EMWA European Medical Writers Association

The Write Stuff

The Journal for European Medical Writers

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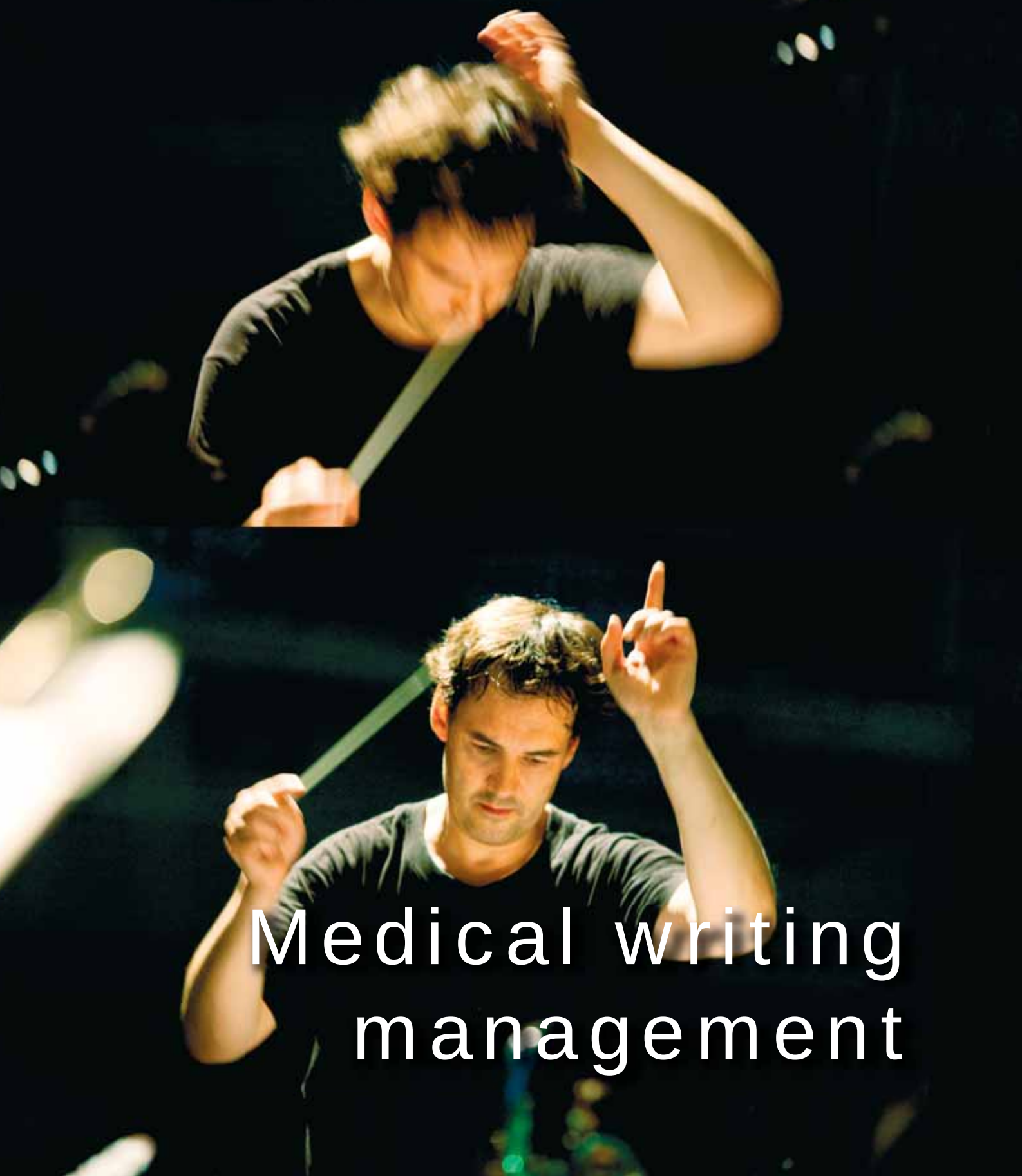

Medical writing management

Journal insights

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

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Instructions for contributors

- The *Write Stuff* typically publishes articles of 800–2500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and e-mail address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by e-mail as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.

Timelines

Month distributed	**Deadline for receipt of articles**
March	28th November
June	13th February
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December	3rd September

Advertising rates

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Behind the press

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The *Write Stuff* is printed on 100% recycled paper.

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Freelance Section

Cover photograph

The French conductor and composer François-Pierre Descamps at the rehearsal of one of the 10 operas and 2 pantomimes from the project "1001 night" by the company SireneOperntheater in August and September 2011 in Vienna, Austria.

www.sirene.at

More photos from the opera can been viewed at http://gallery.me.com/nadja.meister

Cover photograph from Nadja Meister (nadja.meister@inode.at)

Graphic design on pages 230, 231, 237, 239, 241, 247, 256 and 257 by Anders Holmqvist (adobild@yahoo.se)

Regular features

From the Guest Editor's desk

Management in medical writing

by Phil Leventhal

Even if you are not a manager, management is something you need to deal with in one way or another. We all must manage medical writing projects, and sometimes we are called on to manage people in a multifunctional team. All medical writers, including freelancers, should therefore have clear ideas on how to manage people in a way that moves projects forward rapidly and effectively. Managers in a company setting, of course, have many additional responsibilities, such as staffing, strategic planning, and financial and resource planning. From experience, we all probably have a sense of what good management is, but this special issue of *The Write Stuff* takes some of the guesswork and intuition out of what this entails.

Painting of Mencius, a Chinese philosopher born in 372 BCE. After Confucius, he was probably the second-most important philosopher in Chinese history. He believed in the inherent goodness of people and that "the most important asset of a state or organisation is human capital" [1].

Source: http://www.wikipedia.org

The basic principles of good management have been known for millennia. Mencius, a Chinese philosopher born in 372 BCE, wrote that "the most important asset of a state or organisation is human capital" [1]. More than that, he believed in the inherent goodness of people. This is a great place to start to understand management…even if some companies or managers do not act on this basis or have not considered what this implies.

