *no work* for the first time in my life. I told important clients I had other long-

term projects, new clients were referred to reliable colleagues, and I said no to a couple of projects. I thought I had become 'my own boss', but I hadn't: other people were still managing *my* time and therefore *my* life. So what was I doing wrong?

I am a disciplined worker and am not easily distracted. I used to sit at the PC for 12 hours or more 6 days a week. This was the problem. It took a while for me to admit it to myself, but I was being 'overconscientious', to my and my partner's detriment. So I decided that work was to be done between Monday and Friday from about 08:00 to 17:30, and that was it, and, importantly, that e-mails did not have to be answered *immediately*. E-mail stress is one of the worst evils of the E-age, especially since it is obvious that your carefully considered responses are often not read properly. And I had to convince myself that I could say no without causing my business endless harm. Two years later, I have fared well despite my self-imposed restrictions and have worked on three weekends and two public holidays (yes, I have counted!), and have *even* taken days off during the week to do things I want to do (like learning [again] how to enjoy an hour in a bookshop, or just wandering about town, or even just reading the newspaper *properly*). To meet deadlines, I used to take work to conferences and try to sneak in half an hour's editing before, during and after workshops, and before social events, usually at an uncomfortable hotel room table with bad lighting and a seat that was too low. I have not done this at the last two EMWA conferences nor at other events for the past two years. I really had to resist not doing it; but all events have been all the more enjoyable for not doing so. At last, some time for a chat with colleagues! Or just sitting for 15 minutes after lunch watching the world go by.

The other thing was how best to say no. I decided never to say no outright, but always to try to find a colleague who could take on a job. And I really do try. Judging by the e-mails and telephone calls I have had with thanks from colleagues for referrals, I am not always unsuccessful in helping colleagues and clients alike. I also stopped taking on jobs that are just too 'big', and now stick to 'smaller documents' (investigator brochures, study protocols, study reports, patient information sheets, Summaries of Product Characteristics, journal articles, small websites), but no more ambitious things like dossiers, or projects that need coordination across several countries and people.

Apart from a couple of hectic, but brief, periods over the past 18 months, I now feel that *I* am basically managing *my* time—even though only just. I am still at the beck and call of the client and do my best for them, but I don't feel that they are at the helm.

Like Virginia Watson in this issue, I don't think I was suffering from burnout. I was just chronically tired. This is obviously one of the precursors of burnout and something you should watch out for. If you feel you are close to burnout, Lydia Goutas has plenty of advice in this issue on how to recognise the signs and symptoms, and on the countermeasures you can take, including 'mindfulness-based stress reduction', and even extending to taking a sabbatical. I suppose my 2 months were like a sabbatical, although she has longer in mind. Maybe it would do you good too! What may also do you good is meditation—although I haven't tried it yet. EMWA's very own neurophysiologist website manager, Shanida Nataraja, recently published a book entitled *The Blissful Brain*, in which she explores the workings of the brain and the history and benefits of meditation. I need go no further into its contents here because we have a 'rave review' in this issue from Helen Baldwin, who says: "I have been meditating regularly for the last year (ed: before she bought Shanida's book) and I have been astonished by the results. I am much happier and less stressed than before: time seems to go more slowly, and I am able to finish my projects faster with less effort!" Because the wish for 'time to go more slowly' must be uppermost in all of our minds (and not only so we can do more work!), it sounds like this and many other books on meditation should be on every medical writer's bookshelf—and should be read!

Sometime in the 1990s, companies started setting up whole departments responsible for 'reverse planning', as if it were a new discovery and would be the solution to everything. I appreciate that preparing a dossier is more complex than preparing a meal for 8 people or planning a week's cooking—but anyone responsible for feeding a family or planning a large social or sporting event knows that you have to work backwards from a target time (the time your family wants to eat or your guests will arrive, or how many rounds you have), even sometimes several weeks or months hence, to work out your starting time. This is a balancing act par excellence. So there is nothing new about 'reverse planning': valiant homemakers have been doing it for centuries. Wendy Kingdom seems to have the business of cooking and providing for her husband and friends under excellent control, and would also have the business of writing under excellent control, if it weren't for that often incalculable confounding factor: the client. The essence of her advice is: do less so you are able to respond better to changes, and, as a freelancer, don't be afraid to have breaks of a few days when you have 'nothing to do'. It takes time, of course, to build up your clients, but again the message is: at the same time, build up the confidence to say no.

The word 'deadline' hangs over the head of every manager, writer and editor in our business. We can be glad that 'deadline' has lost its original meaning, which is explained by Ursula Schoenenberg in a light-hearted look at the term in this issue. She does, however, more seriously caution that deadlines are viewed differently by different cultures, and candidly identifies three 'personality types' by the way they respond to deadlines. Which type are you?

A truly frequently asked question is "How long does it take to write a …. (document)?" It is also frequently answered,

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and often unsatisfactorily. I can still remember 5-page study protocols and 25-page study reports with hardly any appendices, but study reports (and almost all the documents we deal with) have now turned into vastly complex documents prepared by a large team of specialists, sometimes with hundreds of thousands of pages, often with an astonishing network of electronic cross-references. Several contributors to this issue have looked at this question from different angles. There seems to be general agreement now that there are low-complexity, medium-complexity and high-complexity assignments, that these degrees of complexity have blurred boundaries, and that it is not possible to account for all possible confounding factors. This means that it is easy to get into a real mess if you don't plan properly. 'Can't you just put more people on the job?'—another comment from management I used to dread. In this issue of *TWS*, Stephen de Looze passes on a distillation of the wisdom he has gained from 20 years as a manager of a medical writing group, first in a leading pharmaceutical company, and later working for a contract research organisation. It is packed full of sound advice on how to approach managing resources on multiple projects, each with their own shifting timelines. This article—longer than usually accepted for *TWS*—should be compulsory reading for all writers and managers of medical writers—and also for the bosses of medical writing managers. Why not casually deposit a copy on your boss's desk?

Sam Hamilton reports on an EMWA workshop she runs on writing proposals, study protocols and clinical study reports (CSRs) from the time-management point of view. She presents some interesting results on the participants' experience of how long these activities take, like 'first draft of CSR to final CSR, including review in 6–100 days'. Most of us will be used to fairly high two-digit time-spans for reports (and perhaps we should keep quiet about the 6 days so we don't give our bosses ideas: a dream figure if ever I saw one!). Inadequate coordination of review cycles is often the problem; they can be the bane of our lives as writers and can be very disruptive to timelines. How often do you *not* get the promised 'consolidated comments', but 10 e-mails with contradictory comments in each attached 150-page document? While I was working as a salaried employee, a German physician colleague of mine, herself an excellent writer, always asked with a twinkle: "Is this the 'final' review cycle, or is it the 'absolutely bloody final' review cycle?" Needless to say, she refreshingly stuck keenly to any timelines set (a rare beast in our business)—we knew where we stood with her.

Christoph Pfannmüller answers some questions on what it is like to manage a high volume of medical writing and publishing projects in a division of a large Germany-based pharmaceutical company. His company mainly uses a preferred partner for medical writing and has in-house publishing, and he spends his days mediating between external writers and internal specialists vying for priorities and setting up and (sometimes almost daily) revising project 'route maps' to meet submission deadlines. Christoph has three wishes that he thinks would make life much easier; two are in the realms of Utopia, but I am sure that one related to ICH E3 has occurred to many of us already.

Andrea Rossi has the dilemma that he is expected to write *and* manage publications and congress contributions amongst a huge range of other documents for a multinational pharmaceutical company in Italy. This requires a degree of flexibility and patience that his colleagues in other departments do not always appreciate. Everyone wants to be served first, especially when a conference is looming: suddenly, everybody's abstract becomes the most important and everyone wants to claim Andrea's time. But it wasn't planned that way!

Debbie Jordan provides us with practical advice on planning your year (yes—your year! And you do need to), your week, and your day—for freelancers and salaried employees alike. Have you heard of the 2-hour rule? If not, take a look at what she has to say in this issue—a simple device to make your life easier. Salaried writers should take heed of her advice and use this in discussions with management. And the 2-hour rule is not a bad idea for freelancers either.

I asked Thomas Mondrup to tell us about a typical working week as a medical writer for an international biotechnology company in Denmark, and tell us how, by Friday, he had managed to fulfil his aims for the week set on Monday. He decided to apply the ABC task system he had learned at Debbie Jordan's time-management workshop in Barcelona. The problem is that the C tasks keep encroaching on the B tasks, and the B tasks on the A tasks, and suddenly, you have more A tasks than you can handle, with little hope of downgrading them. Also, your C task is a colleague's A task, providing great potential for conflict! After a 16-hour working day on Monday, things seemed to be going well on Tuesday (despite receiving three sets of unconsolidated comments on three clinical study reports), but Wednesday had some unplanned surprises. By Thursday, he had banned all statisticians and programmers from his office so he could just get on with his work, and actually managed to get away from work 'early' and enjoy a barbecue with family and friends. On Friday he didn't get away until about 20:00 because of the late arrival of more comments. This was followed by a busy private weekend, with the prospect of a similarly hectic week ahead. Sound familiar?

After all this talk about too little time: what do you do when you have too much time? Short periods of 'inactivity', which do occur sometimes, both for freelancers and salaried employees, should not make you feel lazy or guilty. Jack Aslanian shares his thoughts with us on such periods, which often fill themselves with those 'jobs' you have put off, but still have to be done, like clearing out those 2,253 e-mails in your inbox. Or sometimes work itself tends to expand into the time available (at last you have time to research that term *properly*, or make a start on

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working through that ever-growing pile of interesting papers). Nor should you be guilty about telling a client or colleague that you really will need 2 weeks to edit their paper, even though the actual time spent editing will probably be only 15 hours. This is because you have other projects, need time to think, and need some time to let the piece of work 'lie' so you come back to it afresh because you want to deliver a good product. Jack reaches an interesting conclusion on 'What' as opposed to 'Who' should be managing our time—a concept which we all know very well—but I will let you discover what it is by reading his article.

Stefan Lang continues his report on setting up as a freelancer in this issue in the Out on our Own section, also focussing on time management. And John Carpenter, who has been an enthusiastic medical and scientific communicator and a freelancer for many years, actually admits that he is thinking of 'slowing down' (What is that?), but almost in the same breath tells us that he would take on a full-time job again if it paid well enough and 'stretched my knowledge, experience and skills to their limits'. Looks like another one amongst us who will never really 'slow down'!

Nancy Milligan brings us welcome relief from the pressures of time in Journal watch. In this issue, she focuses on papers she has found on the importance of guidelines when reporting on medical research and the adequacy of treatment descriptions in manuscripts (with the astonishing statistic that in 80 papers reviewed, only 39 described the treatment given well enough to enable other clinicians to apply it without asking for more information). A paper on the effect of the online availability of journal articles on citations also makes interesting reading. This issue also sees the second part of Françoise Salager-Meyer's article on medical book reviews where she examines how the critical voice or 'rhetorical persona' of the book reviewer has changed over time, with examples from the mid-20th Century, when reviewers were often merciless in their criticism—but not without humour—and said quite directly 'Don't buy this dreadful book', and the closing years of the 20th Century, by which time a greater degree of objectivity had come to prevail.

Back to time management: our webscout has been on the lookout for tips from the Internet. Joeyn Flauaus has found good advice, including ten tips from a blog and a worthwhile video with a presenter who says that time must be managed as carefully as money. A good principle: but as we know, clients are not infrequently as fickle as the stock market. So do your best!

As usual, we can find sound advice elsewhere in the non-scientific literature about the value of our deeds and whether it is worth pushing yourself to your limits. And where better than in Shakespeare? In *Troilus and Cressida* (Act 3 , Scene 3), Achilles has done heroic deeds in battle and is distraught that Ajax, described elsewhere as a lubber (lazy fellow), is getting all the credit for them. Ulysses has good advice for him (which Achilles did not heed, by the way!):

Achilles*: ... they [the Grecian Lords] pass'd by me/As misers do by beggars, neither gave to me/Good word nor look: what, are my deeds forgot?*

Ulysses*: Time hath, my lord, a wallet at his back,/Wherein he puts alms for oblivion,/A great-sized monster of ingratitudes:/Those scraps are good deeds past; which are devour'd/As fast as they are made, forgot as soon/As done.*

This may sound rather pessimistic and not encouraging: the wallet of time is greedy; it relentlessly gobbles up your time; some of us don't get many thanks for all our efforts; and basically good deeds are forgotten, although there may be some momentary glory. But this reflects the harsh reality of many peoples' working situations. I hope that this salutary message from antiquity via the 17th Century and all the good 21st Century advice you will find in this issue will alert you to the importance of making the most of this vital (in the truest sense of the word) aspect of your professional and private lives: take control of YOUR time. Trite and hackneyed: you only have it once. And it is one of the few things that belong only to YOU.

Alistair Reeves
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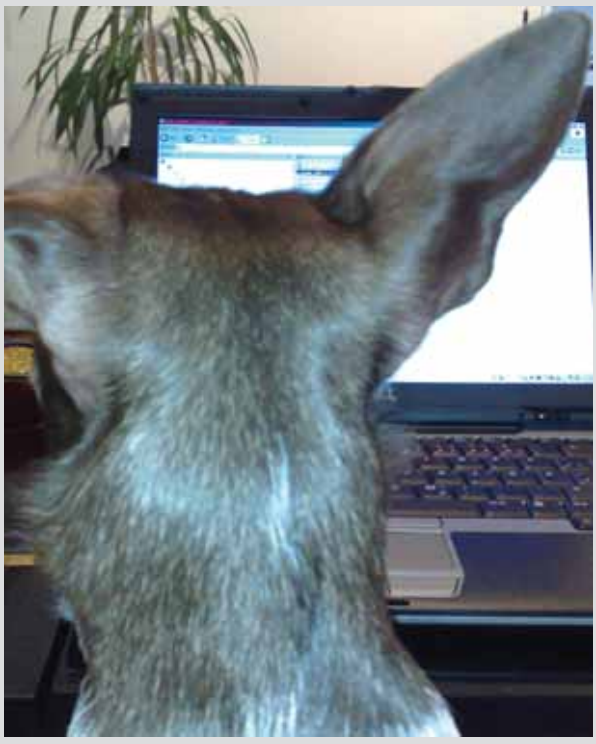
Received any dog-eared e-mails recently?



Credit: Photo model Pheobe. Photographer Gabi Berghammer

Message from the President

by Julia Forjanic Klapproth

Time. It's something that nobody in today's technologically developed world has enough of. While it is undeniable that technology has made things possible we could never have conceived of previously, it also hinders us in ways we could never have imagined. Just take mail as an example of how technology turned a simple means of communication into a potentially time destroying beast. If you think about it, previously, an average working person on an average day (i.e. not a superstar or politician) would have received a few letters by normal mail. And that was it. There was no other form of mail. And often, a working person who was in a position to be receiving mail probably also had an assistant who filtered the mail for them. So on any given day, that person would only have to deal with a few communications. Now consider today's state of mail. We continue to get the regular mail. But e-mail has taken over life. Ignoring spam mail, a working person can get a hundred or more e-mails a day. And very few of us still have the luxury of having an assistant to filter those mountains of mail. We are expected to read, process, respond, and file all of these e-mails by ourselves. And due to the immediacy of the technology, if you haven't replied within a day, senders begin assuming something is wrong! The time needed each day just to process mail has gotten out of control before we even begin to do a minute of productive work.

Other demons possessing the industry and turning it into a frightening reality are share holder value and management bonuses. These two things lead executive level managers to invent timelines driven by the timing of dividend payouts or management performance goals rather than the humanly feasible. As a result, the expectations of what an individual, let alone a team, are meant to achieve or produce are moving into the realm of the absurd. Each time I work on a project for which the timelines have been dictated by upper management, I recognise a sickening trend. By helping the teams I work with meet those gruelling timelines, we are setting precedents for future teams. The ridiculous timelines we met by the skin of our teeth and a considerable lack of sleep become new goals for executive level managers to beat. Ultimately, by meeting timelines that are verging on the inhumane (because of the need to work around the clock 7 days a week, sometimes for 2 to 3 weeks at a time), we are supporting an industry-wide trend to push timeline expectations beyond the achievable.

Clearly, however, not all is as bleak as it may sound. There are some people who manage to get more done in a day than others, regardless of the fact that they are faced with the same beasts and demons as the rest of us. So the question is, how do they do it? This issue of *The Write Stuff* focuses on just that question. How can we manage time to make it work for us instead of against us? Or, at a very minimum, how can we squeeze a little more into a working day without cutting into the non-working day? These are questions that relate to all of us, and a few tips on how to optimise our time management can never be a bad idea.

Speaking of managing time… make sure you mark 20–22 November this year in your calendars for the upcoming conference in London. In response to requests from our members, we are adding a new seminar to our programme. This will be a training session on GCP issues for medical writers for anyone out there who needs to provide a certificate of continued training in GCP to an auditor. The full programme for this conference will be available on the website by September. So be sure to check in then to find out what else is on offer and register early so you are sure to get a place in the sessions you are interested in.

I look forward to seeing you at an upcoming conference. And until then, may time be on your side.

Julia Forjanic Klapproth
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A new Medical Translation section for *TWS*!

Following the great success of the medical writing theme of the EMWA conference in Barcelona this spring a new medical translation section is being scheduled for *TWS*. I would be delighted if anyone interested in contributing ideas, articles, boxes with tidbits of practical information, dictionary or website reviews, terminology, etc. would contact me.

Gabi Berghammer
gabi@the-text-clinic.com

Introduction to EMWA's new Head Office

As one of the key contact people for you at your new head office, I wanted to take a moment to introduce myself and MCI to you. Your new head office team is made up of four members of staff, all based in MCI's Petersfield office in the UK. Our close-knit team benefits from a variety of experience and we will be applying the combined knowledge we have in the association world and events industry to the running of EMWA.

We have been working as your head office for just over two months now and have already had the opportunity to meet most members of the Executive Committee and to speak with many EMWA members on the telephone. Our experience so far has been very positive and we feel that members have welcomed us into the association. We'd like to thank you all for your patience during the transition period and hope that the service we provide will be up to the standard EMWA expects and deserves.

We are looking forward to the next few months and the opportunity to meet many of you at the London Conference. This will be a period of continued learning for us and we expect that after organising our first conference with you, we will begin to settle in fully to our role as your head office. We are keen to hear your feedback on all matters, as this helps us to maintain EMWA as an association run by and for its members. So I want to thank those of you who completed the Executive Committee's Member Satisfaction Survey. I am sure the feedback we receive from this will help guide us in supporting you in the future.

From left to right: Jenna Hornett (Project Manager), Julia Phillips (Programme Manager), Kelly Taws (Project Manager) and Eila Macneish (Project Co-ordinator).

Kelly Taws, MCI
info@emwa.org

Call for nominations for executive committee positions

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

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

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

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

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

Julia Forjanic Klapproth
President EMWA
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Themes of upcoming issues of *TWS*

The December issue of *TWS* will have the theme 'control/policing' with articles on image manipulation, confidentiality, ethics committees, screening for plagiarism, medical writing metrics, SOPs for medical writers and much more.

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

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

In addition I would be pleased to receive contributions for a future feature in *TWS* on the lost art of science writing. Examples of the style used to report science in the past would also be welcome.

Elise Langdon-Neuner
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Shaping EMWA's future

EMWA is an association run by its members, for its members. To make sure EMWA stays that way and to help us shape EMWA's future, the Executive Committee is always seeking ways to gather the opinions of as many members as possible. With this aim, we recently performed a survey to determine the level of member satisfaction with EMWA and to ensure that members are well represented in all of EMWA's diverse activities. The survey was anonymous, and the results were compiled by an independent body (Survey Monkey).

We would like to take this opportunity to say thank you for taking the time to complete this survey. Your opinions matter and our association will only continue to evolve and improve to meet your needs if you tell us which areas you are happy with and which areas need attention.

All participants were given the chance to enter into a prize draw to win either one year's free EMWA membership or a €120 Amazon voucher. The prize draw was organised using a separate online service with no risk of compromising the anonymous nature of the survey. EC and EPDC officers were not eligible to enter the prize draw. The name of the winner will appear on EMWA's website by the end of September 2008.

Full details of the results of the survey will appear in the December 2008 issue of *The Write Stuff*.

Coming soon: Important ghostwriting survey for EMWA members

Some EMWA members may remember participating in a survey that asked about whether medical writers who contributed to publications were acknowledged, in accordance with guidelines by EMWA and other bodies on transparency of medical writers' contributions. The survey was done in 2005, shortly after the EMWA guidelines were published. We are keen to know whether practice has changed in the intervening 3 years, and we will therefore be repeating the survey in the period 13–25 November this year. All EMWA and AMWA (American Medical Writers Association) members will be invited to participate, and it is important that we have a good response rate if the results are to be meaningful. All EMWA members will receive an email with the details of the survey nearer the time, so please keep a close eye on your inboxes in November.

Adam Jacobs
Leader of EMWA's ghostwriting task force
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Cindy Hamilton
President AMWA
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The difference a hyphen can make

Treatment was randomly assigned to test fields on the back.