The idea of a special issue on management in medical writing came about through discussions that I had with my father, Roy Leventhal. After over 50 years of experience as an employee and manager in different companies, he has useful insight about what makes for good management. In his article, he advocates empowering employees by creating a bottom-up problem-solving system (page 216). This kind of empowerment gets the most out of employee expertise, maintains their motivation, and adds value to the company.

Diarmuid De Faoite (page 222) adds to this theme of motivation. In his article, he explains how ideas of motivation have evolved since the early 20th century from considering employees as machines motivated exclusively by a desire for high wages to the more modern view that a desire for self-fulfilment drives motivation.

Collaboration is a management word that we hear a lot when working on team projects. Barrie Dubois, an organisation specialist in the Silicon Valley area of California, explains what collaboration really means and how to foster it (page 219). She explains that sustainable collaboration implies not acquiescence but conflict, and she provides tools for creating an environment where these conflicts can be quickly resolved.

Two articles in this issue discuss what a medical writer needs to know to become a manager. Martin Robinson, Principal Director at the International Academy of Clinical Research (page 225) writes that being a good writer does not imply that you will be a good manager. Becoming a good manager requires getting out of your 'comfort zone' and learning a completely new set of project and people management skills. Virginia Watson, Company Director of Dulcamara Ltd., discusses what she learned from many years as a manager in multinational corporations (page 227). Like Martin Robinson, she emphasises the need to learn new skills, and she breaks these down into three areas: operations, personnel and strategic.

To learn about managing a medical writing agency, *The Write Stuff* interviewed Julia Forjanic-Klapproth, Senior

Partner and CEO of Trilogy Writing & Consulting and former president of EMWA (page 229). Julia's advice and experiences are of great value not only to EMWA members wanting to start their own companies but also to medical writing agencies and departments wanting to make improvements in their management style.

Much information about managing can be found on the Internet. Fortunately, Karin Eichele has already sifted through the mass of information. In this issue of Webscout (page 244), she describes and gives links to five excellent websites providing advice and tools to help managers communicate effectively and get the most from their teams.

After reading these articles, I came to the same conclusion as Mencius: people are a company's greatest asset. Good management means trusting people and giving them the opportunity and encouragement to contribute. This issue of *The Write Stuff* should help medical writers make several steps in the right direction.

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Reference:

1. Rarick CA. Mencius on management: managerial implications of the writings of China's second sage. Journal of Comparative International Management 2008;11:55-61.

What else is there in December's *TWS*?

As usual there is a lot more! Everybody is talking about it but few are experts. We are fortunate to have two feature articles from Julia Cooper and Alison Rapley that discuss the new Development Safety Update Report (DSUR). These articles will be followed up in 2012 with an article on the practical experience gained in the meantime in writing DSURs. Regulatory writers will also find the article by Maria Fernandez-Piera on answering regulators' questions useful, not to mention Greg Morley's regular column for regulatory writers on page 260. He elaborates on questions that have popped up on EMWA's LinkedIn discussions concerning review cycles for regulatory documents and the amount of work needed to write a clinical study report. Manuscript writers will find their questions on how to select a manuscript answered in Phil Leventhal's manuscript writers' corner. Keep a lookout also for some research which will help you select your target journal for vaccine papers in our next issue of the journal.

Ursula Schoenberg writes about some tricky terrain on page 240. She discusses the specific challenges that patients, physicians, healthcare companies and regulators face when interacting via the Internet. Ursula has agreed to become the journal's social media editor so we can look forward to more articles informing us about this important area for medical writers in future issues.

Ghostwriting is the topic of the Journal Watch column and by the time you read it you will have received a request from Adam Jacobs to participate in a ghostwriting survey. I hope you complete the questionnaire because it's important that EMWA collects data so that we can deal with facts rather than suppositions in this critical debate.

Life coaching, writing an annual family report (appropriate because it is Christmas round robin time again) and the last in a series of interviews about going freelance can be found in the Freelance section as well as two fun items: a medical writing puzzle to tease your brain and a competition to match samples of some pretty terrible handwriting to 'well known' writers at EMWA.

I always enjoy the book reviews in the journal and will certainly be buying the 'worrying' book Alison McIntosh reviews on page 245 It always amazes me that we think things will go on as they are. Changes in morals and politics often creep up on us when we are not listening. It only needs the first domino to fall and a process becomes unstoppable.

The translation section has taken a break for this issue but will be back with us in March. The first article in a new series of articles on clinical pharmacology will also be published in the March issue (see announcement on page 231).

Take a rest from all the doom and glum in the general media and enjoy reading *The Write Stuff*—as well as a few mince pies or whatever—this Christmas. EMWA continues to move forward. EMWA's 34th conference in London in November showed that EMWA is heading towards an optimistic 2012. We have new members, a new proactive head office and a new look for the next issue of the journal and there is Cyprus (see back cover) to look forward to in May too.

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Message from the President

2012: 20th Anniversary

by Rita Wellens

The 33rd EMWA Conference, which took place on 3rd – 4th November in London, welcomed 43 new EMWA members. About 250 delegates participated in this energising meeting and enjoyed 24 workshops.

It was a truly international gathering with delegates from—in alphabetical order—Austria, Belgium, Denmark, France, Germany, Greece, Israel, Italy, Japan, Norway, Spain, Sweden, Switzerland, the Netherlands, United Kingdom and United States of America.

As previous presidents have emphasised, key to the EMWA spirit is pooling knowledge and providing a generous forum to medical writers to further the medical writing profession. These positive vibes definitely resonated throughout the London conference—thank you all for honouring the EMWA spirit and for making it happen. Thanks are also extended to EMWA's new head office, Kingston Smith Association Management, for the impeccable organisation of this event.

I mentioned during my welcoming speech in London that our upcoming spring conference on 14th - 18th May 2012 in Cyprus will be quite spectacular. Not only because of its extensive workshop programme, international selection of plenary speakers, paediatrics theme and location near one of the most beautiful beaches in the world—but also because it will mark EMWA's 20th anniversary.

To be precise, 21 February 2012 will commemorate that twenty years ago on that exact date, 32 EMWA visionaries met for the first time in Brussels, Belgium. This represented EMWA's all-in-one first meeting and spring conference. It did not yet feature a workshop programme but consisted mainly of brainstorming sessions on how to form a permanent group of medical writers in Europe. I refer the history buffs to the *TWS* archives, namely to the 10th Anniversary issue published in 2008 (vol 17 (1) pages 9-11), for the full details. This article entitled 'The history of EMWA: Personal (and possibly unreliable) recollections' gives a lively history of EMWA's fledgling years, founding veterans, growing pains, heroic feats and glorious achievements. I highly recommend this heart-warming account written by the late Geoff Hall, beloved EMWA founding father, vice-president and Nick Thompson awardee.

As part of our 20th jubilee celebrations, yours truly Executive Committee (EC) is putting together a festive sponsorship package and will soon also appeal to your goodwill to join in a membership drive. Don't be selfish; share EMWA with a colleague!

On another note, this issue of *The Write Stuff* will be the last *TWS*—part of EMWA's transition to 2012 will include a change in name and publisher. Maney Publishing will become our publishing partner and *TWS* will continue as *Medical Writing*.

My head is spinning, much to get organised and to look forward to in 2012. I wish you a joyous, happy and healthy 2012 and may all of your medical writing endeavours be successful.

All the best

Rita Wellens
EMWA President

The Write Stuff's relaunch as *Medical Writing*

This issue of *The Write Stuff* marks the end of an era. The journal, originally called the *EMWA Newsletter*, was first published with the title *The Write Stuff* in the summer of 1998 when medical writing was in its infancy as a profession. In the meantime medical writing has flourished with ever growing numbers of experts working as medical writers or in related fields of translation and editing. To open up the association's journal to a wider community of readers engaged in medical writing in academia or for the pharmaceutical industry it needs to join a health science 'stable' of scientific journals and take advantage of the promotional apparatus that such a specialist publishing house can provide. From the first issue of 2012 in March *The Write Stuff* will be published as *Medical Writing* (*MEW*) by Maney Publishing (www.maney.co.uk/journals/mew). As before it will be owned by EMWA and received by members as a benefit of membership.

EMWA would like to take this opportunity to say a big 'thank you' to Ziga Arh who has published *The Write Stuff* for EMWA throughout the last 9 years. Ziga's invaluable expertise and support has helped the journal progress to the successful journal that it is today, placing it in a position to take its next step forward. He has been accommodating and patient, has never missed a deadline and brought creative ideas to the table, in sum, a joy to work with. Thank you, Ziga.

Call for papers: share your expertise

Articles: long (1000-2500 words) and short (100-1000)

Are you a medical writer, translator or editor working in **paediatrics** or **diabetes/obesity**? These topics will be covered by *Medical Writing* (*MEW*) in 2012. Do you have expertise in any of these fields that you would like to share with colleagues? Add to your CV and increase your media exposure. *Medical Writing* would welcome an article from you!

Articles and short reports on the following topics are also accepted for publication:

- Regulatory matters
- Medical statistics
- Medical communications
- Publication ethics
- Medical translation
- Social media
- Manuscript writing
- Medical writing freelancing
- Language, grammar and style
- Working as a medical writer

And if you can think of any **other** subject that would interest fellow medical writers just let *MEW* know about.

Book reviews: Have you read a book that you would like to review? Or do you know of a book you would like to review that *MEW* could acquire for you?

Letters to the editor: Do you have an opinion on an article you have read in the journal or about EMWA? Send a letter to the editor.

Please send articles, book reviews, letters to the editor and suggestions for articles or future issue themes to the editor at editor@emwa.org.

Themes of upcoming issues of *TWS*

The theme of the **March 2012** issue will be **Medical writing in oncology.** Other upcoming themes for 2012 are **Paediatrics, Writing matters** and **Diabetes/obesity.**

Call for nominations for upcoming Executive Committee positions

EMWA is an organisation run for its members and by its members, and we actively encourage and seek out participation from all our members. We are now looking for members to run for election for the following Executive Committee positions:

- **Vice-President**
- **Conference Director**
- **Website Manager**

Have you ever thought about getting involved in EMWA 'behind the scenes'? Would you like to help manage our rapidly-growing association and be involved in deciding how we move forward in the next two years and beyond? If so, here's your chance! As an Executive Committee member you would know everything that's happening at EMWA, make many new contacts in the medical writing field, learn useful management skills, receive free registration, travel expenses and 2 nights' accommodation at EMWAs biannual conferences during your term of office, receive great exposure for your company or freelance activity, and significantly improve your CV!

If you're interested and would like to know more about these upcoming Executive Committee positions, please contact: Rita Wellens (president@emwa.org), Susan Batti (vicepresident@emwa.org), Sarah Choudhury secretary@emwa.org, Sunethra Wimalasundera (conferencedirector@emwa.org) or Shanida Nataraja (webmanager@emwa.org).

Getting the most from your staff through empowerment

by Roy G. Leventhal

Companies often fail not because they lack good products or services but rather because they remain rooted in the past. Companies that survive over the long-term do so by avoiding major mismanagement problems and by innovating to stay ahead of their competitors.

What differentiates successful from non-adaptive companies? Instinctually, we all know the difference. Many of us have worked for companies that have failed. In dysfunctional companies, problems fester and opportunities are missed because of an inability or lack of desire to fix problems and make improvements. Time is lost and the quality of the products and services suffer. When this happens, employees become demoralised and unproductive. On the other hand, in effective organisations, employees and management work together to efficiently deliver products or services. Although communication may not be perfect, it is at least effective. Most importantly, the employees matter.

A common characteristic of well-run companies is employee empowerment

A common characteristic of well-run companies is employee *empowerment*. Empowerment means giving employees the opportunity, responsibility, resources and motivation to solve problems and make improvements. Empowered employees are employees that excel.

Employee empowerment provides several benefits. For the company, empowerment results in bottom-up improvement and innovation of products plus services. Empowerment also reduces communication problems, saves time, and cuts costs. For employees, it means improved job satisfaction, self-determination, and a real chance to contribute.

Employee empowerment requires putting into place a bottom-up problem-solving and a top-down project vetting system (Figure 1). In bottom-up problem solving, instead of having solutions handed down 'from above', solutions arise organically from the people most directly affected by the problems. Problems are identified and solutions are refined into a coherent plan with support of the manager. The plan is then reviewed and vetted by management, that is, they are provided resources and officially given management support. This system focuses organisational energy and avoids a random approach to problem solving. The system is not complicated, but it does require commitment and follow-through from both employees and company leadership.