Without a hyphen between 'test-fields', 'to test' above is read as an infinitive, and the reader has to backtrack and think how to understand this sentence. With a hyphen: *Treatment was randomly assigned to test-fields on the back*, the meaning is immediately clear, because you turn 'test-fields' into a compound noun.

This would also be solved by adding the number of test fields: *Treatment was randomly assigned to 12 test fields on the back*. And then you don't need to hyphenate.

Alistair Reeves
a.reeves@ascribe.de

A recipe for chaos: Medical writing, time management, and cooking for friends

by Wendy Kingdom

There is one area of my life in which I am so organised I amaze myself. Our meals at home are planned on a weekly basis and I shop just once a week. I check my diary to see when I will have time to cook and when I need to take something out of the freezer, or if I don't need to cook at all. I also have a little red book of what is in the freezer so that I can see if I need to use something up (or throw it away). This approach to shopping and cooking saves time because I don't have to rush out to the supermarket midweek for a vital ingredient, it saves money because I only buy what I need, and our meals have variety and are healthy because I look at our menus for the week as a whole.

The rest of my life is a shambles.

Have you heard of Nigella Lawson? She published a book called Nigella Express [1] and presented a series of cookery programmes based on the recipes in the book. Watching Nigella is always a delight because she doesn't just cook food, she somehow seems to have a relationship with it. Anyway, the principle of the express part of the title is that, for example, instead of peeling, crushing and frying garlic in olive oil, you use olive oil infused with garlic. This means that Nigella's larder is about the size of my house, but that is not the point.

After watching a couple of these programmes, I came to the conclusion that the real time-saving comes from the fact that she doesn't do any washing up. We watch her waltz out of the kitchen leaving behind a sink full of used pots and pans, food spilled on the work surface, a jug of apple juice left out of the fridge (a jug?), and abandoned kitchen gadgets dripping with chocolate sauce. So, while we watch Nigella pouting at herself in the mirror and brushing out her luscious brown hair in preparation for the arrival of her guests, the rest of us would still be in the kitchen in our aprons and rubber gloves, desperately trying to clean up before people arrive.

What does any of this have to do with medical writing? Well, possibly nothing at all, but I believe that there are quite a few analogies between medical writing and cooking.

As medical writers it is important that we allow sufficient time for the stuff that is not project (chargeable) work—the washing-up. The amount of stuff that you have to do will vary according to your job, but my stuff includes dealing with what has been done (e.g. filling in timesheets, generating invoices, logging payments, banking cheques), dealing with future work (e.g. responding to requests for proposals, reviewing contracts and negotiating changes), and the unexpected (e.g. writing an article on time management for *TWS*). It is easy to spend an hour replying to an e-mail from a client if you need to take care about your wording. In my experience, this stuff takes an average of two hours per day.

Since we are all knowledgeable about the principles of time management, we set aside two hours every day, or one day every week, and we deal with our stuff in this time. We allow the time for this stuff when we agree timelines and we make sure that the duration of elapsed time from starting materials received to first draft delivered takes account of a working day that includes only five to six hours of chargeable time. This is why we are calm, organised, and we work a set number of hours per week.

Does this sound like your life? I know that it isn't anything like mine.

The first problem that causes our time management to go horribly wrong is when timelines change. We all know about this problem, so there's no need to dwell on the point. They are just part of life, and we have to learn to work with them. However, I believe that our problems arise not because timelines change, but because so few of our clients think to tell us in advance and to discuss the new timelines with us.

If you invite someone to your home for a meal, you can be confident that they will turn up on the right day and at the agreed time, give or take half an hour. They will then get the food you planned, prepared in the way you intended, served hot (assuming this was the intention), and that you will enjoy it together. If your guests arrive an hour late, the food will be somewhat spoiled. If they arrive a day late, the food will be in the dog. However, in normal life, if your guests arrive late, they would apologise and would happily accept a compromise suggestion to get a take-away or go out to eat. I have not yet had the experience of anyone turning up on the wrong day, nor have I done this myself—yet.

In work life, our guests don't seem to think it matters whether they turn up on time, a bit late, a day late, or even a few weeks after the date and time that you agreed. Long after you have given up on them, they send you an e-mail announcing the date that they will arrive, and that date could be today. Not only that, but when they do turn up,

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they take it for granted that we will rustle up something tasty. If you're lucky, you are free on the new date but if not, you have to work out what you can prepare using the food that you already have, and how to fit everyone round the table because a different set of guests have also arrived. Not a sophisticated dinner party as planned; more of a Mad Hatter's tea party[1]. If it were only the occasional client who behaved in this way, we could be firm with them and explain that they have missed their time slot. Unfortunately, most clients do not keep to their own timelines so if we want to stay in business, we just have to do the best that we can. There is, however, a limit to what doing our best can include.

I think that there is a window of opportunity of about two weeks during which clients can provide starting materials late without causing too many problems. When starting materials or comments are a day late, you can chase up the client and you might be given a new date. You can chase again after the new date is missed and maybe you'll get another new date or possibly just a vague response. However, eventually, there comes a point at which if the client hasn't sent you something by now, there's no way of guessing when it might turn up—or if it's going to turn up at all. By the time the materials or comments do arrive, you have moved on, and your timetable is full of other work. You then have to try and find a space for the work in a period of time that is already seriously overcrowded.

There is a trend for timelines to be shortened, which makes it all the more difficult when clients forget to tell us when the timelines change. Medical writing is hard work. If you are working on a document, then working is exactly what you are doing. Keeping the numbers simple, we can expect a 40-hour project to take 6 or 7 working days, allowing time for the other stuff. When timelines become compressed, you can't do the work in fewer hours, you just have to fit the same number of working hours into fewer days. There comes a point at which there are no more waking hours in the day. Working through the night won't help because you will start writing rubbish, and what will you do the next day when you haven't had enough sleep?

Can we do the work more efficiently? I don't think that we can because a document cannot be finished until it is complete, i.e. until you have incorporated information from every publication that came up in the literature search, you have described and discussed everything that was measured, you have ticked every statistical table, figure and listing off your list, you have summarised every study, etc. Most of the time we are working to regulatory or publication guidelines. If you haven't done something about everything in those guidelines, the document is not finished. If you want to make a cake, you have to include all of the ingredients in the correct proportions and in the correct order, and you have to bake it in the oven until it is cooked, otherwise you will end up with something that cannot legally be described as a cake and is probably inedible.

Have you ever tried to prepare vegetables, grate cheese, stir a sauce and whip cream all at the same time? It's impossible—unless you can get someone to help. In the same way, medical writing is not something that can be multi-tasked. You can make a phone call and talk about more than one project, you can send an e-mail and contact several people at once, you can attend a meeting and, well, do nothing at all really. You can save time in all of these tasks by preparing in advance, not chatting on the phone, excusing yourself from parts of a meeting that are not relevant to you, or by surreptitiously sending e-mails during a meeting by using a discrete mobile device. But medical writing requires you to spend time at your computer, working on one thing at a time.

When you have too much to do, the next step in effective time management is prioritisation. If you can't do everything, then you must prioritise your work according to the relative urgency and importance of each task. This brings us to another major problem that medical writers have in managing our time: most of our chargeable work is both urgent and important. The work is urgent because there is a deadline for submission, or just because that's when our clients want it, and meeting our clients' needs is our core business. The work is important because regulations dictate that the work must be done, or the publicity is needed to sell the product. Essentially, although we occasionally have the luxury of doing some preparation in advance of a deadline, most of our project work has to be completed within a period that is usually challenging.

Therefore, the project work always takes priority and the other stuff goes onto a 'do later' pile. If we neglect the pile for too long, something starts smouldering, then a fire breaks out and a task that we had put to one side as not being urgent suddenly becomes urgent. You can't use the food processor again until you have washed, dried and reassembled it from the last time it was used. So, you have to stop what you were doing and get the now urgent task out of the way. Great! You can cross one thing off your list but you still have to finish the same amount of project work by the same deadline.

Is there any hope for us? Changing timelines can work in our favour. We can go from mad panic to nothing to do in the same week because of changing timelines. The interesting thing is that in those rare periods when there is no project work to do, my first reaction is to think that I have nothing to do. In fact, the time needed to accomplish everything on my to do list is longer than my life span, but once the

1 The Hatter is a character from Lewis Carroll's *Alice's Adventures in Wonderland*. Alice meets him at a tea party. He is popularly referred to as the 'Mad Hatter,' but is never called by this name in Carroll's book—although the Chesire Cat does warn Alice that he is mad.

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time pressure is off, the need to go outside, breathe some fresh air, feel the sunshine on my face, and look at the real world rather than a computer image of it, takes over. In essence, I need to rest. In reality, the nothing to do period doesn't last long at all and before I'm halfway down the most recent 'do it later' pile, I'm back up to top speed with project work. I have tasks on my to-do list that have been there for more than a year.

Some stuff goes away by itself. By the time you get to it, it is no longer relevant. I do not recommend this as a method of clearing a to-do pile because you often find that you have forgotten about something important and there are consequences to not having done whatever it was. This is why it is necessary to control the project work, if at all possible. Sadly, every time I chat to other freelancers at EMWA and ask (if they haven't asked me first), 'How do you control your workload?' they all sigh wearily and say, "I don't".

I would like to finish this article by telling you the secret to successful time management. Perhaps I should finish by appealing to you to tell me how to manage my time successfully. I believe the answer for a freelancer is to take on less work and accept longer gaps with nothing to do. However, this takes courage, and that is another subject. All I can say for certain is that Nigella's recipe for chocolate pear pudding (see Box) is easy to prepare and scrumptious to eat—I substitute the coffee with brandy or rum.

Wendy Kingdom
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Reference:
1. Nigella Express. Publisher: Chatto and Windus (6 Sep 2007) ISBN-10: 0701181842; ISBN-13: 978-0701181840

Wendy Kingdom is treasurer of EMWA and quite a good cook.

Chocolate pear pudding

Serves 6-8

2 x 415 g cans pear halves in juice
125 g plain flour
25 g cocoa powder
125 g sugar
150 g soft butter, plus extra for greasing
1 teaspoon baking powder
1/2 teaspoon bicarbonate of soda
2 eggs
2 teaspoons vanilla extract

1. Preheat the over to 200°C and grease a 22 cm square ovenproof dish with butter.
2. Drain the pears and arrange them on the base of the dish.
3. Put all the remaining ingredients in a food processor and combine until you have a batter with a soft dropping consistency.
4. Spread the brown batter over the pears, and bake in the oven for 30 min.
5. Let it stand out of the oven for 5-10 min then cut into slabs.

Serve with the chocolate sauce.

Hot chocolate sauce

75 g dark chocolate, 70% cocoa solids
125 mL double cream
2 x 15 mL tablespoons coffee essence or 2 teaspoons instant espresso powder dissolved in 2 tablespoons water
1 x 15 mL tablespoon sugar syrup

1. Break up the chocolate and put into a heavy-based saucepan.
2. Add the remaining ingredients, then place the pan over a gentle heat and let everything melt together.
3. Once everything has melted, stir well, take off the heat and pour into a jug to serve.

A new website initiative for learning or teaching English for medical purposes

The International Medical Communications Center at Tokyo Medical University has created a free educational site for English for medical purposes at http://www.emp-tmu.net. This site is free and is great for anyone interested in learning or teaching English for medical purposes. To register you only need to supply your email address and a password of your own choosing. The site was created to help the move to globalisation in medical communications standards.

Political interference in science is not funny

The 2008 winner of the US's Scientific Integrity Editorial Cartoon Contest can be found at http://www.ucsusa.org/scientific_integrity/science_idol/. The competition is run by the Union of Concerned Scientists which is "building a foundation to guide the next president in restoring scientific integrity to federal policy making." The website refers to reports of political interference in science.

Get more time out of your day

by Debbie Jordan

"There can't be a crisis next week—my schedule is already full" Henry Kissinger (US Secretary of State), June 1969

How many of you read the quote above and agreed with it? I suspect most of us! For the most part (with the obvious exception of protocols), medical writers seem to find themselves at the end of the clinical development process, and, as such, any delays during the clinical trial are compacted, because as we all know, the final end date is unmovable. Therefore we are constantly under pressure to complete a task within a shortened timeframe. Contrary to popular belief though, we are not miracle workers and we cannot create more hours in a day, so the only solution is for us to try to manage our time effectively. Unfortunately, magic wands and fairy godmothers only exist in fairytales, so we have to come up with some more realistic ways of managing our time.

Realistic timelines

The first part of this process is to have a realistic idea of how long a task normally takes you and how much 'real' working time you have in a day. Too many medical writers work on the principle that to write the first draft of a Clinical Study Report (CSR) will take them 70 hours, therefore, based on a 35-hour working week, the first draft will take them 2 weeks to write. Is this achievable?

Firstly, where does this number of 70 hours for a first draft come from? Is it backed-up by proper data? The best way of finding this out is to look at the actual time you spent working on several CSRs and then calculate the average number of hours that are applicable to YOU. We all work at different speeds, so it is important you know your own timings, not those of your colleagues or some 'company standard'. Most of us have to keep timesheets at work (and if you don't you should do this anyway so that you know how your time is spent). Finding out this information is therefore a relatively easy process—and a worthwhile one. I think you will be surprised at the actual time it takes you to write and update various documents…

Secondly, it is naïve to assume that you will spend all of your working day on project work. Once again, this is where timesheets come in useful: how many hours a day do you actually spend on project work, versus time in meetings, dealing with e-mails and telephone calls etc? In the EMWA Time Management workshop, we routinely see that people only have half of the working day available for project work—which comes as a bit of a shock to some! Thus a project that needs 70 hours will realistically take you about 4 weeks to complete, and not 2 weeks.

Once you know the above 2 numbers, then you can realistically estimate how long a project will take you. There is no guarantee that a project manager will allow you the time you need, but if you can back up your request with numbers, it certainly helps. Also, if the worst comes to the worst and your timelines are shortened, then if they are shortened from realistic timelines you might still achieve the goal and retain your sanity, but if timelines are shortened from already unachievable timelines, you are either going to fail, or be so overworked and tired that you will produce a poor quality document.

Planning the year

The first thing to consider in planning your work is to look at the big picture. It is very important to plan your work and your home life together, because too often home life takes a back seat. Remember we work in order to live—not the other way around! I always think it is a good starting point at the beginning of the year to look at when you want time off for holidays or family events and put these in first. That way they won't get squeezed out when you find that there is no suitable time left to take holiday because you were too busy with project work. Remember everyone needs time off, and it helps you to work better if you can unwind and have a break from it all. Once you have these periods blocked out then you can fill in the months in-between with project work. If you have worked out your timings based on the above points, then you will know how long you need to write each document and you can get a rough idea of how many projects you can take on over the year. For example: if you have worked out that it takes you 6 weeks to write a CSR (4 weeks to write the first draft and 2 weeks to deal with meetings, several rounds of revisions, quality control checks etc.) and you have 6 weeks of holiday planned during the year, 1 week of public holidays, and 1 week away at the EMWA conference (essential for all medical writers!) then you are looking at having time for a maximum of 7 CSRs per year. If you then keep this number in your head it should help you to avoid taking on too many projects.

Planning your week

Once you have a rough outline of the projects you are working on each month throughout the year, then you can start looking at your projects on a weekly basis. The first

step in this process is to have a goal for the end of the week. For example, if your goal for the month is to write the first draft of a CSR, your goal for the first week might be to write the methods section. The goal for the second week might then be to write the demography and efficacy sections, for the third week to write the safety section, and for the fourth week to write the discussion, synopsis and re-read and check the document before issuing the first draft. By breaking the task down into chunks it becomes manageable and allows you to focus on attainable goals. Importantly, it also allows you to be more aware if you start getting behind on a task. If you get to the end of the first week and you still haven't written the methods section of the CSR, you can correct the situation in the following weeks. If you only plan on a monthly basis it could get near to the end of the month before you realise you are behind, and then you could end up working long hours and at the weekends to try to catch up.

However, when setting the weekly goal, it is again important to balance your work and home life. Are there particular evenings during the week when you can't work late due to social events or evening classes, for example? Are there days in the week when you are involved in meetings that may take up part of a day? Do you need to build in travel time to meetings? All these things need to be built into your weekly plan so you can see if the goal for the week is achievable.

Planning your day

Once you have your yearly and monthly schedule roughly mapped out, how do you go about ensuring that you maximise the amount of time you have each day? After all, it is all too easy to find yourself at the end of a day having done very little of what you planned to do because you have been dealing with e-mails, other people's problems and emergencies that have come up. So how do you deal with these issues and leave enough time for project work?

The 2-hour rule: A good rule to follow for planning your day is the '2-hour' rule. This is where you block out 2-hour periods to concentrate on project work and avoid all other interruptions. This can also help you deal with projects that you don't like and have been putting off because if you have your 2-hour blocks planned in, it helps you to stay focussed on the task rather than looking for distractions to avoid doing it.

The reason the rule is set at 2 hours is because this is deemed to be the maximum time you can work efficiently on a single topic before you lose momentum and concentration. However, you need to make sure you are interrupted as little as possible in the 2-hour project block you have established. Did you know that it takes 10 minutes after an interruption to get back to the point where you were before the interruption happened? If you are in an open-plan office, try to go to a quiet room where you won't be disturbed. If you have to stay at your desk, turn your e-mail notification off, forward your phone to voicemail, and then put a note on your door, or on a nearby partition if you are in an open-plan office, saying you are busy and don't won't to be disturbed but you will be available at a certain time. The important thing here is to let people know when you will be free again so they don't waste time constantly checking to see if you have finished, or, worse still, they interrupt you anyway. This also applies if you go to a different room to work, so leave a note by your own desk telling any visitors what time you will return, which will hopefully then stop them hunting you down. After 2 hours you need to take a break or switch to an unrelated task (e.g. responding to e-mails or returning phone calls that occurred while you were doing your project work) to give yourself time to relax and refocus.

E-mails: One of the biggest problems these days: e-mails constantly arrive in your inbox and you feel obliged to answer them immediately. The first step to deal with this problem is to switch off your e-mail notification so you are not distracted by e-mails arriving. Then allocate set times during the day to deal with them: maybe first thing in the morning, just after lunch, and then at the end of the day. During these periods you then need to deal with each e-mail only once. You read it and then do one of the following:

- delete it
- if it is a short task (e.g. replying to a straightforward query or responding to a meeting invitation), then deal with the task straight away, respond to the person who sent you the e-mail, and then file it or delete it
- if it is a larger task (e.g. review of a document someone else has written, or a series of questions that is going to need you to do some research) then assign it the status of a project and plan when you are going to deal with it (this will depend on its priority versus the priority of other work you have). The important thing in this case is to allocate a specific time you will deal with it and then you must inform the person that sent you the e-mail of the timelines you have set, otherwise they will chase you

If you follow the above rules you will take control and manage your e-mails to fit in with your plan, rather than letting your e-mails plan your time.

Meetings: Meetings can take up a large part of your day, and if you are not careful you can spend most of the day in meetings without achieving a lot. The first thing to do is to ask for the meeting agenda. This will not only encourage the person organising the meeting to structure it if they haven't already done so, but will also allow you to see if it really is relevant for you to attend. A lot of meetings are routine project meetings that cover all aspects of a clinical trial. It may therefore not be necessary for you to attend the whole meeting; you could just join in for the medical writing sections. If you don't attend, or only attend for part of the meeting, then make sure the rest of the team knows that you are doing this (otherwise they may waste time waiting

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>>> Get more time out of your day

for you!) and then make sure the meeting minutes are written up and you are sent a copy so you know what is going on with the project as a whole.

Chatty colleagues: Although it is nice to have a chat, and I am by no means suggesting you should avoid being friendly and building relationships with colleagues, sometimes it can interfere significantly with your day if someone pops in for a quick chat and then spends an hour telling you all their problems. Once again, the key here is for you to take control and plan in this time as much as you can. If someone pops in unexpectedly and you are in the middle of something, then tell them straight away that you are really busy, but why don't the two of you meet for coffee or lunch later (defining a set time) and you can chat then. That way you are in control and are planning a time that suits you. You also get a break from your work and a bit of downtime at the end of your 2-hour project block, and your colleague feels that you are taking time out for them and taking their issues seriously—a win-win solution!

Emergencies: Emergencies, or unplanned work, can really disrupt your day and can cause a big problem if they are not managed properly. If you find you are constantly dealing with emergencies or unplanned work that starts to adversely affect your planned work then you might want to consider actually building these in as 'projects' and allocating time for them. If you have a 2-hour block booked out for emergencies every few days then you have the time built in if they happen. If they don't, then you have some extra project time or even a 2-hour slot for catching up on all those other things you never have time for, e.g. filing, reading up on a new topic or tidying your desk!

Emergency work or unplanned work should always be questioned: just how important is it really and what are the consequences if it isn't done immediately? A good way to visualise this is to use the grid in the Box below.

		URGENT	
		Yes	No
IMPORTANT	Yes	Do now	Plan in work
	No	Query: is this really needed?	Query: is this really needed?