Step 1: Identify problems or opportunities for improvement

Deal with problems and complaints professionally

People often complain about problems at work. Too much complaining can create a negative environment for everyone, and without an organised solution, problems get worse and employees become demoralised.

The first step in employee empowerment is a professional and effective response to a complaint or problem. Whatever the complaint or problem, the supervisor's response should be some version of the following:

> *"You were hired as a professional. As a professional, you need to help find a solution to this problem. Go think about what needs to be done to fix it and come back with some concrete ideas, or explain how you would do things differently if you were running this company."*

Such a response empowers employees. It shows that you respect them as professionals, and it encourages them to be part of the solution.

The first step in employee empowerment is a professional and effective response to a complaint or problem

Sometimes, you, the supervisor, may find a problem. You can start the problem-solving process by diplomatically pointing out the problem to your direct reports and asking for their professional input to help solve it.

Detect problems and opportunities for improvement early

Early problem detection helps keep problems from getting worse and can help the company come up with innovative products and services. Early suggestions of new ideas can be facilitated in several ways:

- Hold regular one-on-one meetings with your direct reports
- Hold regular group meetings
- Have an open-door policy and respond to issues quickly
- Write clear communications to your direct reports
- Budget time to discuss problems and opportunities
- Determine whether the new idea is good for customers, employees, and the company

Step 2: Define the problem or opportunity and develop alternative solutions

Work together with your direct reports to precisely identify the problem and its source. This will help identify a solution. Sometimes, the source of the problem is complex and difficult to identify. Remain professional and do not assign or allow your direct reports to assign blame.

Be supportive

Employees should feel that they have your and the company's support to come forward with complaints or ideas. Give your direct reports the time, resources, and whatever help they need to come up with solutions. Make your direct reports aware that identifying problems and making improvements are part of their jobs. Remember that proactively solving problems and implementing improvements will help save or make the company money.

Make direct reports aware that identifying problems and making improvements are part of their jobs

You may feel that some of your direct reports complain excessively, have impractical ideas, or have complaints that are not really work-related. Asking them to act professionally, having them participate in the problem-solving process, and helping them to come up with practical solutions will transform them from complainers into problem-solvers and innovators.

Step 3: Create a credible plan to solve the problem

Create a detailed plan to solve the problem or implement the improvement

Once the problem has been clearly identified, involve your direct reports in a careful planning phase. This is your chance to act as a mentor. Carefully coach your direct reports to create a well thought-out, detailed proposal. The plan can include:

- The description of the problem
- Detailed descriptions of the alternative solutions
- The time needed for the proposal, including extra time for dealing with the unexpected
- The resources needed for the proposal
- A time line for putting the plan into place
- Measurements to quantify progress and return-on-investment
- Explanation of how the idea will benefit the customers, employees, and the company
- Mutual planning and commitments with other departments that need to provide plan inputs and will be affected by the plan

Make a plan that helps your direct reports look good

Show that you expect your direct reports to be professional and to make contributions. Ensure they know you will back them up. The goal is to create a plan that makes your people look good, is accepted by the company or management, and adds to the company's bottom line. Also ensure that the plan is well thought out and practical because it will reflect on both you and your direct report. Mutual planning creates individual and organisational buy-in. Lastly, put your employees in charge of the implementation. You will create real champions for getting the project done.

Step 4: Obtain management support

Present the project to management for their approval and support. Management is responsible for controlling and allocating resources. Their active authorisation and support is usually crucial to the success of a project. This way, new ideas are developed bottom-up and managed top-down. The organisation then operates as a team.

Step 5: Implement and follow up on the plan

Implement and follow up on the plan

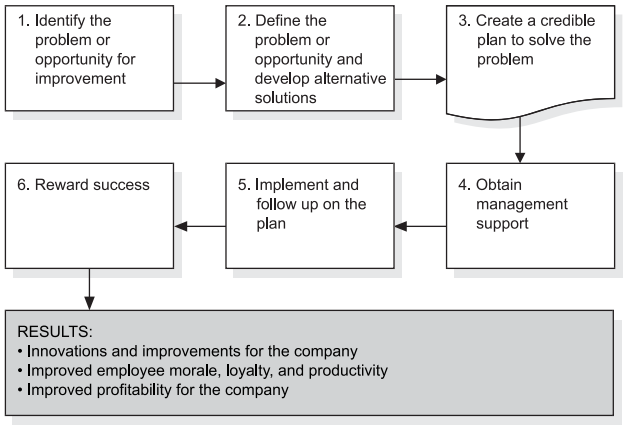
Let your direct reports know that they are personally responsible for implementing and following up on their plan. Require that they report back to you about their progress, outcomes and adherence to time lines. This will show them that you are serious about problem solving and innovation, and it will add emotional investment to the problem-solving system.

Stick to the plan

Insist that you will be sticking to the plan as much as possible. This will encourage detailed thinking and planning as well as commitment from the employees. Detailed planning also should imply that the plan will be met without extraordinary effort and without substantially more time or resources than originally envisioned. Successful plans will build credibility and trust between you and your direct report.

Successful plans will build credibility and trust between you and your direct report.

Figure 1. How to bring about employee empowerment



Getting the most from your staff

Allow room for adjustment

Although you should hold your direct reports accountable, remember that even the best-laid plans can go awry due to unexpected circumstances. If that happens, be careful to not assess blame and simply adjust the plan as necessary.