Planning your next day: A good habit to get into is planning the next day at the end of the current day. This means getting straight in your mind what your tasks for the next day are and getting things ready that you might need. For example, if tomorrow you have a meeting in the morning, then print off the agenda and put it in a folder, along with some spare paper, a pen and any reference documents you may need for the meeting. That way in the morning you have everything ready to start the day afresh. It can also help you feel more mentally prepared for the next day and can help you to switch off and relax when you get home because you have everything organised for the following day.

So, in summary, there is no 'quick-fix' to managing your time, but I hope the above has given you some ideas to think about and some tools to manage your time more effectively. Good luck with your time management, and in the words of the poem below, make the most of the time you have…

This is the beginning of a new day.
I have been given this day to use as I will.
I can waste it or use it for good.
What I do today is important, because
I am exchanging a day of my life for it.
When tomorrow comes,
this day will be gone forever,
leaving in its place something
that I have traded for it.
I want it to be gain, not loss;
good not evil; success not failure;
in order that I shall not regret
the price I paid for it.

(Author Unknown)

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Is plain English plain enough for product labels?

Misread labels on pharmaceutical products result in around one in five incidences of drugs taken at the wrong dose or time. Examples from a survey of approximately 2,000 people questioned for Lloydspharmacy included a man who sprayed his cat with his asthma inhaler to cure his cat allergy. Another patient had problems with his inhaler because he had not removed the cap. The palette of drugs taken by older patients also leads to confusion. One old lady was found to be taking her sleeping tablet first thing in the morning.

Source: http://news.bbc.co.uk/1/hi/health/7536728.stm

Thanks to **Adam Jacobs** (ajacobs@dianthus.co.uk) for this contribution

A week in the life of a medical writer

by Thomas Mondrup

At the end of May, I corresponded briefly with Alistair Reeves relating to a workshop run by him and Susanne Geercken that I attended at the EMWA conference in Barcelona. By the end of this correspondence, I had agreed to write a piece for *TWS* based on the following brief: 'Who manages YOUR time'; a Monday-Friday diary of a typical working week describing problems with time management, objectives set for the week, whether objectives were achieved, pressures from e-mail, telephone conferences (TCs), colleagues, bosses, and strategies to ease stress and manage your time successfully—or do you feel 'managed' by other things beyond your control?

So why did I accept? Apart from networking with Alistair, I was driven by selfish reasons. In Barcelona, I had attended a time management course with a similar preworkshop assignment: filling out a time schedule for a three-day working period. Apart from returning the preworkshop assignment too late to be integrated into the workshop, I have to admit that it was done *post-hoc* with assistance from Outlook and very little actual time keeping. On top of this, I had scheduled 3 abbreviated first-draft results-independent clinical trial reports for review the day I left for Barcelona. Hence, before my one hour packing on the morning on the day of departure, I had a 14-hour working day which also included the night. Two reports were sent for review from my office 2 hours before the flight departure. 30 minutes later, including running to the subway, I was at the security check-in at Copenhagen airport. The third report was sent for review during the night after the EMWA banquet. Bringing work to Barcelona was, of course, not part of my original plan …

My first workshop in Barcelona was the time management workshop with Debbie Jordan. Different techniques for efficient time management were taught, and though some seemed rather straightforward (e.g. don't be late for meetings and skip the ones you can) I knew that there was room for improvement in my own working life with regard to time management. My selfish reason for writing this piece was therefore that it was a good opportunity to try out one of the techniques taught on the course, and I knew writing this piece would give adequate motivation for me to get the time tracking right this time.

I decided to use the ABC technique where you prioritize your working tasks into three groups. Your top priorities go into the A group, and for a medical writer this group should mainly comprise the products we write and closely related processes. Work should be focused on A tasks in timeslots of two hours. Group C tasks such as reading e-mails and making short replies are dealt with in timeslots of 30 minutes. The B group contains everything in between, and can be labelled 'maintenance', e.g. attending meetings, training, reading SOPs, planning work, reviewing documents, writing minutes, preparing more demanding e-mail replies (if the importance is higher, any such tasks can be upgraded to an A task). A balanced working diet containing six timeslots, two of each category, is supposed to make up an efficient and healthy working day, with room for coffee breaks and social interactions. If every day could be like that, I would certainly improve my work-life balance.

Next, I planned to time-track the week that I received the first complete end-of-text (EOT) material for the three abbreviated interim reports of ongoing trials that currently constituted my A tasks. Hence, my A task for the entire week was to review the EOT material for the three reports and to start writing the data-dependent sections of the report first scheduled for Draft 1 review.

Knowing how much trouble can accumulate if you fail to identify errors, inconsistencies, and bad programming at an early stage in your EOT material, I was initially surprised how difficult it actually turned out to be to achieve two A slots on a daily basis. B tasks (e-mails, meetings, and training) stole more time than I thought was healthy and I had decided to report on a 'healthy' work-life balance!

I did actually succeed in keeping a record of my time and tasks. By the fifth day, I had managed to get in a decent amount of A slots and maintain a healthy work-life balance. The ABC diet was also fairly balanced, and the working week included social activities such as birthday celebrations, and an after-hours visit to the 'Bodies' exhibition. I did, however, encounter a few 'pitfalls' that gave me something to write about. But when was I going to write about it, I was caught up in a submission Gantt chart, so writing for *TWS* hadn't made it into my ABC list, and with approaching deadlines, the healthy work-life balance vanished, making it impossible to use any of my scarce private time on semi-work related things like writing for *TWS*.

My last resort was to write this piece on the first Saturday of my summer holiday. But my A tasks got in the way. The three final draft 2 reports were supposed to be reviewed while I was away (one was being prepared by a new medical writer for whom I am the mentor), so I ended up in a

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>>> A week in the life of a medical writer

2-week sprint before my vacation, including Saturdays and Sundays with a seemingly interminable series of A slots. I didn't find time to bring cake to work to celebrate my own birthday, and I ended up working on my reports until 30 minutes before leaving for a ferry on the first Sunday of my vacation. That was 8 days before, and I hadn't turned on my laptop again until that day, the day that Alistair provided as my extended deadline.

Hmm … I guess there still is room for improvement in my time management abilities. My Monday–Friday diary notes are of course in the office, so once again I have to draw on *post-hoc* assumptions. Not to stress my memory too far; I'll focus on my latest Monday–Friday working week. The week I had scheduled to be the most hectic working week this year.

Monday *(16-hour working day)*.
The first task was to sort comments from the draft 1 review (first full draft with data) for the third report. I had agreed to extend the deadline for comments until start of business on Monday, but comments were also sent after end of business on Monday, and contrary to agreements with our partner, I received comments from the individual reviewers rather than a combined log of comments (combined logs of comments from our partner were missing for all three reports). So, apart from incorporating the comments, I also had to spend time sorting the comments so that I could have a combined log of priority comments to go through on the 'web-ex' roundtable teleconference scheduled for Tuesday. Organising the web-ex conference was also 'fun': the IT service gave me a web-ex account with misspelled log-in details. When I finally got the correct log-in details, I could not get any assistance regarding how to set up meetings, only the reassurance that everything was straightforward and people usually have no problems. This was almost right. Setting up a meeting was indeed straightforward

Tuesday *(10-hour working day)*
Still preparing the combined log of priority comments and including suggested solutions. The combined log was distributed half an hour before the web-ex roundtable teleconference started. The meeting ended up as a teleconference, as the shared desktop facility would not work. This being the first web-ex conference where I was the host, I realize that I should have done a rehearsal. Having sent the combined log of priority comments to all attendees, we did however have something common to hold onto. After the 4-hour teleconference covering two reports, solutions to most issues were agreed upon. Now, I ***only*** had to implement the agreed solutions, get final Draft 2 EOT material, and replace all in-text EOT material with the final Draft 2 EOT material. The 4-hour TC was exhausting and I dropped dead in bed before my children went to bed.

Wednesday *(16-hour working day)*
Within normal working hours, the entire day was devoted to getting the final Draft 2 EOT material right. Unfortunately, issues already identified from the review of table shells were still pending because the statistician and programmers had had to work on the pivotal study as a priority over our 3 abbreviated interim reports. Rather than showing understanding towards this prioritisation, I should have made more noise from the start. A timely solution could perhaps then have been reached. Instead the noise started the week before when the statisticians suddenly announced that they also would not have time to correct the titles in the EOT material that we were to send for final review. The number of inconsistencies was unacceptable and we had promised to fix it, so finally a programmer from another project was brought onboard our project for two days. As the programmer was new to the project, I had to invest a whole day providing very specific input on approximately 600 titles and reviewing the output from the programmer. Considering that I had plenty of more substantial issues related to the interpretation of the safety findings, this was bad timing. It should have been done before Draft 1 review as previously requested.

After normal working hours, it was finally possible to do some undisturbed writing, accompanied by a menu of frozen pizza and buckets of coffee.

Thursday *(8-hour working day when I actually managed to be at a barbeque with friends and family after work!)*
Statisticians and programmers are BANNED from my office. OK, they had to disturb me a few times, but basically I was able to get on with my work.

Friday *(14-hour day. Looking forward to the weekend. But I know that will be busy too.)*
The final EOT material was due Friday morning at the very latest for the two reports I was writing. It was only available for one, and when I was replacing the first in-text table, I noticed that numbers had changed. 4 hours later it was ready, and—luckily—the old numbers were valid, so I didn't have to change them after all. In the afternoon, the EOT material was finally available for the second report as well. However, I had enough going on with the first report to keep me busy Friday night.

It was indeed a busy weekend.

Were the objectives for the week achieved?
The reports did go into final review, but I could easily have spent a day more working on the discussions. I would like to have spent more time discussing things with the medical officer and less time with the programmer. I guess I will learn whether I managed to satisfy the reviewers when I get their comments back.

Strategies to ease stress
I recommend yoga and never to schedule document review cycles when you have holiday planned or are attending a conference, especially when your deadlines depend on reviewers, statisticians, and programmers meeting deadlines you have provided for them. However, even if every deadline is kept, you still need the review periods to get a

A week in the life of a medical writer

healthy ABC balance. Lately, I have spent very little time on my B and C tasks, and this may get in the way of another colleague's A tasks. Shared deadlines help: if you can, make sure that you are always working towards deadlines that have been agreed in advance and are incorporated in whatever shared planning software you use.

Who manages my time?
I do, in collaboration with my superior (pan-galaxy Genmab Medical Writing Director, Ulla Jessen). For the three reports, we looked for the ***latest*** date they could be finalised without interfering with the critical path of the pivotal trial and subtracted a bit. With this target I made an ambitious plan including scheduling of reviews during the EMWA conference, the Roskilde festival, and my current summer holiday. Bear in mind that submission plans are ***not*** made to ease stress.

However, even submission plans are not set in stone, and you should always remind yourself that very few people on their deathbed regret that they didn't spend more time in the office..

I think I'll adopt the balanced ABC working life once my holiday is over.

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Can you edit? Yes, then why not run for the presidency of the United States?

"Mr. Obama arrived at the law school in 1991 thanks to Michael W. McConnell, a conservative scholar who is now a federal appellate judge. As president of *The Harvard Law Review*, Mr. Obama had impressed Mr. McConnell with editing suggestions on an article; on little more than that, the law school gave him a fellowship, which amounted to an office and a computer, which he used to write his memoir, *Dreams From My Father*."

From an article in *The New York Times* (30 July 2008) titled 'Teaching Law, Testing Ideas, Obama Stood Slightly Apart' which is about Obama's time at University of Chicago Law School: http://www.nytimes.com/2008/07/30/us/politics/30law.html?ref=education.

Thanks to **Mary Ellen Kerans** (mekerans@telefonica.net) for this contribution.

Gross! or Gerne!?

In a recent project, I had the 'pleasure' of doing a literature review on maggot therapy. I found these two descriptions of the therapy particularly entertaining.

"It very often happens that a certain part of a wound offers more delicious food than any other part … hence with only a few maggots they all seek the green pastures … Maggots are like dogs—they seek the shade … So voracious are they in their struggle for food that they will stand upright on their heads with their tails in the air, as puppies do to crowd around a basin of food where the basin is too small for the number of puppies. They apparently continue this process of sucking day and night and never seem to tire …" [1].

"Nature has conferred on certain insect species an unsurpassed degree of biochemical expertise in exploiting down-market environments such as necrotic tissue. The principle *raison d'être* of the adult Greenbottle blowfly … is to seek out such locations as a nursery for its supernumerous progeny. In circumstances of tissue infestation, termed myiasis, a typical wound can nurture hundreds of Greenbottle larvae, each secreting enzymes directed against devitalized host tissues in order to derive sustenance for growth and differentiation. In biosurgery, otherwise referred to as larval therapy or maggot debridement therapy … the *modus operandi* of non-parasitic larvae is hijacked in order to cleanse and debride wounds for the benefit of the host. Interestingly, these stowaways often compete with microbiological colonists but triumph nevertheless by virtue of their bactericidal secretions" [2].

The therapy has barely changed during the last 75 years, but the descriptions have. Can the words influence a patient's reaction from "yuck!" to "yes!"?

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2. Smith AG, Powis RA, Pritchard DI, Britland ST. Greenbottle (Lucilia sericata) larval secretions delivered from a prototype hydrogel wound dressing accelerate the closure of model wounds. Biotechnol Prog 2006, 22:1690-1696.

Deadlines

"I love deadlines. I like the whooshing sound they make as they fly by."

Douglas Adams

Are we nearly there? Resource planning—step by step

by Stephen de Looze

It is not certain that everything is uncertain.
Blaise Pascal, Pensées, 1670

The good old days?

When I started my professional career as a medical writer in a large pharmaceutical company nearly twenty-five years ago, resource planning was unheard of in the clinical research department. Projects came along, people were allocated to them, deadlines were written down, and then everyone muddled along as best they could. In most cases, keeping to deadlines was not remotely possible, but this seemed to have little consequence other than some hand-wringing here and there. The inherent uncertainty of clinical research, of the many confounding factors that could lead to alterations in 'the best laid schemes of mice and men' (in the immortal words of Robert Burns), and the absence of any real pressure from without were considered just part of the way things were.

The best laid schemes of mice and men

To further confound the situation as far as medical writing was concerned, the whole area was something of a free-for-all: there were no document standards or templates, no defined processes or boundaries as to where medical writing began and ended, and not even a clear idea of which skills would contribute to document development and writing.

One of my jobs in those early days was to write up the minutes of a quarterly departmental meeting where all projects were discussed. Although that involved the rather onerous task of chasing up countless details of projects I barely understood, I quickly realised that this afforded me a unique insight into what was in the pipeline and was potentially coming my way. Before long, I was being asked to take on new staff and build the medical writing function within the company. This is when things began to get interesting.

As soon as word got around that there were folks who actually enjoyed the business of preparing documents, and weren't that bad at it either, the floodgates opened. Project leaders began calling me daily to ask for support in writing their clinical study protocols and reports, publications and investigator brochures. Sure enough, the day came when I was ask to rewrite an entire clinical submission dossier that had flopped badly at the German health authority, and deadlines became rather more serious.

With my knowledge of what was in the pipeline, and a developing sense of how long projects could take, I realised that, at least in theory, I could attempt to calculate just how many new writers I should be hiring to meet the rising demand for our services. By now it was the late 1980s and our first PCs had arrived, still considered by many to be just glorified typewriters.

One day I discovered how to use a spreadsheet, and how I could just update some numbers and the whole thing would recalculate itself instantly. This was a revelation indeed, and opened my eyes to the power of the PC. I set to work in my spare time, linking scores of spreadsheets, producing some fancy graphics and what I thought was irrefutable proof of the need for a quantum leap in the medical writing staff numbers. I was a writer, after all, and knew the power of documents. Ignoring the advice of an older and wiser colleague, who said that higher management would not believe what didn't suit them, I sent my thesis to the appropriate senior manager with a request for half a dozen new writers—and sure enough, the response was, "Don't you have anything better to do with your time?"

"Don't you have anything better to do with your time?"

How times have changed!

From these inauspicious beginnings (and the careful reader will realise that I was not to be defeated so easily), the approach that I had developed was taken on by other departments as the pace and pressure stepped up in the industry. My group did indeed grow rapidly to a dozen or more staff. Since then, over the years, I have been able to refine and extend my calculations, gather and share experience with others, and try out different tools to manage the task. (I'll return to this last point later.)

When our department was spun off six years ago to form our present company, a clinical research organisation, the calculations acquired a vastly greater significance, because they enabled a cost estimate for the client to be made for any given assignment. And yet in its essence, my approach today is little changed from that of twenty years ago, and I will share the key elements with you now.

Step 1: Define the scope of each assignment

For example, when a client requests 'write a clinical study report', does this mean just the text body and any in-text, word-processed tables? Does it include the patient safety

narratives? Literature searching? What about assembling the appendices? Quality control? Electronic publishing? And how many review cycles, each requiring a revised document? Will you receive consolidated comments from reviewers, or will you have to resolve disagreements between them? Is a mock report to be written and separately reviewed? Is there a template and style guide to follow? These and similar questions apply to every sort of medical writing project and will differ from organisation to organisation, or from client to client. In many scenarios, the medical writer is often (sometimes explicitly, sometimes merely by default) a project manager too, and this must also be factored in. So you must establish a sort of 'baseline' or standard scope, perhaps standard 'sub-projects' (such as patient safety narrative writing or appendix assembly) and then you can make adjustments if the particular job differs from that.

Step 2: Define the skills needed for each project

Is it regular medical writing or senior medical writing or a mixture of both? If your organisation has more than two grades of medical writer, do the job descriptions give a guide as to what the contribution of each grade will be to any given project?

What about contributions of medical writing support staff such as technical editors and e-publishers, if you have them? I am assuming that the planning of the contributions of other disciplines, such a biostatistics and data management, will be dealt with elsewhere—but sometimes it is just as well to check. You may also have different medical writing needs if you are, say, developing a clinical study protocol with in-house physicians and statisticians, or if you are joining a fully staffed client team, or working as a writer-cum-project-manager with a bunch of different service providers.

Sometimes it is just as well to check

Step 3: Define the complexity of the project

This is by far the biggest challenge, sometimes based only on a few sketchy details, and occasionally little more than crystal ball gazing. And yet it must be done.

The number of documents that take a given amount of time can be graphed approximately as follows (Figure 1):

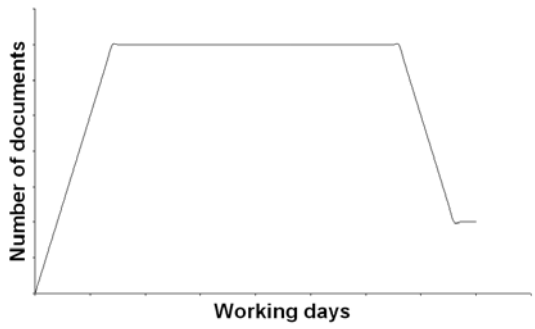

Figure 1: Number of documents that take a given amount of time

The scale of the x-axis will depend very much on the type of document: it may be from, say, 2 to 100 working days for clinical study reports, or, say, from 50 to 500 working days for submission dossiers. Yes, I have seen a simple abbreviated clinical study report based on a 'twin' report generated in two days by search and replace of a key parameter and entering a few new numbers. By contrast, reports on 'megatrials', with their extensive analyses and multiple subgroups, may take considerably more than 100 days.

That being said, the only point on this curve which is certain is the origin (x=0, y=0)—in other words, no document uses no resources! Otherwise the curve carries the fairly obvious message that a few documents may be quite 'quick', the majority will fall somewhere on a broad continuum, and there will be a few super-complex documents to round things off at the high end.

The important thing to note here is that we are considering *resource time* (per skill) and not *calendar time*, as we would be doing in project planning. This is not just because 'working days' (or 'working hours') need adjusting for 'calendar days' because of weekends and public holidays (though freelance medical writers may make no distinction on this point!). More importantly, if a particular project is to take 50 medical writer working days, it could theoretically be achieved by two medical writers in half the calendar time *if* they could work entirely in parallel. By contrast, when parts of the project fall outside medical writing—such as review time at the client—this must be added into the overall project timing but does not necessarily affect the resources needed. We'll talk later about the limits of staffing and 'telescoping' project timelines by adding resources, and why I italicised the word 'if' above.

For resource planning purposes, you would probably agree that such a continuum is not much help, especially if the details that are supplied are incomplete. We need to be able to categorise projects if we are to come up with a first estimate of complexity. In general, three categories will be sufficient: let's call them 'low', 'medium' and 'high' complexity projects. However, even before we take this step, we must never forget that this simplification is exactly that—a simplification.

The real world still remains a smeary continuum, and what we are now doing is to pick out three arbitrary points on the curve shown in Figure 1. Even if we allow a little uncertainty in our categories, as shown in Figure 2, this is still a simplification of reality. Nevertheless, it does give some sort of framework to our planning.

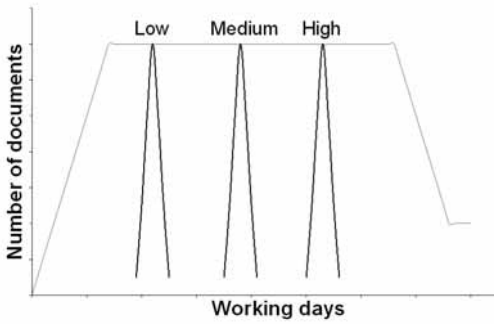

Figure 2: Categorisation into 'low', 'medium' and 'high' complexity assignments

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>>> Are we nearly there?

The next challenge is to define what 'low', 'medium' and 'high' mean for any given project, in the light of the scope that you have defined in step 1, and the skill you have defined in step 2. To avoid a mere tautology (where 'low' is just defined as 'low'), the complexity should be pegged to some measurable 'variable'. An example for clinical study reports is given by Sam Hamilton in her article 'Effective Scheduling of Clinical Study Reports' in this issue. For resource planning purposes, the scheme she describes as a 'rough guide' can be refined. For example, if the overall project contains several reports that will all be very similar (this might be the case for a set of studies with the same design and analysis plan but a different comparator drug or different dosage), the first report of the series might be, say, medium or high complexity, and the follow-on reports may (again, for simplicity's sake) drop down one level of complexity, to low or medium, as the case may be.

I'm not aiming to provide hard and fast rules that span the whole complexity of all medical writing assignments

Similar considerations apply to any sort of medical writing project. For a clinical submission dossier, the relevant variables might be the overall number of studies, whether the dossier is for a full, new submission or a variation, whether it includes subgroup analyses or a particularly complex integrated safety summary. For an investigator brochure, the number of new clinical and non-clinical studies to be summarised, or a pre-existing document that needs updating rather than writing from scratch (or whether you were the author of the earlier version!) may be relevant.

It is not my aim here to provide you with hard and fast rules that span the whole complexity of all medical writing assignments, and still less to provide you with 'magic numbers' that you can put into your calculation as a 'quick fix'. These will be much influenced by the scope you define for any project, by constraints imposed by your working environment, and by the skills and staff available. This includes such things as whether you have to follow complex style guides or standard operating procedures, whether you have a slow staff turnover and few 'interface' issues, whether you often have new staff training-on-the-job, or whether you are dealing with nearby or distant departments, subcontractors or clients. Nevertheless, I hope these considerations give you an idea of how to begin to dissect this complex issue of complexity and arrive at numbers that suit your own situation.

Over the years, I have noticed that some projects, such as clinical study reports or investigator brochures, can be relatively tame animals, provided (and this is a big proviso) your team has a fair idea of how the final document should turn out. There may be a reasonable template or other documents to serve as models. Danger lurks even here, however, in uncertainties inherent but often not apparent in the process: review cycles are a particular source of grief, but technical steps such as document assembly processes, or electronic specifications (especially if these change midway) can bring unexpected additional complexity. In the case of study results, unwelcome or ambiguous findings at the last minute can also set the cat amongst the pigeons, which in practice means increasing the number of review and re-writing cycles and hence increasing the complexity and resource needs.

By contrast, some projects seem by their very nature to be wild beasts, most notably writing clinical protocols, or other planning documents. In these cases, the production of draft documents often will trigger new ideas, or whole re-planning cycles, sometimes starting from scratch. Frequently it would be a more sensible use of resources if the medical writer were not brought onto the project until ideas are fairly well advanced, but many teams, once having been provided with the service, are unwilling to manage without the luxury of letting the medical writer iron out the wrinkles and reveal the issues needing re-discussion. This is good news for medical writers searching for interesting work, of course, but it introduces a lot of uncertainty into the planning.

A signal to recruit new staff or to expand your reservoir of freelancers, or—perish the thought!—turn away business

Your best friend is your experience and instinct, and your ability to balance taking a certain amount of risk (if you are providing a cost calculation to a client, you may lose the project if you assume a worst-case scenario) with some built-in safety net if the goalposts move. You must also be in a position to keep a close eye on things as the project unfolds. The more details you know about a project, the more you can pinpoint its location on the real-life curve in Figure 1—whether 'lower than low', 'higher than high', or at some intermediate point between categories.

Step 4: Determine long-term and short-term availability of each resource

If you are managing a pool of resources, you need to know how much of each skill is available at any given time. If your long-term planning reveals a chronic shortfall, it should be a signal to recruit new staff members or to expand your reservoir of freelancer subcontractors, or—perish the thought!—turn away business.

So the first step is to calculate the baseline or yearly availability of your resources to projects. For a full-time staff member, this will be:

[Total number of working days per year] minus [paid leave] minus [sick leave] minus [non-project related time].

The total number of working days per year is of course the number of weekdays minus public holidays. This should be straightforward, but a few things need to be considered. Public holidays vary from country to country and in some countries from region to region as well. In some countries, public holidays falling on a weekend will be replaced, in other countries (such as Germany), it's hard luck. For a baseline value, the average number of total working days per year should be estimated—I find that 20 days per month or 240 days per year is as good an estimate as anything else in my own working environment. For part-time staff, everything has to be adjusted accordingly.

The paid leave will obviously vary from company to company but should be easy to determine. Check the records in your company's personnel department to get a reliable average figure for the number of days lost to sick leave. Non-project related time includes everything from the number of days training you provide (EMWA conferences and other training events), to the time your staff spend reading background material, studying company SOPs, and maintaining their personal training folders, to all non-project related meetings and social events. It includes the time you allow your senior staff to spend training the junior staff. You'll be surprised how much non-project time comes out of this calculation.

These times will reduce the theoretical 20 days/month availability quite considerably—in my experience, 15 days/month (180 days/year) baseline availability for projects is the most realistic average estimate for medical writers: but this will vary from country to country, from company to company and from skill to skill.

Christmas never goes away

However, when you are planning short term, different considerations apply. Months do vary in their total number of working days. Christmas never goes away. Your staff member may not have holiday planned in that month (or you may have the authority to cancel holiday). Alternatively, they may have the whole month away. In a particular month, no training may be scheduled, and after surreptitious scrutiny of your employees during regular meetings, you may reasonably assume that no days will be lost to illness! So in the short term, you might in some circumstances assume 100% availability (i.e. 20 days), which is markedly different from 15 days. You may even have more than 100% availability from a dedicated worker who is prepared to put in substantial overtime in the short term to meet project timelines. But then you have to remember that this particular resource will need to be correspondingly under-planned in the months ahead.

You may have come across an entirely different approach to quantifying resources that is sometimes used. This is to think of resources in terms of 'full time equivalents' (FTEs) and fractions or multiples thereof. This approach may work best for projects which require dedicated staff over long periods—study coordinators, for example, working over several years on a single project. In all my experience, the FTE approach simply does not work for medical writing projects, which are most commonly of short duration and are characterised by frequent changes in the assumptions needed for planning, and by the requirement for flexibility of staffing in the short term. The FTE approach also masks the difference between short-term and long-term availability and can lead to serious mistakes in the planning calculations.

Your most important task is to allocate your staff to projects so that they are not chronically over-planned or under-planned… I would go as far as to say that this is the most important management skill you should develop

Step 5: Allocate resources to projects

If, like me, you are a manager of a medical writing function, your most important task is to allocate your staff to projects so that they are not chronically over-planned or under-planned, both of which lead to frustration and job dissatisfaction—and underperformance or worse. I would go as far as to say that this is the most important management skill you should develop. It is essential to remember that your staff are not just numbers on some resource planning sheet but each are at their own stage in their professional development, have their particular knowledge, strengths and interests, and 'learning curve'. If you are building medical writing teams on large projects, then you will also take into consideration which of your staff best complement each other and how you can bring newer or less experienced colleagues up to speed by working alongside more senior colleagues.

For this human side of resource planning, there is no substitute for your own well-developed skills as a manager, your knowledge of your staff through regular meetings, assessments and training programmes, and your ability to step in and support them when the need arises. But alongside the human factor, software tools are indispensable to enable you to establish some sort of framework to optimise your staff's projected workload. They also tremendously ease the burden of re-assessing plans and work schedules as project scope and timelines shift and change.

Over two decades, I have used several tools, from my first simple spreadsheets to customised and complex project management software, to off-the-shelf products such as Microsoft Project. I now firmly believe that a simple spreadsheet is the best help. This is because a spreadsheet is something that you can devise and customise to your own needs, that you can instantly access and update, and most importantly, you can make available on a shared server to

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>>> Are we nearly there?

your staff who can review and adjust their planning themselves. After all, your staff are closest to the project details, can implement planning shifts as soon as they emerge, and work best when empowered to manage their own time within the framework that you have established.

The more complex, company-wide tools I have had to use in the past often required data entry by a dedicated project management department and involved handovers at each stage, whether the entry of new specifications, or checking the information has been understood and handled correctly, or the distribution of the outputs generated by the software. The scope for 'disconnects' was consequently large and, in the case of rapidly shifting project requirements (often on crucial deliverables such as submission documents on tight timelines), these complex tools and processes had too much lag time to be useful in my day-to-day work.

A simple spreadsheet also has the great advantage that the entry of numbers in columns gives a strong visual element to the resource spread, as well as the all-important quantitative information as to how many days (or hours) are required over a pre-determined time span. With a basic knowledge of spreadsheet functionality, you can easily sort the numbers and subtotal them by project, by type of activity or document, and most usefully, by staff member.

A simple spreadsheet is the best help… something that you can devise and customise to your own needs

The spreadsheet I use is little more complex than the example shown in Figure 3, which is an excerpt for the skill medical writer (MW), identified here by the person's initials.

Project code	Activity	MW	Sept 08	Oct 08	Nov 08	Dec 08
XYZ123	CSR	DS		5	10	10
XYZ456	IB	RA	10	5		2
XYZ789	CSP	RA	5	5	5	
XYZ532	CSP Amend	DS	5			
XYZ999	CTD 2.5, 2.7	LL	20	20	20	
XYZ999	CTD 2.5, 2.7	PJ	20	15	10	
ABC456	CSR Tables	WV	2	2	2	2
ABC987	CSR	WV	15	15	5	5
ZZZ321	CSR	DS		15	5	5

Figure 3: Overall resource plan (excerpt)

The number of columns assigned to the months ahead is flexible, though I find that almost all plans will be accommodated within a 12- to 15-month forecast. Projects that are further off into the future can be listed without defined resource allocation by month or medical writer, but with a comment on the likely resource need. More columns can be used to capture essential additional information (such as contact names, drug indication or notes on the uncertainty in the planning). At any one time, my 'master' spreadsheet will contain a few dozen rows. A printout of the spreadsheet with filtered data subtotalled for each staff member serves as a basis for our routine discussions on the overall planned workload and the status of the projects.

I also add a row for planned holiday or training for each staff member, so that this is included in the total planned time in any given month. It is precisely the flexibility that makes this tool so well suited to my needs.

As an added bonus, at the end of the year, I archive a copy of the spreadsheet to serve as a 'snapshot' record of what sort of documents we have worked on during the year—information sometimes requested by prospective clients. The 'master' spreadsheet itself has a constantly roaming window on the future, shifting forwards as the months roll by. It remains a planning tool: we do not retrospectively capture the time actually used on past projects on this spreadsheet but have other systems better suited for recording that.

The limitations of planning

So finally, with Figure 3, we have arrived at 'The Resource Plan'. The spread of resources over time also reflects detailed project planning knowledge, such as timing of crucial deliverables from other departments or your client (protocol outlines, analysis plans, programmed tables, draft package inserts, or whatever), planned review cycles and other steps. The first thing I check at each update is the subtotal per staff member, and whether this matches their baseline availability. My underlying assumption is that the plan will never be nearer to within 15% of real life. So if a staff member is theoretically available 20 days per month, I am happy if their monthly planned work is between 17 and 23 days. The inexactness of project plans means that the chances are high that a couple of days planned in one month will actually be used in the preceding or following month. If there is, however, chronic short-term over-planning—23 days per month over more than three months, for example—then this gives me a signal to monitor the project more closely and start thinking about corrective measures such as negotiating longer timelines, adding resources to the project, or re-assessing the resource requirement more critically. Or maybe I know that the staff member will be able to take on a higher workload in the short term. Analogous considerations apply to chronic under-planning. The further off a project is, the more relaxed I can be about deviations from real life.

So finally we have arrived at 'The Resource Plan'

Sometimes I plan projects half a year or more away with more marked over- or under-planning. This is partly because I may need to give the project a 'home' with the underlying assumption (in the case of over-planning) that the assigned staff member will be the lead writer, but that we will find a support writer or a contractor nearer the time if the planning remains critical. This can be captured in a

comment on the spreadsheet. But I also live with uncertainty because experience has taught me that the planning of far-off projects often changes: for example, it may be possible for the assigned writer to begin the project earlier, or the deadline may shift backwards because a study runs longer than the planned schedule. These changes have the effect of stretching out the estimated resources over more time and bringing the required resource per month to a realistic level even if the overall resource need remains the same. In addition, the actual resource need may be better defined nearer to the start of the project when more details have become apparent. By then planned staff allocation may have to change anyway because of unforeseen clashes with other projects that have drifted out of scope in the meantime.

A job that can be done by a medical writer in 25 days cannot be done by 25 in one day!

I mentioned earlier that you should never forget that resources are real people and not numbers on a spreadsheet. A job that can be done by a medical writer in 25 days cannot be done by 25 medical writers in one day! Even though this seems like a statement of the blindingly obvious, I deal almost daily with requests that imply something along these lines, often when projects have spiralled out of control and people are desperate to meet deadlines. On large projects, it may be possible or indeed necessary to assign several writers to work on pieces in parallel. This may be desirable even on smaller but critically important projects, where the unplanned absence of a writer due to illness or some other event, or a sudden shift in resource need, may endanger the deadlines. I regularly assign more than one writer to clinical submission dossiers, for example, even if the work appears theoretically achievable by one person in the timeframe. This reduces stress all round and provides a safety net if the planning changes. However, additional communication and project management time must be added into the overall resource time allocated to the project if several people are working on different pieces of a project. Of course the writers may then work on other (ideally less critical) projects in parallel to fill out their individual resource plans.

Don't take out a mortgage on your future worries

A crucial understanding is that planning is a tool: it is a means to an end and should not become an end in itself. You should only devote a limited amount of time to drawing up plans for a far-off project that are likely to change even before the project begins, if it begins at all. In the words of my grandmother, "Don't take out a mortgage on your future worries". I have encountered people in project management departments who did nothing else except produce vastly detailed project plans extending over dozens of pages with thousands of items, and whose working days were completely filled with tracking all the changes to the planning even before anything had begun. This is a looking-glass world and should remain where it belongs: in the realm of the fairy story, delightfully captured almost one hundred and forty years ago by Lewis Carroll:

The most curious part of the thing was, that the trees and the other things round them never changed their places at all: however fast they went, they never seemed to pass anything. "I wonder if all the things move along with us?" thought poor puzzled Alice. And the Queen seemed to guess her thoughts, for she cried, "Faster! Don't try to talk!" Not that Alice had any idea of doing THAT. She felt as if she would never be able to talk again, she was getting so much out of breath: and still the Queen cried "Faster! Faster" and dragged her along. "Are we nearly there?" Alice managed to pant out at last. "Nearly there" the Queen repeated. "Why, we passed it ten minutes ago!"

Lewis Carroll, *Through the Looking Glass (1871).*

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Illustration:
Alice and the Red Queen from an original Illustration by Sir John Tenniel for Lewis Carroll's Alice's Adventures in Wonderland and Through the Looking Glass; JM Dent & Sons 1954, 1970: 139.

Effective scheduling of Clinical Study Reports

by Sam Hamilton

The Clinical Study Report (CSR) is a highly complex, multi-component document which slots into a wider clinical-regulatory documentary process jigsaw. It is this overall process that drives a drug's clinical development.

For those of us working in a clinical-regulatory environment, there is a tacit understanding that even days shaved off a deliverable timeline can make 'all the difference'; but at whose expense? As a CSR author burning the candle at both ends, you probably realise you are not alone. Does the empathy of medical writers the world over alleviate your feelings of stress? Not even marginally? Then let us consider the wider picture.

For every 10,000 chemical entities screened, of the 1,000 or so with biological activity, only 10 will ever be administered to humans, and only one will reach the marketplace. Then consider that the patent life on that single drug that you are writing about started on the day the molecule was registered. By the time 'your' drug is launched, only 5 or 10 years of its patent life may remain [1]—a relatively short period during which the marketing authorisation applicant must claw back some return on their huge investment. So all things considered, the applicant's drive to minimise each individual timeline, including that of your CSR, along the way to drug launch, should now be a little easier to comprehend, if not fully accept.

'…even days shaved off a deliverable timeline can make all the difference; but at whose expense?'

Meanwhile, back in your world, that still leaves the problem of how to meet that exacting timeline whilst remaining calm, professional, and in control at all times. The answer has to lie in effective and proactive scheduling. This is a subject that I feel strongly enough about to have delivered my first advanced EMWA Professional Development Programme (EPDP) workshop in Barcelona (May 2008) entitled 'Scheduling and proposal writing: The clinical study protocol and report'. I shared my scheduling experiences in the workshop and enjoyed hearing first-hand from participants that it seems that we all have common issues and similar gripes.

The results of the pre-workshop assignment are worth sharing. Participants were asked to collect information based on their personal experience, to ascertain the timelines to which other functional groups (data management and statistics) and medical writers are currently expected to work to when cleaning, analysing and reporting study data. I asked those working for a Clinical Research Organisation (CRO) or for a pharmaceutical company to determine typical average durations (working days, not ranges) in their company for the tasks listed below for a moderate complexity Phase 3 study in 200–400 subjects. Freelancers were asked to draw on their experience of past projects to make an estimate of average durations. For the purposes of the exercise, the moderate complexity CSR was defined as having no more than 8 secondary efficacy variables; statistical analysis rather than simple summarisations of the efficacy data, and approximately 24 summary tables (including disposition, demography, efficacy and safety) in the statistical output. The tasks for which average durations were required were:

'…wide variability of durations for analysis and reporting tasks are inherent within the industry.'

- Last subject data in-house to database lock (DBL)
- DBL to draft tables, figures and listings (TFLs)
- Draft TFLs to final TFLs
- Draft report writing from final TFLs to first draft CSR (only medical writing hours)
- First draft CSR to final CSR, including client review steps, with the usual number of review cycles
- Quality assurance (QA) on the final integrated CSR

Nine of the participants, with representation across the CRO, pharmaceutical and freelance sectors, completed and returned the assignment. The results are presented in Table 1:

Table 1 Results of the Barcelona 2008 pre-workshop assignment on CSR scheduling

Task	N	Mean duration (working days)	Range
Last subject data in-house to DBL	8	19.3	10–30
DBL to draft TFLs	9	16.0	5–38
Draft TFLs to final TFLs	9	9.5	5–14
Draft report writing from final TFLs to first draft CSR	9	13.9	10–25
First draft CSR to final CSR, including client review	9	23.5	6–100
Usual number of client review cycles	9	2.2	2–3
QA on final integrated CSR	9	3.6	1–10

DBL, database lock; TFLs, tables, figures and listings; CSR, clinical study report; QA, quality assurance.

Most participants gave the proviso that these 'ideal' timelines were not always adhered to. The take-home message is that wide variability of durations for analysis and reporting tasks is inherent within the industry. It will be interesting to see figures collected from future workshops, not to mention cumulative figures across successive workshops. I am sure that wide variability will remain apparent.

This real state of affairs underpins the fact that as 'mini' project managers for CSRs, we can control the timelines we are expected to work to, with careful planning and scheduling, simply because there is no industry standard. The starting point of this 'control' is the proposal you prepare for the client for the preparation of their protocol, or report.

Like many of my colleagues, over the years I have encountered enough challenging scheduling scenarios, inadequate writing resources, poor or even no planning, and creeping scope on projects to help crystallise my thoughts, and indeed actions on this subject.

I apply three self-determined and simple guidelines when preparing a client proposal for a CSR. These are largely based on my time served as a salaried employee in CROs, where medical writers can be expected to write to timelines originally set some time ahead of reporting, often by business development associates or by generic proposal writers with responsibility across all functional areas. Medical writers are aware that individual project scope can significantly affect standard algorithms for calculating CSR timelines, but business-orientated functions may not fully appreciate this. One solution may lie in educating those who agree on reporting timelines. If the end result is involvement of medical writers earlier on in overall project scheduling, then the educative process must be worthwhile. For writers working directly in pharmaceutical companies, where there is room for improvement in internal processes, volunteering for process development committees may be the first step. Following my more recent foray into freelancing, I maintain that the freelance contingent has a degree of individual control perhaps not enjoyed by others: a well-researched proposal, I have found, often wins the day.

This brings me to my first guideline:

1. The scoping information apparent to me is not always apparent to others, so I must share it.

With this in mind, I determine the scope of the project and share it, along with the rationale behind my conclusion, with my prospective client. Prerequisites for scoping include the clinical study protocol (CSP) synopsis and any CSP amendments. The likely complexity of the CSR can be gauged from these documents. Although a strict set of criteria cannot be defined, a rough guide, modifiable as appropriate to an individual project, is as follows:

- Low complexity CSR—few subjects; possibly an early phase (Phase 1/2) study; simpler indication; up to six secondary efficacy variables; few unique TFLs; no complex statistical analysis.
- Medium complexity CSR—more subjects; possibly a Phase 2b/3 study; more complex indication; six to twelve secondary efficacy variables; some complex statistical analysis.
- High complexity CSR—larger numbers of subjects; Phase 3/4 study; complex indication (hence more 'interesting' laboratory test results, adverse events and narratives likely); twelve or more secondary efficacy variables; multiple unique TFLs; much complex statistical analysis.