Step 6: Reward success

An essential part of the problem-solving and employee empowerment system is rewarding and recognising employees for positive contributions. These rewards can come in many forms, some of which cost the company little but go a long way to encouraging employees to participate in the problem-solving system and in their own empowerment. Rewards can include:

- Simply putting the plan into place
- Personal thanks from you or company leadership
- A chance to tell the story of success or lessons learned. This could include an article (e.g. for *Medical Writing*), a company-wide presentation, or a presentation or poster at a conference. An article or presentation at a conference can be beneficial to not only the employee but also to the company, which will be recognised as fostering innovation.
- Recognition of contribution in a company-wide e-mail or announcement
- Training, attendance at conferences, and other chances to improve skills and knowledge. Again, this can be beneficial not only to the employee but also to the company.
- A bonus or raise
- A promotion

Conclusion

Empowering employees means giving them the opportunity, responsibility, resources, and motivation to solve problems. The problem-solving and employee empowerment system is not complicated but requires commitment and follow-through from employees, managers and company leadership. Everybody benefits from this system: the company from optimised processes and innovative products and services; and employees from the knowledge that they are valued. Success in making innovations and improvements will transform frustrated employees into trusted and loyal colleagues with a vested interest in the company.

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Word order challenge

In September's *TWS* ('Prepositions and their role in Abba's downfall', pages 157-158, vol 20, No. 3, 2011), Neville W Goodman described how he was asked at the age of 11 years to answer the following question in an English exam: "write a single sentence composed of parts of speech in the order given". The order given was preposition, adjective, common noun, pronoun, verb, proper noun, adverb, and finally adverb. Neville suggested that readers of *The Write Stuff* might like to attempt to answer the question. Alistair Reeves submitted the following answers:

Preposition	Adjective	Common noun	Pronoun	Verb	Proper noun	Adverb	Adverb
With	due	caution	he	climbed	Everest	very	slowly
In	long	conversations	she	got to know	Queen Elizabeth	awfully	well
On	good	advice	we	quit	Paris	pretty	sharpish
After	many	years	he	knew	Roget's	inside	out
With	copious	alcohol	you	can entertain	the Viennese	quite	royally

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Neville Goodman's comment on Alistair's answer

Number 1 is fine. Number 2: compound verbs (and nouns) were not allowed. Each sentence was to be composed of eight words. Number 3: I was tutored for the exam, and I know that my tutor (in 1959) would have slapped my wrist about quit and sharpish: they are grammatical but poor style. Number 4: hmmm—interesting: Roget's as a contraction for Roget's thesaurus (that's a figure of speech, a syzygy or something). Number 5: again a compound verb, and where did that definite article come from? If they'd wanted a definite article, they would have asked for one!

Number 1 is excellent, because it has the correct parts of speech and makes good sense. I don't know how I answered the question in 1959, but my example is "At first attempt he beat John really well."

Neville W Goodman
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Fostering collaboration

by Barrie Dubois

Everybody talks about collaboration. We all say that we collaborate, and we all work with collaborators in multi-functional teams. Collaboration is promoted as critical in business because the problems and organisational structures are more complex than ever; people with different perspectives and from different functional, cultural, regional, and international backgrounds must come together to get things done.

So, what is collaboration? How can it be developed and maintained by a group or project manager?

Some definitions: Collaboration is not the same as cooperation

Cooperation is when people willingly and voluntarily help each other out to accomplish something. The issue, programme, or project on which they are working is generally simple and straightforward, and it is rather obvious what is needed from all parties. Cooperation may involve a group of individuals who are not part of a team or it may involve a work group in which members do not directly depend on each other. There is low risk, and a high level of trust between participants is not required. People develop their own ideas and share them. There is joint discussion, but the focus in cooperation is on individual actions and ideas. Cooperating team members help each other to get jobs done, but all are focused on their specific needs and goals. In cooperative situations, 'being nice' is generally a high priority.

Conflict is part of a collaborative environment

Collaboration, on the other hand, occurs in teams or work groups where there is inter-dependency. That is, unless things are done together, nobody will be successful, and the project will fail. Collaboration often implies that people of different backgrounds, different functional expertise and perhaps different geographies or cultures have been pulled together by someone else to accomplish something. Collaboration requires subordinating individual goals for the good of the whole. It also involves risk-taking. This will not happen successfully unless there is significant trust amongst the individuals because it requires engaging in tough and often emotional trade-offs and often working in ways that are new or uncomfortable.

Conflict is part of a collaborative environment. Conflict is necessary to bring out and bring together the best ideas and knowledge from a diverse group of individuals who often have different priorities, agendas, and perspectives. In other words, cooperation implies getting along and helping each other accomplish individual goals or tasks, whereas collaboration implies problem-solving and risk-taking, and it means putting aside individual goals to complete a project.

There are four main components that underlie sustainable collaboration:

- Trust between team members
- Clear criteria on which to base decisions
- Defined decision-making responsibilities
- Alignment in decision making

Trust is essential for sustainable collaboration

True collaboration implies a personal commitment from and the emotional investment of each team member. Of course, such personal involvement creates the probability of conflict and debate, but conflict and debate are essential for finding solutions to complex problems. The most innovative solutions require team members to suggest and debate different options and to sometimes make difficult decisions or compromises. Team members therefore must have the opportunity and willingness to test their opinions against the opinions of others, otherwise they will likely agree without feeling any personal responsibility. They will also be less likely to be supportive and may actually sabotage others' efforts. These problems are amplified in teleconferences where body language cannot be read.

Key to successful conflict and debate—and therefore problem solving—is trust between team members

The key ingredient in successful conflict and debate—and therefore problem solving—is a high level of trust between team members. Without trust, healthy conflicts and collaborative teamwork are impossible.

Developing trust requires that team members know each other. They must consider each other reliable and credible, and they need to respect each others' motives. Establishing these components of trust is best done in person, but, admittedly, this is not always possible. >

Fostering collaboration

> To develop and maintain trust, have team members take the time to learn about each others' professional skills, strengths, interests, and needs at the kick-off meeting or when a new member joins the team. Having team members know each other does not mean that team members need to be friends; rather, the members need to have enough respect for each other to be able to have constructive conflicts and debates. Focus on building the three main components of trust: reliability, credibility, and motivation.

The three main components of trust

Trust component	Definition	How to develop or encourage
Reliability	Team members need to believe that the other members will do what they say and when they say the will do it.	Can only be established with time, but can be encouraged through various measures, including being clear about expectations up front, keeping notes on what commitments were made by whom and holding people accountable.
Credibility	Team members need to trust that the other members have the skills, temperament, connections and knowledge to do the work.	Give team members the opportunity to introduce themselves at the kickoff meeting or entry into the team. Members should give a brief summary of work experience, highlight related experience, describe what they can bring to the team and explain where they might need extra support from the team.
Motivation	Team members trust that you are doing things for the right reasons.	Give team members the opportunity during an introduction to explain their motivation for being on the team and what they expect to accomplish. Also, give team members the opportunity to explain their reasons for certain statements or decisions during the course of the project.