Once project complexity is determined, a timeline and the necessary hours, based on project scope, can be proposed.

The second guideline is:

2. The staging approach for CSR components is not always apparent to others, so I must share it.

I explain that the CSR will be broken into components that will be authored in a staged manner. Components include the mock/shell/prototype CSR; the draft CSR; the clinical narratives; the appendices and the final CSR. I create a timeline for each component and list the prerequisites which drive individual component development.

The third guideline is:

3. Make all assumptions clear at the outset.

I clarify my expectations of the client and what my client can expect of me in a list of assumptions. I divide these into general and project-specific assumptions. If an assumption is not met during the course of the project, then the ensuing task may be outside the scope of the agreement. With clear assumptions at the outset, both parties are more likely to recognise changes in scope before they occur. Changes in scope, however, may often be accommodated with reasonable regard for existing timelines and budget.

With growing freelance experience, I have found that application of these three general guidelines facilitates the construction of robust proposal text, which ultimately keeps the CSR on track and within budget…and saves on candle wax!

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Burnout

by Lydia J. Goutas

Relentless understaffing, an economic recovery between 2004 and the end of 2007, burnout has been on the rise again. Like fashion comebacks, it's resurgence has been different this time; hitting management—those sandwiched between meeting expectations from 'above' and demands from talented, high-maintenance teams 'below'.

The world was experiencing an economic boom and people were working extremely hard to achieve dreams made seemingly attainable by media hype. The recession of 2000 in the US, corrupt leaders in Enron, etc, were of great concern before 9/11 shocked people into reevaluating their priorities and searching for meaning in their lives and careers. People became conscious of having worked too hard, sometimes for the wrong reasons, sometimes without rewards. Next came economic fear and the phenomenon of 'mobbing', creating a hypercompetitive environment. People started working harder again but now to survive in their jobs. This multitasking, overworked, understaffed workforce, fearful of taking sick time, penalised if they did, created the new trend of 'presenteeism', the antithesis of absenteeism [1].

What is Burnout?

Put simply, burnout is a lack of hope. It is not workplace stress—instead, workplace stress leads to job burnout. Barry Farber, burnout specialist, defines burnout as "the gap between expectation and reward" [2]. It is a "state of emotional and physical exhaustion by excessive and prolonged stress" [3,4]. Unsurprisingly the relationship between prolonged stress and burnout is not simple. For example, studies have shown that women in the sandwich generation, caring both for young children and elderly parents, are less likely to suffer from burnout if they are emotionally supported by the family.

When the challenge and demands of work become excessive, the pressures of the workplace exceed workers' capacities to handle them, and satisfaction turns into frustration, that is a recipe for burnout. However, burnout can also be caused as much by feeling trapped, bored or lacking challenge as by working with unrealistic goals and expectations, or in an environment where an ethical conflict occurs.

Under-engagement and loss of passion was an issue 6 years ago when it was suggested we had lost our 'umpf' [5]. People now talk again about recreating 'buzz' in organisations because when there is 'buzz' people tend not to get burntout. But how does an organisation develop soul or buzz? Recent research shows trust to be the single most powerful factor for good corporate performance and innovation [6]. Researchers have also identified four characteristics that result in an employee having a strong motivation to help the company succeed, beginning with the need for the leader to bring both personal passion and recognition for the contributions of individual employees to company success [7]. This puts the responsibility for passion and buzz back with the leader, supporting Christina Maslach, burnout doyenne and author of *Burnout: The Cost of Caring*, who claims that burnout is as much about the organisation as about the person affected.

Burnout has a wide range of possible symptoms as well as causes. Symptoms include, but are not limited to, powerlessness, hopelessness, detachment, irritability, despair, apathy, frustration, feeling trapped, isolated, detached, emotional exhaustion and cynicism.

Who is most likely to get burnout?

Personalities such as perfectionists, 'yes men (women)', idealists and 'helpers forever' have been identified as types most likely to fall prey to burnout. Usually the job-fit is inappropriate. In an interview Dr Mark Gorkin, a well-known American psychologist and specialist in workplace stress, told me that many burnout sufferers subconsciously recreate family relationships and dynamics at work, selecting a role or a situation which is comfortable because it is familiar. In doing so they also fall into the pattern of behaviour—trying to compensate for the past and prove they can be successful, manage the workload, not be a victim, be popular etc. Some have pre-existing mental health problems that are exacerbated by a stressful work situation.

Cultures of individualism, such as North Americans, have a greater tendency to burnout than cultures of collectivism, such as Mediterranean cultures. This difference may be partly due to the burden of success or failure in individualistic societies, where people see work problems as something they must resolve on their own, and partly due to the more helpful family cultures in collectivism, which support a more balanced view of the importance of work challenges in relation to the rest of 'life'. People with few non-work stimuli in their lives tend to be more likely to burnout than those with families, pets and other ouside interests. Singles are more likely to burnout than those who are happily married, just as those with children are less likely to burnout than those without them, although objectively

speaking the responsibilities are greater [2]. Ironically, younger employees are more likely to burnout than older ones who have either seen a cycle or bring a longer perspective. Part of this stems from a flawed work environment and paradigm. My interviews with human resources directors in the US revealed that 60 hours is a 'normal working week' for a manager, and 40 hours is considered part time.

Some countries keep statistics on burnout. In Germany, where burnout is covered by some insurance policies, 5% of the population between 25 and 45 years of age are being treated for burnout. In the Netherlands, roughly 10% of the workforce is burned out at any given time, with teachers and primary care health professionals most burned out. Statistics are not complete in the USA for various reasons (data privacy) [2].

Burnout and middle management

Burnout was first recognised in the helping professions (nurses, social workers, public service), then it hit those in services such as call centres, sales and jobs that deal with customers' demands or complaints in high-pressured environments, and finally management and other professions not normally perceived as being under extreme pressure, e.g. lawyers. Middle management struggled with right-sizing and centralisation, resulting in decision makers not only having responsibilities for team leadership, mentoring and attending meetings, but also taking on, rather than delegating, operational responsibilities and 'special projects'.

Most people were pleased with the economic growth in 2004 and 2005. Work was hard but people still remembered the lean years. It was not until 2006 that complaints about overwork began because growth continued and staff had not been recruited at a high enough rate to cover the increased work. At the same time pressure of expectations of targets (sometimes unreachable) increased and ethical issues started to be raised.

As burnout moved from affecting lower to higher management levels, the shame was removed. Now, it is seen as a syndrome of hardworking power players. Job stress is 'trendy'; and some take pride in having a stressful life and a stressful job.

'Presenteeism', perceived as a problem by 56% of employers [8,9], has made people hesitant to take time off for illness or vacation, as if they feared that their office could not do without them. But while absenteeism productivity loss is measurable, presenteeism productivity loss is not. Presenteeism affects vacation time, which, in turn, adversely influences creativity, productivity and anger management. More than 50% of US workers fail to use up annual leave [10] even though taking vacation increases productivity by 82% [11,12]. Recognising this, some companies require vacations or offer sabbaticals.

Multitasking and technology misconceptions

The demands of multiple stimuli over a sustained period and of multitasking take their toll as prolonged 'stressors'. When we multitask, we assume we are more efficient. However, various studies have illustrated the ineffectiveness of multitasking, including one in which three groups were asked to take an on-line IQ test: the control group took the test working without interruptions, another group answered emails and calls at the same time as taking the test and the third was 'stoned'. Unsurprisingly the control group scored best, but the 'stoned' group came second and the multitaskers had the lowest scores [2].

Futurists point out how Internet technology will redefine our work and how we will eventually redefine ourselves independently of our position or place in the hierarchy as we do now. Technology frequently promotes the myth of increased leisure time but in reality often the hours that technology saves us translate into un-usuable time interspersed between tasks. Where technology genuinely offers us options to work less and to have more free time, we instead choose to work longer to retain a position of higher status or wealth. Human nature apparently values status and money over free time, a constant stronger than time and technological advances. Thus our lives are not easier even if we are constantly hearing that they are.

What happens in the organisation and economy?

In the worst case senario, burnout can result in staff who are considered to be permanently disabled. What is different when burnout hits the manager is the widespread effect commensurate with their sphere of influence. Because more stakeholders are affected organisational development and staff turnover are also affected. The costs to the organisation are high, and middle managers are among the hardest people to replace.

Workplace stress is currently estimated to cost US companies more than $300 billion a year in poor performance, absenteeism and health costs [14]. With decreased productivity and their best staff leaving, companies are starting to address burnout prevention. To quote Christina Maslach, "Getting the most out of people did not mean getting the best out of them". In addressing the issue US and UK companies are faced with 'disability protection' against discrimination or firing (Americans with the Disabilities Act) while in countries such as France and Germany socialised medicine, collective agreements and strong union agreements extend to management. With litigiousness increasing even in Europe, the question of accountability, may also affect how companies and countries address burnout.

Alternatives: prevention, treatment

Mindfulness-Based Stress Reduction (MBSR) developed by Professor Jon Kabat-Zinn (University of Massachusetts Medical Center) in 1979, and now offered at more than 200 medical centers worldwide, is one of the best methods for

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preventing burnout. MBSR uses a variety of techniques: daily awareness (charting progress, thankfulness, negative perceptions), visualisation, 'body scanning' (tracking every breath and sensation), mindfulness meditation, yoga, and mindful dialogue group discussions. The goal is to integrate mindfulness techniques into daily work-life routine to prevent or optimise stress, dealing with it as it arises and actively addressing the work-life balance. In 2007, our company conducted a 10-week MBSR program under the direction of MBSR expert, Joerg Trettler and observed significant improvements in the experimental group.

Dr Mark Gorkin, US stress expert, author and lecturer is one example of the need to increase access to help. He is available online (www.stressdoc.com). His techniques help people to become more comfortable and skilled in setting boundaries and saying no and sticking to it. His philosophy is to deal with critical agressors by laughing in the face of stress, burnout and depression. Through effective assertiveness training, he helps people to identify when a boss is taking advantage and when they are allowing the boss to undermine their credibility and authority and play on their fear of slacking.

He points out that we often recreate family relationships at work, which makes it harder to say no, or react in a way that sets appropriate boundaries. Usually that role is recreating the 'unfavored child'. Gorkin recently commented in an interview with me that in the US in situations where people feel misused, devalued or neglected, especially in government positions, they file grievance procedures. In Europe where grievance procedures are in place but as yet little used outside of the UK, or when there is a collective bargaining violation, this might be the next step for victim retribution.

Burnout—a personal view

How many of you, I wonder, have worked late into the night to finish a document? How many of you have sat at your computer and found that words have failed to flow? Have you struggled on occasions to 'get your head around' some data? Mention the word 'submission', add the adjective 'global' and immediately a mental picture is conjured up suggesting loads of work, not enough time, and being surrounded by colleagues under stress.

Medical writing is a demanding occupation. We can find ourselves working with a high degree of mental intensity for hours on end to meet a tight deadline. This is a feature of the job, and we may be left mentally and physically tired at the end of an arduous project. But this is not burnout.

So when, and how, do you recognise that you are heading towards burnout? A few years ago, I found myself in a situation when I felt that I was beginning to spiral downwards, I was not enjoying my work, and my health was suffering. Was this stress, was it burnout, or was it just fatigue? I don't know; there was never a definitive diagnosis, and in one sense it did not matter. After 5 weeks of sick leave during which time I had lots and lots of sleep and complete mental rest, I was absolutely fine.

On reading Lydia Goutas' article in this issue of *TWS* I don't think I experienced burnout. Nevertheless, there are points with which I identify—understaffing and work overload, the pressures of substantial management responsibilities including special projects and initiatives, yet, at the same time, being expected to work at the operational level. Yes, job satisfaction can turn into frustration and probably ultimately to loss of hope. However, before the onset of symptoms described in the article, there is the physical and mental exhaustion, the difficulty in maintaining concentration and focussing on the main task in hand, which in turn eventually lead to decreasing self-confidence. Signs of negativity may surface which will affect those around you.

We know there is an increase in stress-related illness and stress in the workplace but I believe the changes started long before 9/11. Looking back over my many years of work and comparing then and now, workplace culture has changed considerably. Small national companies have been replaced by the multinationals, reorganisation and large scale redundancies have considerably reduced staff levels. Employer-employee relationships have changed, with a loss of loyalty on both sides; staff have become depersonalised, are seen as a headcount or resource rather than people. The advent of e-mail has led to expectations of an instantaneous reply as well as creating additional work in terms of reading, writing, filing and deleting them. Personal computers have led to the demise of the secretary and other administrative support, thereby reducing the time available to concentrate on the activities for which we are primarily employed. The mobile phone and the 'Blackberry' greatly facilitate communication in the global working environment, but they also mean that it can be difficult to escape work at home and on holiday. How sad it is to see someone on holiday checking their 'Blackberry' over breakfast with their family!

The key message to me lies in the conclusion which highlights the importance of aiming for the work-life balance that suits you.

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In Gorkin's book *Practice Safe Stress*, he describes how he helped a group of trial attorneys, who had serious conflict, to accept that many serious things are also absurd—a mind-set paradigm change. In this way, the energy of stress is transformed into exercise, creative and journal writing, poking fun and laughing at ourselves. Laughter and humour help people to move from negative to positive, to work on their stress and to make the changes needed. The four 'Rs', results, rewards, recognition and relief need to be kept in mind. Gorkin warns that without these and if you cannot say no or let go you've set the stage for burnout.

Gorkin is now moving from multitasking to multipurposing—recognising the opportunities, e.g. seeing the need to shovel snow to clear the driveway before driving to work as a substitute for a daily workout rather than as a nuisance.

Solutions can sound simple yet be difficult for people who feel trapped or unable to change. The recommended solutions all require change and some courage.

Susan Greenfield says we have the option to work less with less prestige but we opt for more prestige and money, and more work [13]. It takes a strong person to have the courage to clarify a job description, or request a transfer or change of duties.

Sabbaticals and career changes are increasingly popular alternative solutions. Recent studies report that 16% of US employers offer unpaid sabbaticals and 4% gave paid ones in 2007 [15]. Some companies, such as Accenture, offer 3-month sabbaticals without salary but with paid benefits and guaranteed re-entry for employees with at least 3 years' tenure. Sabbaticals can be a good use of the overworked employee's accumulated vacation from presenteeism but the goal is to acquire a different perspective, gain new skills, or perhaps design a new job. Sabbaticals need preparation and seriousness of purpose, and sabbatical coaches can help by assuring a plan. Career Transition groups who help each other make the transition to a new career are also springing up in the USA.

The primary purpose in tackling burnout is to get the 'umpf' or passion back into work. And that comes from new stimulation, the feeling that your work is significant and that you make a difference. Ayla Pines, an Israeli researcher, found that staff in the insurance industry who had had childhood experiences in which insurance resolved some catastrophic issue showed passion in what most people consider boring work [2]. Avoiding the lack of interest in or boredom with work is a factor in burnout.

Conclusion

To avoid burnout, you should aim for a role that challenges but does not overstretch you, where you are contributing and your value is recognised, where you build and use your gifts and talents, but where you can take time off. Finding out what you do best, and doing it, concentrating on your strengths and thinking positively about the things you can change—all of these contribute to a happy working life. Success needs to be redefined to incorporate energy, intelligence, and integrity while remaining authentic, i.e. being yourself as well accepting that to be authentic to yourself, as you change, you may need to make changes in your career to maintain the right balance.

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Lydia Goutas is managing partner of Lehner Executive Partners (LEP), formerly part of the international Plaut Consulting Group. Leading an international team the primary focus of her work is recruiting top management and key players in advanced technologies. Together with her business partner, Lydia regularly conducts relevant studies identifying trends, strategic changes, demographic and other factors affecting individuals, companies and communities. She is a contributor to Economy Austria, serves on the advisory board of Webster University´s Vienna campus and is the current President of the American Womens Association in Vienna. Prior to her work at LEP, she has worked in the university, and training and development sector as well as in Cancer Research at Memorial Sloan Kettering in NYC.

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Always manage your time: The point of view of the medical writer in the pharmaceutical industry

by Andrea Rossi

Working in the medical writing function of a medium-sized affiliate of a large pharmaceutical company gives me the opportunity to experience many aspects of medical writing and its management. Italy has one of the lowest rates of investment in research among developed countries. In 2004, it accounted for only 1.1% of the gross net product, compared with 1.9% for Europe as a whole and 2.8% in the USA [1]. 'Italian creativity' together with a strong push from universities mean that despite this, much research is still published in high-quality journals: for instance, the ratio of oncological papers to all medical literature from 2000 to 2006 from Italy was second only to the USA, and corresponded to the highest ratio between number of publications and gross domestic product [2]. So, why does the Italian affiliate of a pharmaceutical company need medical writers? This question often occupied me when I started medical writing more than 5 years ago, and now I think I have some good answers!

My activities are mainly related to the preparation of publications, but I am also responsible for publication planning and tracking, business planning, training, people and vendor selection, and general management. The planning and management tasks take up most of my time, and you can't imagine how grateful I am for these. At Eli Lilly Italia, we also have to prepare and periodically update a vast amount of procedures in line with documentation prepared at the company headquarters. This is not particularly stimulating work, but it needs (always unplanned) time that has to be properly managed—and someone who cares about it.

When a new task lands on my desk, my first question is: will it be time I lose, time I have to spend, or time I have to manage?

Planning activities

Every year, for every marketed product or product under development, our company has to prepare a disclosure plan which forms part of the global business plan. The plan from each country has to be relevant to local scientific communication needs and must be integrated with the worldwide publication programme. The use of Scholar Datavision is a great help in the management of scientific data disclosure planning. Coordination with physicians and the knowledge of the scientific environment is crucial to preparing a good publication plan. Time spent to prepare a good publication plan is always 'good' time spent—and sharing the plan with other groups affected (physicians, Clinical Operations, Medical Information, Marketing) is even 'better' time spent. Planning the best way to disclose the right message to the right customer at the right time and make your colleagues aware of this is the best added value for customers and patients, and therefore also for me and the company. The medical writer has a crucial role in this activity and must drive the process, always with a keen awareness of the main goals to be reached and communication priorities.

Time management is one of the most important aspects of medical writing: colleagues may support you when a new publication has to be prepared or published, but almost all of them have no time for any aspects of planning. They may all have great academic curricula, but Italian universities teach nothing about planning and management: learning is focused purely on the research itself. Medical writers have to be able to manage the actual publishing of the findings, using all their psychological and technical expertise, and conflict-solving abilities. If they are good at this, most of their job is already done (well, almost …). From the managerial point of view, the crucial part is not that a publication is written in-house. It can always be outsourced. But this also has to be managed, and if your planning is not good, your company will not have resources for writing up crucial topics when they are needed.

Meetings: Malediction or benediction?

Do I have to provide updates? What information are we wanting to share? Who is taking part in the meeting? What is the expected outcome? We all ask ourselves these questions when we have to attend a meeting … or we should. Any meeting we are requested to attend might be useful, but we need to be able to evaluate whether the meeting will actually be of benefit. Even if writers are invited as consultants to a meeting, they have to find a way of deriving benefit for their work from the meeting. So every meeting has to be carefully evaluated and prepared for by asking yourself some questions. Would I need the same time to obtain the same information if I didn't attend the meeting? How much time do I need to prepare for the meeting? And is there crucial information I will miss if I do not attend?

We all receive invitations to meetings that will bring us no benefit for our work but which we are expected to attend. But how do you avoid attending? The best way is to be honest with the person convening the meeting and arrange to attend for only part of the meeting so you still have time to discuss important points, or not attend at all, explaining that if you attend, you will lose time for other priorities. If

the meeting convener is your boss, and he or she is insistent, you should still defend your priorities. The result should be either more respect from your boss for wanting to maintain your timelines, or revision of those timelines with your boss's agreement to ensure that you attend the meeting (the one you are desperately trying to avoid!)

Outsourcing

If your day is absolutely full and the only time you have is time when you should be sleeping, you have a big problem! When you plan your activities at the beginning of each year, the evaluation of headcount takes priority over financial planning. If you find that you have time for anything but writing, it is more than possible that you need to revise your plan. When time is short, the first thing that comes to mind (especially your boss's) is: we need to outsource.

Outsourcing without planning is not the right approach. Freelancers and medical writing agencies have their own plans, and you generally have to plan in advance together with them. A good manager needs to know what activities are planned and what the department can manage with the staff available. It is crucial to have a good relationship with vendors. They have to be carefully selected, have a good working relationship with the outsourcing department in your company and, even more importantly, you need a good contact person in the vendor company. Establishing this all takes time and involves meetings with the vendor and with the colleagues who will work with the vendor. This is 'good' time spent, especially because you can also learn new ways of doing things from vendor companies. A good medical writing manager will manage 'writer time', also considering the vendor and the particular areas of expertise that each vendor can offer. Only in this way can you ensure that each of your projects will be completed in line with your expectations.

What does 'prioritise' actually mean?

Prioritisation is a continuous, ever-changing process that needs the right answers to the right questions.

What is the most important thing in your life? Why are you a medical writer? Do your objectives comply with those of your job? Do you support your company strategy? These may not be so crucial for other functions, but medical writers have to communicate to the entire world not only the results of research but also the philosophy of their company. When your boss assigns you a new activity, the first question should be: where does this come on the priority ladder? Your manager's answer is often: THIS is our top priority! You have to be able to overcome your emotional response to this and arm yourself with the tools to obtain a clear answer. Always maintain a task list of short-term and long-term activities, prioritised in agreement with your boss and assume that you have to be the proactive element in this process. Clear prioritisation is the only way to ensure added value, and time spent prioritising is always 'good' time spent. If you can, ensure that priorities are not constantly changing and are in line with plans made at the beginning of the year. There are, of course, exceptional situations, but these must be rare … otherwise they are not exceptions!

My time is more important than yours!

Unlike many activities, medical writing is a cross-functional activity with a multitude of borderline activities with many different colleagues in different departments. This is the main reason why everybody feels free to ask the writer to do something that is 'absolutely urgent' and that the writer is just there to do this. In other words: "Dear colleague, because I am unable to manage my time, please rescue me from this desperate situation". Requesters will never admit that they cannot manage their time, but you nevertheless feel obliged to help them … but sometimes rage wins over reason and you cannot resist saying: "Is your time more important than mine?" or "I can only help you because I am an efficient planner and I have built in enough time to help you" or "I came to you with a similar question last year, and you didn't have time to help ME!" Raise your hand if you have never reacted like this in similar situations. But beware: is this sort of reaction justified? Unplanned things happen every day. How do we plan for the unplanned? It is obviously impossible, and the only way to handle it is to manage the situation by redefining priorities. Much time is lost in useless thoughts, leaving less time for setting priorities, which must always come first.

>>>

Parkinson's Law

Cyril Northcote Parkinson was a professor of history at the university of Malaya. He inspired a number of 'laws'. One first published in the *Economist* in 1955 is 'Work expands so as to fill the time for its completion'. This applies at the individual as well as at the institutional level. He wrote "Thus an elderly lady of leisure can spend the entire day in writing and dispatching a postcard to her niece at Bognor Regis. An hour will be spent in finding the postcard, another in hunting spectacles, half an hour in search of the address, an hour and a quarter in composition, and 20 minutes in deciding whether or not to take an umbrella when going to the mailbox".

Parkinson's Law of Medical Research was published in *The New Scientist* (25 January 1962). 'Successful research attracts the bigger grant which makes further research impossible'. Parkinson wrote "In accordance with this law, we mostly end up as administrators. We should have ended administering, in any event, remember, had we never done any research".

>>> Always manage your time ...

We have to attend a congress: HELP!

I try to plan as much as possible, prioritise urgent matters, solve interpersonal conflicts, and deal with many other matters, but when a deadline for abstract submission to a congress is coming up, however I try to plan things, I seem to be damned never to succeed. I have tried all sorts of different approaches to this. I have familiarized myself with the topics under discussion at the congress, spoken to all those involved, made sure that they know that I am aware of their needs, that I regard their abstracts as a priority, and that I wish to relieve them of the stress of preparing them. After all, it is my job. But somehow time always runs away from my colleagues in this situation. They are subject to many other stresses when preparing for congresses, and what should actually be a fairly straightforward procedure—preparing an abstract—turns into an utterly stressful experience because of the imminent deadline. My approach now is to inform all those concerned very early of the deadline and work out a common strategy to reach this deadline. Early discussion and analysis of new research findings to be communicated is paramount, based on a comprehensive action plan, including roles and responsibilities. But it all takes time!

People think medical writers sit at the computer screen all day writing. But medical writers know different. Any writer working in such a complex structure as a pharmaceutical company or a CRO soon realizes that they are the most appropriate person to coordinate and manage document preparation activities as the central point of reference. This means that they not only have to be able to write, but they also need good managerial skills, which can only be achieved with high-quality training and with the support and mentoring of experienced colleagues.

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International Medical Communications Association Congress

24-27 January 2010
Tokyo, Japan

The first meeting of the International Medical Communications Association will be an opportunity for those involved in the wide range of medical communications to come together, express their views and establish strategies for developments in the future of this vast and essential field of endeavour.

We would like to invite anybody interested in giving a presentation on any of the following listed topics to contact Patrick Barron at jpb@imcc-tmu.jp no later than 31 October 2008:

Authors' editors
Bioethics
Clinical trial design
Congress management
Cultural competency
Editorial matters
Education in communications
E-learning
English for medical purposes (EMP)
Health care interpreting
Graphs and tables
Impact factor—pros and cons
Journal management
Medical editing
Oral presentations
Patient education
Patient-reported outcomes
Peer review
Publication ethics
Society management
Standardization of EMP education
Testing of EMP
Uniform Requirements
Websites
Writing Papers

A public consultation paper on paediatric clinical trial disclosure: European Union (EU) and European Economic Area (EEA)

Clinical trial disclosure, i.e. release of information regarding clinical trials to the public (Internet), is now a topic of mandatory interest for those performing paediatric clinical trials in the European Union (EU) and the European Economic Area (EEA). It is planned that all clinical trials that include children (0 to 18 years) will be disclosed (independent of the clinical development phase, or whether the investigational product used in the trial is still in development or already registered or marketed). Affected trials include those that are performed in the EU/EEA countries (and elsewhere, if the trial is part of the sponsor's Paediatric Investigation Plan). At present, information submitted to the EU database on Clinical Trials (EudraCT) by the sponsor as part of the Clinical Trial Application (CTA), is available only to the respective national drug regulatory authorities in the EU and EEA member states—not to the general public. It is this aspect of information accessibility that is about to change. The European Commission (EC) has recently issued a draft document stating the information segments of the *study protocol* and *study results* that are proposed to go public.

A public consultation was conducted (February to April 2008) on a draft Guidance concerning information on paediatric clinical trials to be entered into the EudraCT and the information to be made public by the European Medicines Agency (EMEA), in accordance with article 41 of Regulation No. (EC) 1901/2006 (Regulation on Medicinal Products for Paediatric Use). The Directive currently includes clinical trials with at least one site in the EU (27 member states) and additionally countries of the EEA (Iceland, Liechtenstein, Norway). The Directorate-General for Enterprise and Industry (DG ENTR) has prepared an extensive list of EudraCT data fields and information that should be made publicly available on trial *protocols* and *results* for clinical trials involving paediatric patients.

The information fields are part of a public consultation paper that is available at:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_07/consultation_draft_field-2008-07-16.pdf.

Comments should be e-mailed by 15th October 2008 to the DG ENTR:
entr-pharmaceuticals@ec.europa.eu.

It is being proposed that EudraCT will release the information to the public through the EudraPharm database. This would occur for the *study protocol* at the time of trial authorisation and for the *results* within a relatively short time after trial completion (e.g. 6 months), and be made publicly available as soon as submitted.

The proposed information released by EudraCT in the EudraPharm public database includes:

- for **study protocols**: trial identification (protocol number), EudraCT number, other international identifier number, title (full technical wording and lay language), identification of the sponsor (name and country, contact details), information on each investigational product, population endpoints, sites (even those outside of the EEA), recruiting status, ethics committee opinion (positive, negative, pending—with a statement of reasons, if the opinion was negative).
- for **study results**: contents and format likely to be similar to ICH E3 summary requirements and the Consort statement, primary and secondary outcome measures, statistical methods, number of participants in each group, flow of patients through the trial (flow-chart), early termination information, information on all important adverse events in each intervention group, interpretation of results by sponsor/by competent authority.

This is the first coordinated effort by the EC (through EMEA) to provide information to the public on clinical studies performed in the EU and EEA. The initial focus is on paediatric clinical trials. However, it is expected that clinical studies with adults will be covered by similar requirements in the not too distant future. These EMEA activities are similar to those implemented in the USA through the new federal law FDAAA 801 (enacted September 2008), which was summarized recently in *TWS* [1].

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Coordinating medical writing and publishing in the pharmaceutical industry

An Interview with Christoph Pfannmüller

Tell us something about your background and how you came to be a Medical Writing Coordinator at Merck in Darmstadt, Germany.
I am a nutritional scientist by training and decided to join the pharmaceutical industry in 1998 as a Clinical Research Associate (CRA) at Novartis Pharma GmbH. In 2000, I joined a medium-sized CRO in Darmstadt as a CRA where my focus was study management and writing study protocols and study reports. In 2002, I started with Merck[1] as a Clinical Document Manager dealing with document management systems and related tools. In 2005, I got the chance to combine both medical writing and document management expertise within the newly created position of Medical Writing Coordinator. The idea behind this position was to have one person to act as an interface with our preferred medical writing partners and to take care of the processing of documents as a whole. Somebody who keeps all the balls in the air. Currently we are 2 medical writing coordinators at Merck.

Can you give us some idea of the annual volume of work that your group deals with?
I oversee "only" our oncology projects: that means about 20 CSRs per year.

What sort of documents do you deal with most frequently, and do you supply your writers with templates, style guides and instructions?
Mainly study reports and study protocols as well as clinical summary and overview documents (CTD module 2.5 and 2.7). We expect all our internal and external writers to use our current set of templates and style guides, and we offer training. This prevents complex reworking scenarios when submissions to health authorities are near.

Who develops the templates?
Template creation is a combined effort of the respective discipline (e.g. clinical or non-clinical) and Regulatory Operations (REgOps). The discipline is responsible for the content of the template, and RegOps ensures that the latest requirements concerning formatting, styles and consistency over the different disciplines are met. The overall goal is to have submission-ready documents that fulfil all health authority requirements so that we can submit dossiers as quickly as possible without reworking.

What are the most complex documents and assignments to manage?
From my perspective, definitely the CSR. One of our latest CSRs had about 85,000 pages compiled from more than 300 single documents. Contributors to this CSR were spread all over the world—so this really was global medical writing, document management and publishing.

Do the clinical teams involve you when they are putting together clinical development plans, or are you not involved until the individual document-planning or writing stage?
Luckily, I and am usually involved at a very early stage, but from time to time it happens that a request for medical writing support rears its head just before a deadline. We try to minimize such 'accidents' as far as possible, but have to be prepared for them to happen.

Do you have standard 'numbers of days' that you put into your plans for certain activities, such as preparation of study protocols, study reports of different complexities, review cycles, QC, and electronic publishing? If so, can you tell us what they are?
Yes, we have standard time slots, but we adapt these standards according to project priority and available resources to enable realistic planning. If a dossier submission is planned, everything is calculated to meet the submission timeline, and this may even mean that standard times are considerably revised. A rough plan is to have a submission-ready CSR approved 12 weeks after results are available.

You have in-house medical writers and work a lot with preferred partners. Does this make planning and scheduling more difficult?
We follow a mixed model with in-house writing and outsourcing to preferred partners. There's no difference with respect to planning and scheduling. With our model, the external partners are members of the team just like internal colleagues. The ideal is to work with the same external medical writers on the same study teams over many years so we develop a close relationship, and we have been successful with this so far.

What are the greatest challenges when planning document preparation activities?
The greatest challenge is to come up with a realistic plan that considers the requirements of nearly all of the func-

1 Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Merck is independent from Merck & Co. although we have common roots. In 1917 the then US subsidiary Merck & Co. was expropriated and has been an independent company ever since.

tions involved. It is no good if your writing team completes their part on time and mandatory appendices for the CSR are still outstanding. So there is a lot of chasing up to do. The ability to deliver submission-ready documents means an increasing degree of technical expertise.

How have you tried to solve these?
On the one hand, each function and our and their requirements must be given equal consideration; on the other, you have to be able to be firm, and sometimes insistent, when the contributors have committed to the plan. Another inextricable step in writing dossiers these days is publishing, and we have learned to start preparing for publishing very early on in a project, even though the actually publishing is one of the last process steps. You have to avoid technical surprises at the end at all costs.

If you had three wishes that would make your work easier, what would they be?
1) Guaranteed user-friendly and robust tools (software, templates, document management).

2) It is a long time since the ICH E3 documentation was first issued, and I think it is high-time we had an update, because there are many improvements that could be made.

3) A Harry-Potter spell (Succedio Submissio!?) that would ensure that all our applications are automatically accepted (exclusive to Merck Serono, of course!).

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Making my day!

The following is an extract from an e-mail from Adam Jacobs that made my day:

"Right, I hope you're sitting down comfortably, because this is going to come as a bit of a shock. Here is my next article for *TWS*[1], submitted BEFORE the deadline."

Elise Langdon-Neuner
langdoe@baxter.com

1 'Inside a research ethics committee' to be published in the December 2008 issue of *TWS*

Database of Uncertainties about the Effects of Treatments (DUETs)

This new database publishes uncertainties about treatments referring to reliable up-to-date systematic reviews of existing research evidence.

http://www.duets.nhs.uk/

European Association of Science Editors

Pisa, Italy, 16-19 September 2009

TENTH GENERAL ASSEMBLY AND CONFERENCE
'Integrity in Science Communication'

Editors are the 'gate-keepers' of the scientific literature, so maintaining integrity in all its forms is a vital aspect of what we do. This topic will be addressed in three plenary sessions and multiple parallel sessions. Submitted papers within this theme are also welcome. More practical workshops may be organised according to demand. There will also be a full social programme.

The deadline for abstract submission is 30 September 2008

For more information please go to http://www.ease.org.uk/con/index.shtml or contact:

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When time is wide open and deadlines do not press

by Jack Aslanian

The following observations and speculative explanations for them do not specifically answer the banner question of this issue of *TWS*, 'Who manages your time?' But I share them to illustrate how time-consuming behaviour varies according to the way stars happen to be aligned. Sometimes, instead of 'time pressure' one experiences time inflation—a sort of a big bang of time to be filled. When I have felt the pressure of an unwelcome deadline I have worked with greater dispatch to complete the task, with results apparently still acceptable—leaving me secretly guilty and wishing I had had more time to do an even better job. (But sometimes the difference between 'good' [or 'good enough'] and 'better' [or 'best'] is discernible only to the person who has both of them side by side to compare.) That I have been fortunate not to have missed a deadline may be because I mostly do editing (infrequently working on de novo first drafts), control inflow mindfully, avoid amassing competing deadlines, and try to be realistic about the turnaround times I promise. And I usually set to work without dallying. Still, there are periods when the synchronism of long deadlines with the absence of short or pressing ones and a spate of time, as before or after a vacation or after a long and, therefore, exclusionary project (as a bout of on-site work recently in my case), sets the stage for vagarious time-filling—as opposed to behaviour that *uses* time.

So, several thoughts on such attacks and the behaviours I have observed during them:

1. 'Laziness' should not be used to characterise the behaviour, because one tends to fill time productively—for example, by reading down the stack of journals accumulated during dearer times. Nor should the behaviour be characterised as 'procrastination'. Because one is not avoiding work, and one is certain that tasks will be accomplished by when they need to be.
2. Short, but reasonable, deadlines may (they most likely do) correlate with efficiency, the task benefiting from the extra surge of adrenaline, which does not happen during lax times. This effect may be a near cousin of stage fright, widely considered to enhance a performer's art. Perhaps that is the brain's self-imposed, subliminally contrived, and involuntarily activated way to achieve efficiency and focus.
3. Imagining that you might soon not have much to do, and therefore perhaps feel functionally irrelevant, if all present projects were completed, you may proactively be protracting their completion to obtain maximum mileage. Work expands to fill time[1].
4. The typical subject with too much time to manage in an organised way (as opposed to too little time) is like a guest at a smorgasbord who is high on the elixir of bountiful time and who randomly and seemingly whimsically is nibbling from this and that, flitting between dishes for short engagements, but never sitting down for a full meal. The priority given to any one of several equi-deadlined [sic] tasks, and the amount of time allocated to each before putting that one aside unfinished, would be an indicator of how attractive each task is. During such spells of dilated time, one serves the pleasure principle more eagerly than duty. And with less stress.

Finally, one other comment relevant to time management and scheduling work flow—this because an impatient client who did not want to pay for a rush job recently asked me why my turnaround time for editing a manuscript is 2 to 3 weeks, when my estimate of the time to edit his text was about six hours. Just before that exchange, I had posed a similar question to a carpenter, because I envisioned the repair in question would take less than a couple of hours. Sure enough, he gave 'backlog' as an excuse. And of course it is safe to predict that all trades people will always have backlogs, and never be able to do the work for the average client right away. Before entering university, I had a summer job in an independent clinical laboratory where I was told by the permanent senior technicians that I was wrongly hasty in giving the patient the test result right away[2]. 'Tell them to come back for it the following day. Or in the afternoon'. In providing the result of a practically instantaneous test to the client there was the real risk of demystifying the test in her mind, and devaluing it; which would make her wonder if she was not being overcharged.

Even if one could succeed (it is doable) to eliminate all backlog—for example by scheduling work so as to edit and return the average manuscript overnight, in doing work that has intellectual, even artistic aspects, there are more compelling reasons besides image and inflation of value to

1 This has been iterated and reiterated in so many places that it is common currency; and I am not bothering to document its original attribution, if such documentation is possible.
2 In those days, typing a blood sample could be done in less than 30 minutes after blood was drawn.

When time is wide open and deadlines do not press

string out the process. It will enhance the final product if after the first go-through (draft or revision) the project is put on the back burner to percolate a bit. It is much better for the manuscript (therefore providing greater personal satisfaction and pride of accomplishment, with less likelihood of clients or down-the-line editors discovering oversights). All manuscripts need editing (even many articles that have passed from the author on through a sequence of editors and have been published!). Therefore, a reasonable, generous turnaround time that allows revisiting a manuscript after a period of detachment should be built into the writing or editing process of medical manuscripts; and the need for it should be understood and accepted by clients. Hindsight is 20/20; but for it to work at that level, it requires that the glare and distraction of the initial spell be allowed to subside.

If done without loss of control, splitting time between diverse activities, now writing, now rewriting, now editing, then billing, and so on, helps postpone fatigue and boredom, so improving quality. But keep in mind that that may cause overall per page time efficiency to decline, just as accelerating and decelerating in stop-and-go traffic increases the energy consumption of a car. Still …

A corollary of this issue's thematic question would be, 'What manages your time?' Atop the list of answers to that should be 'quality'.

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Keep it short

The p-values are of a purely exploratory nature.

You see this sentence every day and think it's fine. Of course, there is nothing grammatically wrong with it. We have a subject *The p-values* (let's not get into whether this is hyphenated or not, or whether the 'p' should be italic or capitalised), a verb *are*, and an adverbial phrase *of a purely exploratory nature*. But what does *purely* mean: p-values can certainly be confirmatory, but can they be *partially* exploratory? And why do we have to lend the *p-value* a *nature*, thereby forcing the reader to read more words than are necessary?

All we are saying here is that *The p-values are exploratory*.

By the way, I still like to stick with *exploratory* rather than *explorative*, but I note that the latter is rapidly gaining ground. Maybe another battle I shall give up on soon.

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'Science' is one of the most difficult words in the English language

Masha Bell, a literacy researcher from Coventry University, UK, believes English is the worst of all alphabetical languages. She describes the English spelling system as 'absolutely, unspeakably awful'. Many words would be easier to read, let alone to write, merely by dropping some letters, e.g. the 'i' in 'friend' and the 'u' in 'shoulder'. The researcher sees English as being unique because the problems relate to reading and not just to spelling. This difference accounts for schoolchildren in the UK having poorer literacy results than the rest of Europe. Some words have the same pronunciation but different letter combinations, e.g. 'clean' and 'gene'. There are words that look the same but are pronounced differently, e.g. 'eight' and 'height'. Any move to simplify spelling would, however, be met with great resistance because people feel that spelling is linked to the origin of words. A list of 100 of the most difficult words is given in the source article below. Interestingly this includes the word 'science'. Some other words in the top 100 that can come up in medical writing are: vomit, properly, opposite, Monday, four, manage, month, once, almost, both, ghost, most, only, powder, salami.

Source: Asthana A. English is too hard to read for children. *The Observer* 8 June 2008. Available at: http://www.guardian.co.uk/education/2008/jun/08/schools.english

Guest editor's note: I agree entirely with Ms. Bell. I would reform English spelling now, and not even wait (weight) until tomorrow! I wonder if she also goes into the ridiculous stigma attached to not being 'good at spelling' as an indicator of intelligence. I edit articles day-in day-out from highly educated (native) English speakers and often find spelling errors. If only English were (almost) phonetic like Spanish. Our lives would be a 'darn sight (site)' easier without this encumbrance to learning—and would our culture suffer? Not in the least.

Falling in love

Falling in love is not at all the most stupid thing that people do—but gravitation cannot be held responsible for it. Albert Einstein

People have been 'falling' in love since the early 16th Century but at that time 'fall' was not associated solely with descent. It also meant a sudden change from one to another mental or emotional state. This makes sense when you consider the even older expression of 'falling asleep' and that, of course, you can also fall out of love.