When trying to establish trust or when trying to diagnose what is wrong in dysfunctional collaborations, focus on the three main components of trust. As a manager, you can intervene and have a specific discussion with individual team members or between team members in which they explain how they feel about the others' reliability, credibility and motivation. This helps the team identify specific ways to repair trust and therefore improve the collaboration.

Setting criteria for decision-making speeds conflict resolution

Clashes between team members are the cornerstones for developing innovative solutions and making wise trade-offs among competing objectives. Resolving conflicts requires providing team members with clearly stated criteria for making decisions, including the goals, timelines, and all other non-negotiable aspects of the project. In a writing project, for example, this may also include the target publication or agency, the audience, the data and main discussion points to be presented, and legal or regulatory guidelines or rules.

Establish these decision-making criteria early, such as during a kickoff meeting. When everyone has a set of clear, measurable criteria against which decisions are made, conflict can easily be resolved or avoided. Each suggestion or approach is evaluated against the criteria to determine the best way to go. This accelerates the completion of the project. In the example of the writing project, an early decision on the target publication can determine the length, format, content, and target audience, avoiding or immediately resolving later disputes about what to include or exclude in the publication.

Without clear decision-making criteria, people do not know what the right end result should be or how to achieve it. Often, they will avoid or work around conflict, forgoing important opportunities to collaborate, or if they decide to confront differences, they may end up wasting their time debating about who's right and who's wrong, fighting over small details, or playing the role of victim. The result is often a suboptimal solution, deadlock or even sabotage, and it can greatly delay the project and affect its quality.

Defined decision-making responsibilities ensure a smooth collaboration

Defining decision-making responsibilities is another critical aspect of developing and maintaining sustainable collaborations. Without defined responsibilities, decisions and projects can be delayed and the quality of the work can suffer. For a writing project, for example, defining who is responsible for managing each review cycle, who is responsible for reviewing each draft, and who makes the final decision on content avoid the common problem of never-ending cycles of review and rewriting. Like decision-making criteria, clarify decision-making responsibilities early in the project, such as during a kickoff meeting.

RACI charting is a simple tool that can help clarify responsibilities [1]. It involves making a grid or matrix in which each person and each task is assigned one of the following single-letter codes:

- R - Responsible for (there can be multiple R's for each responsibility)
- A - Primary Accountability (there can only be one A for each responsibility)
- C - Should be consulted before an action or decision
- I - Should be informed after an action or decision
- X - No role

An example of a RACI chart for a writing project is shown in Figure 1.

Alignment allows projects to move forward to completion

Alignment is a tool or term that enables teams to resolve difficult conflicts. Alignment is not the same as agreement. When the team members agree, they each feel that the final decision was their first choice, whereas when team members are aligned, they can say, "although it may not be my

Figure 1. An example RACI chart for a writing project

	Project manager	Writer	Statistician	Investigator 1	Investigator 2	Vice president of research	Patent Lawyer
Collect background information and data	R	I	X	X	X	X	X
Communicate with contributors	R	X	X	X	X	X	X
Collating comments	R	I	X	X	X	X	X
Statistical analysis	A	I	R	X	X	X	X
Writing and rewriting	A	R	X	C	C	X	X
Review first draft	R	I	X	R	R	X	X
Review second draft	R	I	X	R	R	X	X
Review final draft	R	I	X	R	R	X	X
Final approval	A	I	X	I	I	R	R
Submission	R	I	X	I	I	A	I

Abbreviations: R, responsible for; A, primary accountability; C, should be consulted before an action or decision; I, should be informed after an action or decision; X, no role

first choice, I can accept the decision." This means that the team needs to decide which issues must be agreed on and which simply must be aligned. For example, for a writing project, whether data are presented as a line graph or histogram would be an alignment issue because the project can be submitted either way, while whether a major discussion point is included may require agreement between all parties. Generally, few decisions require agreement and, instead, alignment is what is needed to resolve conflicts and complete a project.

Conclusion

True collaboration is difficult. It requires subordinating individual goals to larger, collective ones; it requires having tough, emotional give-and-take discussions; and it often leads to working in ways that may not be comfortable or easy. Trust is essential. Establishing clear decision-making criteria and responsibilities and understanding the role of alignment helps maintain a collaboration and speeds conflict resolution.

When collaboration does happen, it produces stunning and streamlined results. When teams collaborate, decision-making is faster, costs are reduced, timelines are shortened, and innovation is encouraged. The disagreements sparked by differences in perspective, competencies, access to information, and strategic focus generate much of the value that can come from collaboration across organisational boundaries. So in spite of the difficulties in achieving collaboration, the pay-offs of true collaboration are well worth the effort.

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Shop sign in Kathmandu

What classic and modern business literature has to say about motivation—And how you can apply these theories to your own life

by Diarmuid De Faoite

What gets you out of bed in the morning? Is it the lure of money? The sense of satisfaction that comes from a job well done? An inexplicable need to correct manuscripts? It can be hard to identify what it is that gets you going, and these motivating factors may change as time goes on—as you get older and also as your career progresses.

Over the past 100 or so years as industrialisation changed the working landscape of many countries and work itself became a more abstract task, a slew of experts, often with a background in psychology, dedicated themselves to forming theories of motivation in the workplace.

Knowledge of motivational theories can help both the freelance and contracted medical writer (and those who manage them of course!) to focus on the areas that will assist them in reaching their goals.

Frederick Winslow Taylor's Scientific Management Theory

Frederick Winslow Taylor's Scientific Management theory may be known to you due to his *time and motion* studies. He believed that by breaking down tasks into manageable bites, workers (generally characterised as lazy and stupid) would learn how to do one repetitive task in the most productive way, a view that still finds resonance on assembly lines today. He wrote in 1911, "What the workmen want from their employers beyond anything else is high wages…" [1]. However, he is much criticised for ignoring the human aspects to work.