Source: Dunkling L. *Collins Dictionary of Curious Phrases*. 2004

Book reviews in the medical scholarly literature Part II: "This book portrays the worst form of mental terrorism"

by Françoise Salager-Meyer

In Part II of this article on medical book reviews, I will attempt to show the evolution of what linguists call 'the voice' of criticism. Language, indeed, is not static, but dynamic and it evolves along with, inter alia, societal changes. Therefore, after the brief historical incursion on medical book reviews (BRs) published in *TWS* [17(2):82-3)], I would now like to examine how the critical voice or 'rhetorical persona' of the book reviewer has changed over time. Towards that end, I will provide examples drawn from two distinct corpora of BRs: one from the 1930s-1940s when BRs became a regular feature of most Anglo-American medical journals and another one from the closing years of the 20th century.[1] In a certain way, this small contribution will also respond to the call for examples of the style in which science used to be reported [*TWS*, 17(2):81].

Emotionality and face-threat intensity

One of the pragmatic markers of mid-20th century medical BRs was the emotional, devastating, even downgrading, tone with which critical comments to books were then formulated. This emotional tone (linguistically realised, inter alia, by means of emphatic adverbs like 'very', 'totally', 'undoubtedly', etc) was itself intimately related to the level of threat, mid-20th century BRs being much more face-threatening to the book author than today's BRs are. Obviously, the thornier the issue dealt with in the book, the more cutting and pitiless the dispute tone of voice. It is important to note, however, that whether the book dealt with a delicate (i.e. ideologically tainted) topic or not, critical comments in early BRs were always more categorically and emotionally expressed than those in today's BRs.

For example, referring to the prickly issue of the influence of trauma on disease—which the reviewer, contrary to the book author, fervently supported—a book reviewer uttered the following infuriated critique in highly emotional, violent, categorical and face-threatening terms:

1. '*Trauma and Disease*' is a very bad book. It amounts to such a blatant attack on intelligent inquiry… It portrays the worst form of mental terrorism used against any who is interested in the facts. (1938)

In another BR on a less delicate topic, the reviewer made the following merciless criticism in slightly less emotive terms:

2. For me, the book is very disappointing. That the total number of pages remains the same (as that of the original description of the disease) is due to arbitrariness on the author's part… The senior author fails to discuss important issues… The discussion of radiation therapy completely fails to deal with the fundamentals of this subject. (1933)

Then the reviewer kept on criticizing orthographic errors, careless proofreading and mediocre radiographs reproduction.2

Here are a few more examples which illustrate the cutting, merciless emotional tone of voice of critical comments in mid-20th century BRs:

3. The case reports themselves are so full of speculative and interpretative comments that they do not spell out, in any convincing or clear way, the author's particular psychoanalytic viewpoint… Garma's theory elaborates no boundaries at all between validated fact, informed hypotheses and the still unknown… This claim is not supported by any impressive evidence. (1941)

4. The book totally fails to accomplish what a monograph should. (1942)

Quite frequently, in the 1930s-1940s, BRs ended up with a harsh disrecommendation, such as:

5. The advice to the would-be buyer is simple: don't (buy the book). (1938)

6. Anyone buying the book on the basis of the title and cover is in for a disappointment. (1934)

Here is another example of a categorical negative final appraisal made to a book published in 1958:

7. Students and residents would undoubtedly do better with more selective and organized texts, plus the journals themselves. (1958)

1 For the sake of simplicity, I shall refer to the former corpus as "mid-century BRs" and to the latter as 'today's BRs'.
2 The issue related to the targets of criticims in medial BRs will be dealt with in Part III.

and the sarcastic and cynical final verdict made to another book published at that same time:

8. Psychiatrists and psychologists ought to read this book, even if only to be enraged. (1958)

The tone of voice of critical comments in today's BRs is also very direct and straightforward, but much less emotional, i.e. more dispassionate and matter-of-fact as examples 9 and 10 below illustrate. Moreover, negative comments in today's BR are most of the time followed by positive remarks (not so in mid-20th century BRs) that are themselves preceded by metadiscourse markers such as 'however', 'nevertheless' or 'but':

9. A major weakness of the book is its lack of depth in some subject areas. References supplied are mostly review articles that reflect the author's bias. *However*, this text is an excellent collection of articles written by outstanding expert authors. (2000)

10. The book does not encompass the whole range of gastroenterology and hepatology, *but*, for those topics that it does cover, it provides an excellent reference to current scientific knowledge. (1999)

No cutting tone, no emotion here. Plain, flat, dispassionate negative comments which do not threaten the book author's face as much as the critical remarks recorded in earlier BRs did.

Presence of humour

Another important rhetorico-pragmatic difference between mid- and end-of-20th century BRs lies in the presence of humour in association with negative comments to be found in early BRs only (examples 11 to 16 below).

The following humorous comment was made to a book entitled *Physical Diagnosis* published in 1958, right in the middle of the cold war. After bluntly asking whether there is "a place for a book on physical diagnosis" and whether "such a book makes sense at all", the book reviewer suggests "a bold new step", i.e. the adoption of a new approach to the problem of physical diagnosis:

11. I hereby contribute the following suggestions gratis.... Got the idea? OK.... Our 'text' should consist of some records of sounds, murmurs etc. to replace the totally inadequate written words describing such phenomena. Finally, our 'text' should include a 10 to 15 minute film showing an expert diagnostician performing a complete physical examination, from beginning to end. (For this last section, I recommend that the editors of *Playboy* be canvassed to get nominations for the examinee.) All right, so snicker. I'll bet the Russians are doing it already. (1958)

In the following example, the book reviewer, criticising the extreme eclecticism in a book on the treatment of neuroses, humoristically referred to a book chapter as "a lyrical piece on anxiety" and to the fact that:

12. … obsessiveness has been avoided in the preparation of this work that has more of its share of 'misprints'. (1945)

The following humorous negative remark was formulated to a book entitled *Grow Up .. but Do Not Grow Old. Be Your Sex Age* published in 1952:

13. Unfortunately, the author does not indicate where one can obtain possession of the inner strength which is the prerequisite for such a vigorous program, nor does she provide the key for objective self-analytic appraisal.

Another book reviewer sarcastically ended up his final evaluation (after a rather lengthy and detailed listing of negative comments):

14. After overlooking all the defects (which is hard, alas!) ... (1942)

Full of humour too are the following comments:

15. It is disturbing, for example, to see Eysenck (the book author) quote the 'confirmation' by Shagaas of Eysenck's theories when Eysenck's and other workers have failed to reproduce Shagaas's data! The net result is a feeling of admiration for the author's industry and imagination mixed with a sort of intuitive distrust of the reproducibility of data.... It is difficult to be more genial or more precise than this. (1938)

16. There is also quoted on page 2 what must be the longest word in the English language (antifloccinaucinihilipilificationistically). (1944)

One example only of (black) humour associated with a negative remark was recorded in the corpus of today's BRs analysed:

17. My reaction to Singer's work is akin to discovering that a friend has served me her pet for dinner. (2000)

In the third and last Part of this article series, I shall focus my attention on the evolution of the targets of criticisms in medical book reviews.

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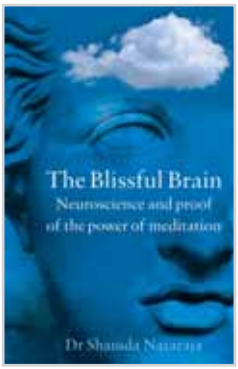
In the Bookstores...

A blissful read



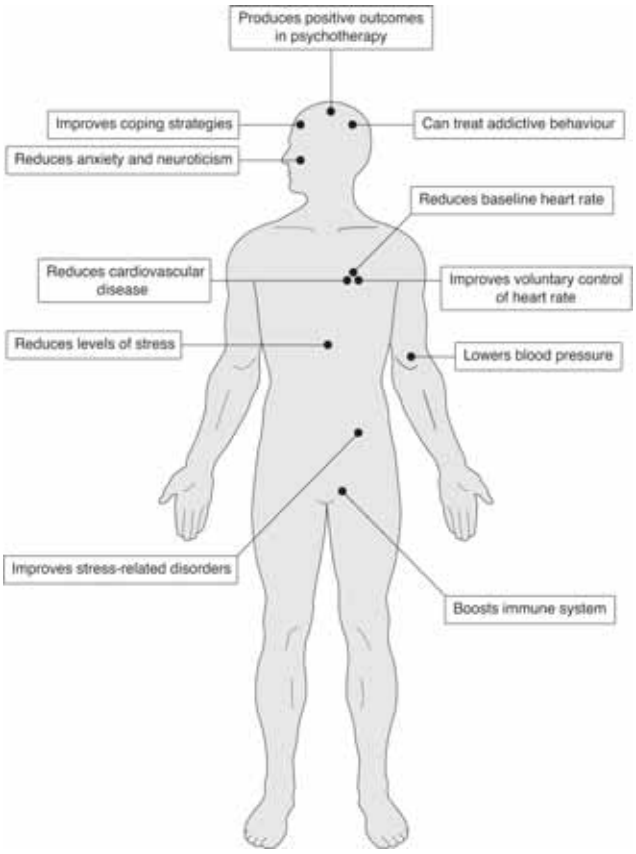
Shanida Nataraja : The Blissful Brain—Neuroscience and proof of the power of meditation. Gaia Books Ltd., 2008. ISBN 978-1-85675-291-6 (paperback). GBP 7.99, approximately EUR 10.15. 240 pages. More information about the book and the author can be found at www.blissfulbrain.com

I was intrigued when I overheard EMWA's website manager, Shanida Nataraja, saying that she had just finished writing her first book. Later, when I discovered that the topic was the neuroscientific proof of the power of meditation, I rushed to buy a copy. Like Shanida, I am a keen yoga and meditation practitioner, and before becoming a medical writer, I was a neuropharmacologist researching into drugs that affect mood and anxiety levels. I have always found it incredible that this lump of reddish-grey jelly we call 'the brain' can contain a lifetime of memories and control our every thought, action and emotion. Shanida has a PhD in neurophysiology, and her post-doctoral research was into the mechanism of learning and memory. In her book, she clearly explains the current knowledge of how the brain works and presents scientific evidence that regular meditation practice can improve all aspects of the functioning of the brain and body.

The book first introduces meditation techniques and other related disciplines, including yoga and tai chi. It then describes how the stresses of modern life negatively affect our mental and physical health, giving rise to an explosion of stress-related diseases such as cardiovascular disorders, depression and anxiety. Our response to stress is the adrenaline-charged 'fight or flight' reaction, no doubt essential for our ancestors when fighting sabre-toothed tigers, but somewhat inappropriate during a teleconference with a demanding client! Unfortunately our attempts to reduce stress—such as smoking, overeating, excessive alcohol consumption—often worsen the situation. Western and Eastern approaches to healthcare are compared: the traditional Western approach, founded by Hippocrates, considers the human body in terms of its separate parts and targets malfunctioning components for treatment; conversely, the Eastern approach is more holistic, embracing the importance of both mind and body. A key aspect of the Eastern approach is that meditative practices play a crucial role in healthcare.

The second chapter entitled 'Peering beneath the skull' is a fascinating tour of the brain's anatomy and physiology. What I loved about this book were the numerous astonishing facts, such as 'the brain houses more than 100 billion individual brain cells' and 'if every single person in the world had access to the Internet, the resulting network would still be only a fifteenth the size of the average human brain'. The key point to understand here is that the brain's wiring is constantly changing and 'it is estimated that there are more possible configurations than there are elementary particles in the universe'! What this means is that your brain produces your thoughts—but your thoughts produce the networks in your brain.....wow, that's philosophical, isn't it? A map of human intellect has been drawn using techniques such as magnetic resonance imaging. Shanida explains how quantum physics and the idea of the 'quantum brain' question our entire scientific reasoning—but I have to admit that my own limited brain couldn't completely grasp this part, so forgive me if I don't summarise it!

The third chapter describes scientific research into 'meditation and mystical experiences'. For example, one neuroscientist invented a motorcycle helmet containing magnets which produced temporal lobe microseizures and apparently triggered religious and mystical visions! This 'God Machine' was a media sensation, but was met with considerable scepticism in the scientific community. Other researchers injected radioactive tracer in meditating subjects and visualised the blood flow in the different regions of the brain. A typical sequence of changes in the brain was observed during meditation including a shift from left-brain (logical, analytical) to right-brain (creative) function and a dramatic decrease in activity in the 'orientation association area' in the parietal lobe (responsible for our sense of



Positive effects of meditation on the body

self and time). Other scientists performed electroencephalograms (EEG) on meditating subjects and showed a typical pattern with a reduction of beta waves and an increase in alpha and theta waves. These results are fascinating, but as Shanida says, they do not answer the age-old question: which came first, consciousness or the brain? Nevertheless the boundaries between science and spirituality appear to be less well defined than we originally thought.

The fourth chapter entitled 'Bridging science and spirituality' discusses the new discipline of 'neurotheology'. I don't want to scare you off the book by making you think it is all about religion—not at all! In fact this section is a fascinating mixture of philosophy and psychology which I will probably read again many times before fully understanding the concepts.

The fifth chapter describes how psychoactive drugs such as psilocybin (magic mushrooms) and lysergic acid diethylamide (LSD) can alter consciousness and have been used by scientists in their research. For example, the horse tranquilliser, ketamine, can produce an altered state likened to a near-death experience with the sensation of travelling rapidly through a dark tunnel towards a light, the feeling of dying and being in God's presence. Needless to say, most of these drugs are highly toxic and not an advisable method for attaining rapid enlightenment! Some researchers, however, believe that meditation is inefficient and slow, and needs to be refined to make it more effective. The biofeedback technique using the galvanic skin response—also used as a 'lie detector'—can help subjects learn to relax and meditate more successfully. Neurofeedback is a similar technique: patients undergo an EEG whilst meditating in order to learn which thoughts produce 'good' brain waves. I have to say I found this part of the book rather disturbing: will we soon all be forced to wear neurofeedback EEG helmets every day to keep our negative thoughts under control in this stressful world!

The sixth chapter discusses the impact of meditation on health. Many studies over the last 5 years have evoked a massive surge of interest in this field. Shanida describes convincing evidence that daily meditation practice reduces stress levels, boosts the immune system, improves outcome and quality of life in patients with cancer or chronic pain, lowers heart rate and blood pressure, reduces the risk of cardiovascular disease, and improves psychological wellbeing. One study even showed that meditation improved intelligence! Shanida argues convincingly that whilst meditation probably cannot replace traditional healthcare, it can play a key role as a preventative or add-on therapy. She says 'our healthcare systems are struggling to deal with the needs of an increasingly unhealthy population; solutions are needed, and needed quickly. Meditation promises to offer that solution, improving our general health and reducing our current reliance on the healthcare system to repair the damage inflicted by our fast-paced, stress-filled lives'.

The final chapter describes two meditation techniques in enough detail to allow the reader to give it a go. I have been meditating regularly for the past year and I have been astonished by the results. I am much happier and less stressed than before: time seems to go more slowly, and I am able to finish my projects faster with less effort! If you have a stressful lifestyle with tight deadlines (i.e. if you are a medical writer), and if you sometimes worry that this lifestyle is not great for your health, I strongly recommend that you read Shanida's book and that you try meditation: even a few minutes a day could change your life!

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E-mails: Don't get too obsessed with the time management

E-mails can "waste huge amounts of time" but help is at hand for those struggling to keep them under control. A nice and useful article on how to handle e-mails and what e-mails are good and bad for can be found at http://www.timalbert.co.uk/shortwords_handleemail.htm

Vital signs

Dear TWS

I have been an EMWA member from Turkey since September 2006. I would like to inform you, actually I should say people, who have worked for the new design and more functional website for EMWA that I think our website is now more appealing to people with variable interests (both medical writers and people interested in medical writing). As the contents of the sections are being regularly updated, I believe that every visitor will be inspired at the first glance. I would like to thank everyone, who has spent their time and creative energy on this successful project.

Evin Isgor
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Some irreverent thoughts on the word 'Deadline'

One of the most evocative words in the business world, and indeed in the life of a medical writer, is 'deadline'. Webster's dictionary defines it as 'a date or time before which something must be done' or specifically (the *TWS* editor will love to read this) 'the time after which copy is not accepted for a particular issue of a publication'. This sense of strict demarcation derives from the word's military origin: the *Wordsworth Dictionary of Phrase and Fable* contends that the phrase was coined during the American Civil War in the notorious Confederate prisoner of war camp, Andersonville, located at Camp Sumter in the state of Georgia. Some distance from the peripheral wire fence a line was marked out and any prisoner crossing this line was shot at sight.

Semantically, the word has kept its originally menacing character across the centuries. Deadlines don't peek, they loom. You may stroll to 'meet a deadline', according to your style of working (more on that later), but more often the deadline will have been 'set' (though not always in stone). If you have a 'tight deadline', the feeling of constriction in the throat is almost palpable. Deadline is, by its very nature, a horizontal word, because both of its compound components denote flatness. When spoken aloud, it transports a feeling of finality. If it lived on your street, it would be the neighbour with the run-down house and the pitbulls in the yard. If you met it at the store, you wouldn't talk back to a deadline. It would just scowl at you, anyway. Its favourite holiday is Hallowe'en.

Of course, these perceptions are heavily influenced by my Teutonic background. How you view a deadline depends a good deal on what culture you come from and how seriously you take the wishes and demands that others are trying to impose on you. A French 'date limite' or Spanish 'fecha limite' is a much less serious thing than a deadline. You aren't envisioning prison warders with guns when you hear the word, for one thing. Of course the Germans have happily integrated the word 'deadline' into their business speak, especially in so-called 'creative' industries like advertising. This is in spite of the fact that they have a perfectly valid term: 'Abgabetermin'. Admittedly, this translates more like 'it would be nice to have the material at this date, please' than 'hand it over, bubba'. In the United States, habitually breaking your deadline may jeopardise that most important line in American business culture, the bottom line.

Besides the cultural bias in viewing a deadline, there is also the individual difference in how people work that affects how they meet deadlines. I would class them into three broad categories: Firstly, there is the group that I will call the 'structuralists'. They are accustomed to applying salami tactics, neatly prioritising and organising their work. They breeze through the project and then casually meet the deadline, like "Oh, hi, nice to see you".

These people are not prone to overly high caffeine use or heart attacks. Then there is the group that I will call the 'pressure cookers'. They sit at their desks, letting the internal pressure build while the deadline looms ever nearer. At some indefinable point they suddenly start working and complete everything at the last minute in a frenzy of activity. Then they collapse with a feeling of exhilaration.

Some people in the creative industries maintain that deadlines spur them on to become even more creative. This may be true. However, I have a hunch that this method becomes ever harder to adhere to after the age of 35, or after you become a parent and chronically sleep-deprived (whichever comes first). Finally, there is the group I will call the 'mañanas'. They never take a deadline seriously, assuming that it can always be negotiated into a future date. They are secretly hoping that the whole project will fold, making the deadline obsolete. They do not stress easily. They can be charming and mercurial characters with an active social life, but they usually like to let other people do the work, which can be a pain if you are a co-worker.

I'll leave you to guess which group I belong to. Just a hint, though: 'The Editor Knows…'

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Webscout:

The art of time management

by Joeyn Flauaus

Can you manage time? Yes, if you have good self management skills you are able to make most out of your time. There are several strategies to manage tasks during a certain time period to make better use of time. There are also different types of time management, e.g. personal time management and project management. Personal time management helps you to define priorities, to achieve goals, and to organise your tasks to meet certain timelines. Time management, as a project management subset, tries to manage scope, human resources, cost, time, etc.

Almost no one is born with the gift of good time management skills and it is rarely something they teach you at schools or universities. But there is hope! You can learn time management and with some guidance and practice you learn how to use time more effectively. And in the end, you may even realise that you can make time.

There are various ways to manage yourself and get things done. The perfect method does not exist you just need to find a method that suits you. I have put together a selection of websites on time management. These provide some useful tips and advice to help you to manage your time more effectively.

http://blog.penelopetrunk.com/2006/12/10/10-tips-for-time-management-in-a-multitasking-world/
Ten tips for time management in a multitasking world are provided on Penelope Trunk's blog. Her blog provides advice on how to make work life and personal life one happy, synchronized adventure.

http://www.randypausch.com
Carnegie Mellon Professor Randy Pausch gave a lecture on time management at the University of Virginia in November 2007. The video of the lecture is approximately an hour long and definitely worth watching. In his opinion "time must be explicitly managed, just like money".

http://www.buzzle.com/articles/creating-personal-boundaries.html
This interesting article about personal time management recommends to set boundaries for yourself in order to make better use of the time you have at your disposal. The importance of making a clear boundary between work time and personal time is also stressed.

Last but not least something to make you laugh:

http://www.netfunny.com/rhf/jokes/93q2/stress.html
Admit it: You love to be stressed. Follow the funny explanations why you don't need any time management skills at all. Only here you can learn clinically proven methods helping you to stay stressed.

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

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Some origins of disease and drug names

Do you know the origin of the words botulism, influenza, digitalis, warfarin or bacitracin? Robert B. Taylor believes that knowing the etymologic derivation of medical words makes him a better medical writer and that knowing how words arise enriches his life. He gives a few examples of word origins in his book *The Clinician's Guide to Medical Writing*.