Implications:

Are there any regular tasks you do that you could schedule to do together? Although they may be boring, there is certainly time to be saved by doing it all in one go rather than, for example, collecting documents and opening up computer programs in a piecemeal way.

Although important, don't overly focus on monetary rewards to motivate your workforce.

Frederick Herzberg's Two Factor Theory and Elton Mayo's Human Relation School

Taylor's view was also criticised by the psychologist Frederick Herzberg who invented the Two Factor Theory [2]. Herzberg proposed that people are influenced by two sets of factors, which he divided into the categories of motivating and hygiene.

- **Typical motivating factors:** achievement, recognition, work itself, responsibility, promotion, growth.
- **Typical hygiene factors:** pay and benefits, company policy and administration, relationships with co-workers, supervision, status, job security, working conditions, personal life.

Hygiene factors, which are job-related, do not motivate, but if they are not present, they will lead to dissatisfaction. Motivating factors will drive employees on to better performance.

Herzberg also believed employees could be motivated by improving the actual job itself through job enlargement, enrichment, and empowerment.

Elton Mayo's Human Relation School was also an attempt to redress Taylor's neglect of the worker by focusing on the human side of employment. He believed that the need to work in groups motivated more than pay [3]. Managers therefore took an interest in the welfare and opinions of their workers. You may know of the "Hawthorne Effect" which was identified in studies he conducted at the Western Electric Company in Chicago [3]. In a nutshell, he discovered that it was the group which decided the pace at which work would be conducted and not other stimuli such as lighting or working conditions. A group sends out verbal and non-verbal clues to get new members to work at the same pace. Mayo concluded that workers are best motivated through better communication, greater manager involvement, and working in teams or groups.

Implications:

Paying attention to hygiene factors help to stop a downward slide among employees' morale, while the motivating factors will be the engine for increased productivity and a satisfied workforce.

If you are taking on a new job, make sure that the hygiene factors at a minimum are in place and then look for motivating factors. Identify the opportunities for job enlargement, enrichment, and empowerment.

Try to interact with people as much as possible. This is especially valuable if you are a freelancer working on your own and are somewhat isolated. If possible, meet face-to-face with clients rather than relying on e-mail. If you can't meet, then phone if possible.

Motivation: What classic and modern business literature has to say

Abraham Maslow and the Five Levels of Human Needs

Abraham Maslow focused on the psychological needs of employees with his theory that there are five levels of human needs that must be satisfied for employees to feel fulfilled at work [4]. The needs are arranged into a hierarchy, and people are motivated to work their way up the pyramid until they reach the highest level of self-actualisation. Each layer of need has to be met before the worker is motivated to move up to the next highest level (Figure 1).

As you can see from the diagram, Maslow believes in the meeting of basic human needs (e.g. food and security) before more emotional needs are addressed. However, one criticism of his hierarchy is that life does not always follow such a neat linear path. For example, everyone has to eat and sleep every day. How does this affect them from achieving self-actualisation? Contemporary author Daniel H. Pink sees a direct link to achieving Maslow's self-actualisation in actions like Google's allowing employees to devote 20% of their time to projects that interest them [5].

Implications:

Applying this theory, businesses should offer different incentives to workers in order to help them fulfil each need in turn and progress upwards. A further consequence of this theory is that workers may be at different levels in the hierarchy and therefore require different incentives to motivate them. Managers should therefore be careful to not offer a 'one size fits all' approach to incentives.

Recent contributions to motivation theory

These theories are of course well-established and can be found in any business textbook. If you want a quick and modern jolt to motivate yourself, the current hit is Timothy Ferriss and his best-selling book, *The 4-Hour Workweek: Escape 9-5, Live Anywhere, and Join the New Rich*.

He espouses fixes such as outsourcing your life (e-mail correspondence etc.) to overseas virtual assistants for $5 per hour, leaving you free to do whatever you want (e.g. setting up companies to resell goods at a higher price or to dance the tango in Argentina). Not surprisingly, he has as many detractors as admirers.

As you may imagine, there is a gap between managers' and employees' perception of what motivates employees. A *Harvard Business Review* article [6] reported on the results of a survey in which 600 managers were asked to rank the impact on employee motivation and emotions of five workplace factors commonly considered significant: recognition, incentives, interpersonal support, support for making progress, and clear goals. The top rated answer was 'recognition for good work'.

But what did the workers themselves say? Analysis of their daily ratings of their motivation and emotions along with almost 12,000 diary entries showed that making progress in work, even if it is only a small amount of progress, is more frequently associated with positive emotions and high motivation than any other workday event. Managers can obviously calibrate goals (or break them up into more manageable chunks) to allow employees feel that they are making headway. >