Botulism comes from the German word *Botulismus*, which means sausage[1]. It seems in Victorian times Germans contracted botulism by eating sausages. Influenza comes from the Italian word *influenza*, which means influence. The Italians once believed that the heavens influenced the disease. Digitalis as you might suspect comes from 'digit', as in finger or toe. The drug came from the foxglove plant, also called ladies' fingers. Warfarin is named after the first letters of the Winsconsin Alumni Research Foundation, which sponsored its development, with the last four letters of its chemical name (coumarin) tagged onto the end. Possibly the most intriguing of all is bacitracin: the 'baci' comes from bacteria and the 'tracin' from the name Margaret Tracey. Her wound drainage provided the first identification of the antibiotic.

1.It actually comes from the Latin word 'botulus' which means sausage; the Germans, who were heavily into Latin, made the word 'Botulismus out of that: 'Wurstismus' doesn't sound half as good!

Journal watch:

Development of reporting guidelines, adequacy of treatment descriptions in manuscripts, and online articles and citation diversity

By Nancy Milligan

Reporting guidelines for medical research

High-quality reporting in medical publications is the primary means of sharing research findings with healthcare professionals and the wider research community. Reporting guidelines, such as the CONSORT Statement [1], have been developed to improve the quality and reliability of publications; however, no coordination or collaboration of reporting guidelines exists and therefore guideline development methods vary greatly. In response to this, the National Knowledge Service of the UK NHS provided funds to set up the EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research; http://www.equator-network.org/) to improve the quality of scientific publications by promoting transparent and accurate reporting [2]. The first project of the EQUATOR Network involved surveying authors of reporting guidelines in order to gather information on their development methodology, dissemination and implementation strategies, and any problems encountered during the process. A survey of 37 generic published reporting guideline developers found that development methods were generally similar (this included generating ideas, literature review, critical appraisal of the evidence, generation and discussion of guideline items, agreement on phrasing, writing and incorporation of comments until consensus among the group) but varied in important details; development usually took a substantial amount of time; only about half of the developers had strategies for dissemination, uptake, and impact of the guidelines, and a lack of sufficient funding was a major problem. 87% of respondents cited poor quality of reporting as the primary reason for the guideline development. An interesting point was that most of the surveyed guidelines (73%) were developed by multidisciplinary groups generally including statisticians, journal editors, clinicians, and epidemiologists. Some included medical writers, social scientists, information specialists, health economists, and representatives from pharmaceutical companies. In conclusion, the authors suggested that 'there is a need to harmonise methods used in the development of reporting guidelines and concentrate more on their active promotion, implementation, and evaluation' to ensure improved reporting of medical research.

Adequacy of treatment descriptions in manuscripts

For clinicians to use the treatments or interventions that are tested in trials, they need to be described in sufficient detail in the original manuscript. Glasziou et al [3] suggest that in manuscript writing guidelines such as the CONSORT Statement little attention has been given to the adequacy of the description of the treatments used. Glasziou et al prospectively assessed 80 consecutive studies selected for abstraction between October 2005 and October 2006 in the journal *Evidence-Based Medicine* (a journal which the authors suggest provides research summaries that are highly relevant to clinical practice). Elements of the treatment or intervention were missing in 41 of the 80 studies; this was most frequently a description of the process, but also in several cases included missing handouts or booklets. The authors noted that the details provided were better in reports of individual trials than in systematic reviews, and for drug treatments than for non-drug treatments. When contacted, most of the manuscript authors (52 out of 59 authors) were willing to provide some missing information so that the completeness of the treatment description improved from 49% to 76%. Glasziou et al suggested that further guidance on how to effectively describe treatments would be helpful; they suggested a detailed checklist covering the 'who, what, when, and where' of the treatment, although this would need to be tailored to different types of interventions. They suggest that a full description of the treatment used would include: procedures used, timing of the treatment (e.g. duration, dosing or session intervals), materials needed (e.g. patient handouts, devices), and accessibility of materials or instructions, including overcoming language barriers. This may need to be supplemented with copies of materials or handouts and a graphical depiction of the flow and timing of sessions of treatment. They concluded by reiterating the importance of this issue to researchers, suggesting that 'providing some additional treatment details could improve the uptake of trial results in clinical practice'.

Effect of online availability of journal articles on citations

As more and more research articles are being published online, James Evans (a University of Chicago sociologist) asked in *Science* what effect this has on work cited in subsequent research [4]. In theory, online access should make more research more readily available and therefore lead to a broadening of the work cited. However, using a database of 34 million articles (from Thompson Scientific's *Science*, *Social Science*, and *Arts and Humanities* citation indexes) and their citations from 1945 to 2005, Evans suggested that as more journal issues came online, the articles referenced tended to be more recent, the number of distinct articles and journals cited was reduced (by 14%), and more of the

Development of reporting guidelines...

citations were to fewer articles and journals. Evans suggested that although searching for articles online is fast, easy, and efficient, they may be used differently than print articles and researchers may be inadvertently narrowing the range of findings they may use in their subsequent research. In response to this, a short article in the same issue of *Science* by Jennifer Couzin suggested, using a number of lines of evidence, that the opposite may be true [5]. She mentions, for example, a US study by Carol Tenopir (an information scientist) and Donald King (a statistician) which suggested that scientists are in fact reading older articles and reading more broadly—at least one article a year from 23 different journals, compared with 13 journals in the late 1970s. Luis Amaral, a physicist in the US, argued that Evans' results might reflect shorter publishing times. He said "Say I wrote a paper in 2007" that didn't come out for a year. "This paper with a date of 2008 is citing papers from 2005, 2006". But if the journal publishes the paper the same year it was submitted, 2007, its citations will appear more recent. However, Evans did not think that this affected his results, suggesting that publication still remains sluggish in many research fields.

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Mid-career depression hits in the 30s

The older you are the happier you are at work. Vodafone commissioned a survey that found 7 out of 10 workers aged over 50 years felt fulfilled in their work but that only 5 out of 10 aged between 25 and 31 years felt fulfilled. Even more surprising, 95% of those over 65 years who were still working felt 'enabled' in their work whereas only 61% of those aged 31–35 years felt this way. Employees in their 30s felt undervalued (58%), unfulfilled (43%) and were also demotivated. Why? The report put the mid-thirties' lacklustre down to the pressures of starting a family but maybe disillusionment is nearer to the mark. The report also warned that those born since 1980 will face 'inevitable disillusionment' when they enter their 30s.

Source: http://news.bbc.co.uk/2/hi/business/7511205.stm

Be prepared for more jargon at the end of the holiday silly season!

An article in *BBC News Magazine*[1] warns readers to be prepared for the jargon that might await them when their boss returns from holiday. The warning is relevant to the theme of this issue of *TWS* because instead of relaxing on the beach with a good fiction book, managers are increasingly falling prey to pop sociology books that are specifically marketed at them. These books according to the article have a simple metaphor, usually expressed in a single word that appears in large-type on a grabby cover. The article lists four books and extracts buzz phrases and golly-ghosh anecdotes from each to help those of us who make better use of our precious reading time to nod along as the envelope gets pushed. The buzzword 'nudge' for example means a reminder that you might be about to do something you might regret. If your boss uses this word you will know he has been reading *Nudge: Improving Decisions about Health, Wealth & Happiness* by Richard H. Thaler & Cass R. Sunstein.

One of the anecdotes related from *Yes! 50 Secrets from the Science of Persuasion* by Noah Goldstein, Steve Martin & Robert Cialdini, a book that presents experiments from psychology journals as foolproof 'secrets', is about persuading people to complete surveys. It was found that adding a sign-off of 'Thank-you' and the sender's initials to a hand-written Post-It note on a survey increased the response rate: personalising a request makes it more persuasive. Another tip in the book is that asking people to give their name makes it more likely they will be civil to you—an argument already long known in biomedical journal publishing to advocates of open peer review (where the reviewer's name is revealed to the author).

Old wisdom is also pepped up in *Fl!p: How to Succeed by Turning Everything you Know on its Head* by Peter Sheahan. The book advises that you 'go outside your company when looking for innovation', supporting the saying with an anecdote of one John Harrison who, having created a longitude clock that located a ship's position at sea, had to fight to receive the £20,00 prize money the king had offered to anyone who invented such a device.

To find out what 'econs', 'homers', 'thin slicing', 'the locked door' and 'capitinitis' mean, you will have to read the article. But maybe you would prefer to join Lucy Kellaway's campaign against office jargon (http://news.bbc.co.uk/2/hi/uk_news/magazine/7453584.stm).

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1. Available at: http://news.bbc.co.uk/2/hi/uk_news/magazine/7540649.stm

Out on our own: From freelancers for freelancers

In this issue, in line with its theme, Stefan Lang concludes his series on setting up as a freelance medical writer in Germany with some thoughts on time management for new freelancers. His message is: keep it simple. Although he does wonder whether it will stay simple, with more and more enquiries and jobs flowing in. John Carpenter, who has been a freelancer in the medical communications sector for many years, answers our ten questions. In the next issue, we can look forward to hearing about setting up in Sweden as a freelance writer from Ingrid Edsman, a physician, who recently took this momentous step.

Sam and I look forward to seeing you at the Freelance Business Forum at the 27th EMWA Conference, 20–22 November 2008, London, England, on Friday 21 November from 17:30–18:30. This session is not restricted to freelance members—anyone interested is welcome to attend.

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Time management for a freelancer novice

by Stefan Lang

When Alistair asked me if I would like to write another article about freelancing in Germany, I wondered if I could provide any further information about setting up business that I had not already mentioned in my last two articles. General terms and conditions, insurance, tax matters—what else could I write about? But when I heard that the topic of the next issue was going to be 'Who manages your time?' I contemplated how important time management might be for freelancer—especially for newcomers.

Once you move from a salaried position to freelance work, there is no boss anymore telling you what you have to do and when and where you have to be. No-one is looking over your shoulder if you take a long lunch. Learning how to manage your time is a challenge and is certainly as important as finding new clients or network partners. So before you switch to self-employment, you need to ask yourself: Am I organised enough to survive as a freelancer?

Usually, I consider myself as a well-organised person. As long as I have a reasonable amount of work, I am pretty self-motivated. I start working at 08:00, earlier if required, and finish at a reasonable time, usually about 18:00. I keep a calendar and appointment book and prepare a daily, prioritised and realistic 'To-Be-Done' (TBD) list. It therefore seems as if I have created a perfect time management system for myself: but why are there so many days when I fall behind?

During my first assignment—I worked on the web pages of an orthopaedic clinic—I had a two-hour meeting with the client in a cafe. Not only could the conversation have easily taken place on the phone, I soon realised that the whole meeting could have been over in a few minutes if the client had been a little better prepared. Moreover, because I somehow felt obliged to drink as many coffees as my client did, I almost suffered a heart attack. Over time, I realised how much precious time is lavished on unnecessary meetings and extra-long-lasting phone calls, and, additionally, how easy it is to waste a few minutes here and there browsing the Internet or checking e-mail accounts.

Certainly, these time-wasting exercises could have been avoided if I had stuck closer to my schedule. Why is it so difficult to do this? I believe it has something to do with the transition from a salaried job to self-employment. As a freelance novice I needed to learn that, regardless of what I do, time is worth money. So I tried to establish in my mind how much every minute of my time is worth. It is obviously not appropriate to always evaluate the financial outcome of every single activity but others will not perceive my time as valuable unless I do. If your rate is, let us say, € 60 per hour, spending an unnecessary half-hour on the phone costs you € 30. Spending two hours hand-collating and assembling copies for your presentation actually costs you € 120, but the people at the copy shop would charge € 15 euros to do exactly the same thing. Considering the value of time certainly helps you both to prioritise your tasks and keep closer to your schedule.

Considering the value of time will certainly help.

Time management for a freelancer novice

However, the dark side is that this might mislead you to neglecting the non-billable—but also important—tasks such as billing and marketing. Moreover, you might be tempted to bite off more than you can chew. Taking more assignments than you can handle and scheduling more than you can ever accomplish in a day is not fair to your clients, your family or yourself. Therefore, while always bearing the value of time in mind, do not overload your list, but prioritise, set specific times for handling the non-billable work, and, also important, do not forget to have a break now and then.

Preparing a detailed TBD list has an additional advantage: you cannot only check the items on your list at the end of the day, but you can also use it as a time sheet. Keeping track of your time allows you to monitor how effectively you are spending your time, even, and especially so in this case, if you are not billing clients on an hourly basis. When you start your business, the question of pricing is a touchy one—and, obviously, pricing is closely connected with the time required for a job. You can easily find out the hourly rates of other freelance writers, but how do you know how long you need for a certain task if you do not have that much experience? I had generally underestimated the time I need to familiarise myself with a new topic, to search the literature, or to prepare a first outline draft. I have therefore started to record the time I spend on these tasks. Although I do not keep my time sheet conscientiously, it has helped me to transform some 'vague' impressions I had about the time I needed into more robust estimates.

In my opinion, using advanced tools to create elaborate systems for time management often requires too much time to manage and takes time away from more important things that need to get done. Some people invest in card and book systems, or project management software that actually waste more time and money than they save. For me, however, experience is the key and, this is why I have kept things simple to start with. Luckily, I have neither regularly found myself at the edge of a deadline, nor have I—yet—needed to negotiate extensions. But then I only started about one year ago. Now that more and more queries and jobs are coming in, I am curious if my simple daily TBD list will be sufficient to manage my time in the future.

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Euro errors

1. The correct way in English to write two hundred and twelve euros and twelve eurocents when using digits and the euro symbol is € 212.12, and not 212.12 €, because one of the many quirks of English is that currency symbols precede sums of money when written as digits, even if when spoken, it is the other way around. The same applies to the abbreviation 'EUR'. This is certainly different from German, where the symbol is written after the amount. I am not so sure about other languages. Maybe others would like to comment on this.
2. Note that I have not capitalised euro in the above sentence. Currencies are not capitalised in English unless they include a proper name (e.g. Canadian dollars). Rare exceptions to this may be the colon (currency unit in Costa Rica named after the Spanish surname of Christopher Columbus) or any other unit named after a person, but as far as I am concerned, these have also reached lower-case status.
3. Note also that I did not write euroes or euro's to form the plural. The version with the apostrophe is clearly wrong, but seems irresistible to some writers for unfathomable reasons. It is also tempting to add an 'e' because of 'tomatoes' and 'potatoes', but those who do not wish to complicate their lives will opt for the plural without an 'e'.

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Competition destroys the spirit of science

Competition among scientists for funding, positions and prestige, among other things, is often seen as a salutary driving force in US science. Its effects on scientists, their work and their relationships are seldom considered. Focus-group discussions with 51 mid- and early-career scientists formed the base of a study that reveals a dark side of competition in science [1]. According to these scientists, competition contributes to strategic game-playing in science, a decline in free and open sharing of information and methods, sabotage of others' ability to use one's work, interference with peer-review processes, deformation of relationships, and careless or questionable research conduct. When competition is pervasive, such effects may jeopardise the progress, efficiency and integrity of science.

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Are opinion leaders allowed to have opinions?

The *BMJ* are running a debate series titled 'Head to Head'. The topic debated in the 21 June 2008 issue was 'Should the drug industry use key opinion leaders?' A letter in response to this debate published in the 19 July 2008 issue described one opinion leader's experience with the pharmaceutical industry. He departed from the script he was given for a presentation to note that the effect size of a certain treatment was significantly lower than for the alternative treatments. That evening he received a warning telephone call from the director of the company programme. Nevertheless he stated his opinions again at a session on the next day. The company never asked him to speak again.

In the following years he continued to give talks sponsored by industry, choosing his own slides and topics. That was until 5 years ago when he was told that in future he would have to use topics and slides provided by the companies with no deviations allowed. He opted not to give any more company-sponsored lectures in the US.

Source: Carroll BJ. How it really works. *BMJ* 2008;337:a788

Belt and braces—just in case those trousers fall down

Braces to hold up trousers are hardly worn these days, except as a fashion accessory. That probably means that they are not needed to hold the trousers up, and that the wearer thinks that they 'look good'. Even if they are, this old (Northern English, I think) saying holds true for writing: you either need a belt or braces, but not both. A typical example of 'belt and braces':

*The results of these studies **support** and **confirm** the hypothesis that <drug> is effective against angiogenesis-dependent tumours.*

If something is *confirmed* by facts, then it is also *supported* by those same facts, so *confirm* alone is adequate. Using both verbs does not 'look good': it betrays insecurity in writing. 'Belt and braces'-writing of this sort is very common. Look out for it and don't do it.

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Room for Improvement on the Medical Innovation System?

At a recent debate on 'Who Owns Science' held to launch Manchester University's new Institute for Science, Ethics and Innovation, Nobel laureates John Sulston and Joseph Stiglitz called for a re-evaluation of the current laws regulating intellectual property rights, in particular with respect to patenting issues in medical research. The geneticist and economist have jointly expressed concern that the global progress of research as well as access to its benefits by those most in need, are actually being impeded by an outdated regime that governs patents [http://www.timesonline.co.uk/tol/comment/letters/article4271555.ece]. In press interviews by *The Times* [http://www.timesonline.co.uk/tol/news/uk/science/article4272828.ece] and the BBC [http://news.bbc.co.uk/2/hi/science/nature/7490384.stm], Sulston cited several specific examples in the area of medical research to support this claim. The forthright Sulston has in the past fought for public access to all data generated from the Human Genome Project and has championed the cause of open access journals. He has now set his sights on revamping the present system of medical innovation, claiming parts of it are "very inefficient and really somewhat morally corrupt". In his view, the overprescription of antidepressants in developed countries is just one symptom of a strong tendency to place shareholders over patients.

These and other equally hot issues were up for further debate at a 'World Knowledge Dialogue (WKD) Symposium' held in Crans-Montana Switzerland from 10–13 September this year. Sulston was present with more than three hundred other leading thinkers from different professional backgrounds to take part in an experiment in interdisciplinary bridge-building. The principal aim of the WKD Foundation's biennial symposia was to turn the tide of a 'Two-Culture' mentality that has, if anything, become more ingrained in academic and professional society, since the term was coined by C.P. Snow in 1959. The broad range of perspectives that different participants brought to the interactive three-day encounter made for lively debate. But the group have at least one thing in common that should keep them talking to each other if tempers begin to overheat. All are part of a growing movement that thinks it is becoming crucial to collaborate in the active development of new tools and new frameworks of mutual understanding that can be shared between scholars of the natural and technical sciences, the social sciences, arts and humanities disciplines.

More information about the 2008 WKD symposium programme and how to participate and gain access to its video archives are available at http://www.wkdialogue.ch.

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Ten questions for …

John Carpenter

by John Carpenter

In 100 words, what is your background and how did you become a freelancer?
As an impoverished pharmacology undergraduate in London in the 1960s, I helped pay my way through university by writing abstracts for Derwent's MedDoc system. Then came a PhD in Canada, and a Lectureship in Pharmacology at Manchester University. In response to an advertisement I started medical writing in my 'spare' time, before joining Gardiner-Caldwell Communications as Senior Medical Writer in 1992, then to Medical Action Communications as head of a medical writing team (1999). When they made most of the writers (including me) redundant and after a short spell with another agency in London, I set up as a freelancer writer in 2001.

What is your most important piece of advice for people setting up a new business?
Be an expert in the services you offer.

What do you like about being a freelancer?
The freedom to work at the pace I want, at the time I want, and to be able to manage my work so that I can go out and play whenever I want (usually!).

What do you dislike about being a freelancer?
Nothing really, except for clients who don't pay their invoices on time.

What are your main sources of work?
Medical communications agencies.

What are the most rewarding projects to work on?
The projects I enjoy most are being asked to advise on communications strategies, facilitating and chairing meetings (e.g. Advisory Boards), and teaching workshops for the pharmaceutical industry. These are also the most financially rewarding types of projects as clients are prepared to pay well for my knowledge and experience.

What are the least rewarding projects to work on?
Copy editing, and rewriting papers written by other writers for resubmission to journals after rejection.

Do you have a preferred type of client? If yes, why?
Without a doubt the best clients are those who discuss everything before you accept the project, provide good unambiguous briefs and have efficient review processes. And who pay invoices on time!

What is the best way to say 'No' to clients?
When I set out as a freelancer, I set myself one golden rule—never refuse work from a new client (unless it was outside my area of expertise). This has worked well and has given me a reasonably broad client base. Most of the 'new' clients I have worked for have become 'established' clients; I feel quite comfortable telling an established client that I don't have the capacity to take on their projects, knowing that they have been satisfied with my work in the past and will probably come back to me in the future. Occasionally, though, I have made the mistake of taking on work when I didn't really have the capacity, as a result of which quality has slipped, and I have consequently disappointed a few clients.

Would you ever consider working for a company (again) as a fulltime employee? If yes, why?
I am quite content to be winding down in order to enjoy my retirement, but yes, I would accept a position working for a company as a fulltime employee. The job would need to be a particularly challenging one, such as setting up a medical writing department or changing the internal culture of a medical writing department—something that would stretch my knowledge, experience and skills to their limits. However, the offer would have to be very special with an enormous salary.

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