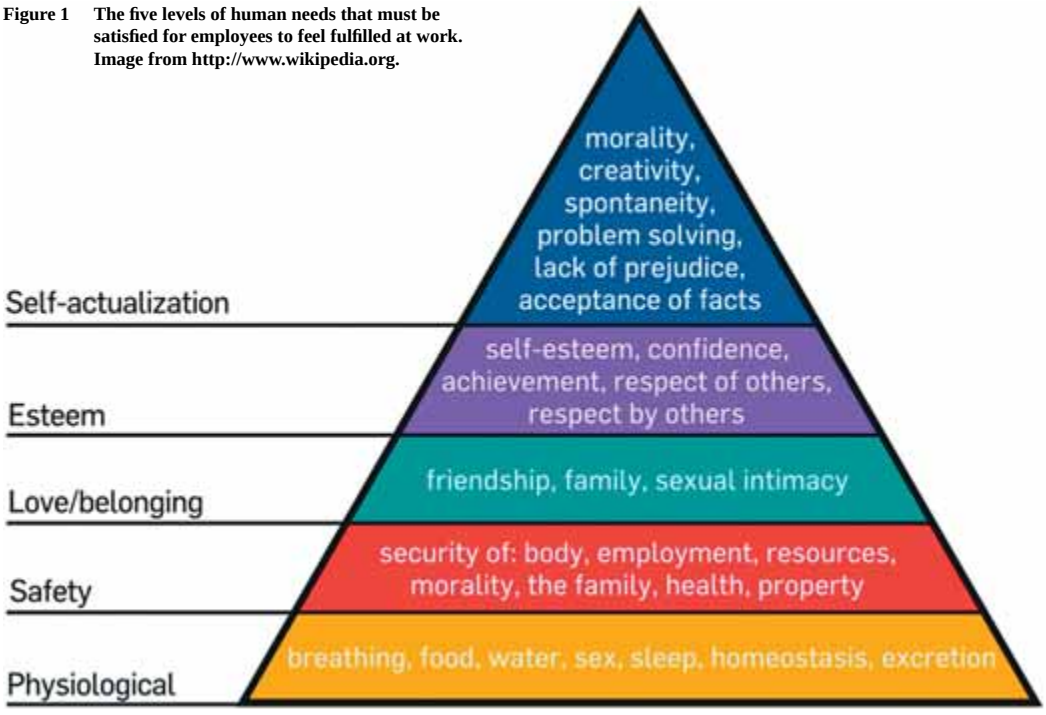

Figure 1 **The five levels of human needs that must be satisfied for employees to feel fulfilled at work. Image from http://www.wikipedia.org.**

Motivation: What classic and modern business literature has to say

> What about the dreaded performance review? Jettison it according to author Charles S. Jacobs, who uses brain science to show that positive and negative reinforcement do not improve performance [7].

Finally, my personal favourite is the recent work by a group of Israeli researchers which demonstrated how turning to sarcasm instead of anger is a better way to motivate employees [8]! In one exercise, engineering students listened to three versions of a customer message, one angry (*Your service is extremely inefficient!*), one sarcastic (*Your service is as fast as a turtle*) and one neutral (*I am at work during your delivery hours*). The test subjects were then asked to solve an analytic or creative set of problems. The study found that observing anger hindered the solving of creative problems, while observing sarcastic expressions of anger actually enhanced the solving of creative problems. Another exercise also demonstrated the positive effect of sarcasm on complex thinking. So, why can't I get paid to research fun things like this?

Conclusion

A quick tour of classic management theories is like walking along a timeline of changes in the workplace in modern times. From nameless labourers toiling on assembly lines a century ago to the current focus on work-life balance and working remotely, it quickly becomes clear how much has changed. Modern theories focus on the mobility and push for self-fulfilment that characterise contemporary life.

What does emerge from these theories is that money does not motivate as much as people think; humans are social animals and combating dissatisfaction is as important a task as supplying motivation.

Regardless of what industry you are in and whatever status you have achieved, you still need to be motivated (and to motivate others). Hopefully this article will encourage you to further explore the research already conducted in this area to find the answers you need to get you out of bed in the morning.

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The English language: Summarised by 100 words

In his article in *The Telegraph* on 14 October 2011, David Crystal details how his book "The Story of English in 100 Words" came about. His book attempts to tell the history of the English language in 100 words and touches on how, through the ages, English language has absorbed words from many other sources and cultures. Each of the 100 words he has chosen represents a story as well as a whole class of words. Some selected words, such as *roe* (5th century), the first word in the list, were chosen to represent a period of English history. *Roe* is old English of the period from the arrival of the Anglo-Saxons in AD 449 until the 11th century.

Crystal sees words "as windows into the world of those who use them". His words were chosen to demonstrate social history. Thus he draws on colloquial words, regional dialects (e.g. the Scottish *wee*), jargon (e.g. *cherry-picking* from business speak) and words that are part of the skeleton of the language, e.g. *and*—an 8th century abbreviation. Scientific words (*species*, *DNA*) have not been left out either, not least because three quarters of English words belong to science and technology. Words that show the flexibility of English in borrowing from other languages include the Yiddish *schmooze* and *doable* (a mixture of languages). A great lost word is *fopdoodle*. Call someone that and see what reaction you get. New words are also on the list with the inclusion of *Y'all* and even rude words, one only being denoted as c_ _ _. Words that are ambiguous (*billion*) or give linguists something to talk about (*disinterested*), product names (*escalator*) and fictional words (*muggle*—do you know where that one comes from?) are all on the list.

If you are too busy blogging and tweeting to read the book in full, you can always have a look at the article from *The Telegraph* found at http://www.telegraph.co.uk/culture/books/8824676/From-Riddle-to-Twittersphere-David-Crystal-tells-the-story-of-English-in-100-words.html

David Crystal's book *The Story of English in One Hundred Words* was published by Profile books on 13th October 2011 (ISBN: 9781846684272)

Making the transition from operations to management

by Martin Robinson

A common career move for many people working in clinical research is to move from a technical 'operations' role like medical writing into management. For some, this transition will be gradual. You may get some responsibilities such as managing an individual, supervising a limited area of work or coaching a couple of people. For others, the move into management will be more sudden, for example brought about by a promotion or when moving to another organisation. Making this transition can sometimes seem overwhelming and is often stressful.

Managing people is one of the most difficult and demanding aspects of any job. A survey conducted by the Chartered Management Institute revealed that 47% of people felt they were in a badly managed workplace, leading them to leave their job [1]. This is a serious problem because replacing staff is costly. The accountancy firm PricewaterhouseCoopers reports that the cost of hiring a new person to replace an existing employee who is performing is equal to that person's annual salary [2]. If someone broke £30000 worth of equipment a year, there would soon be an inquest into what was happening and disciplinary action might be taken. So it makes sense to think about what is needed to make the transition to management.

Managing people is one of the most difficult and demanding aspects of any job

New skills are needed

Organisations sometimes assume that because someone has several years' experience in a technical role, they can automatically manage a team. Some people are intuitively good people managers, but most of us need a significant amount of training, development and support to become competent in people management. Being a manager is not like being a 'super' medical writer, where you are doing technical tasks at a more advanced level. It is a different job. True, there are some transferable skills but also plenty of new ones to learn.

Look at your organisation's job description of a Line (people) Manager, if there is one. (There should be one or, if not, management competencies should be in place!) If a job description is not available then it is worthwhile asking other managers in the organisation for an overview of their responsibilities. You can then draw up your own job role. Compare the skills required in your medical writing role with those required for management. Make a list of the gaps and then take action to fill them, such as getting the appropriate training and support.

Change your mindset and move out of your comfort zone

In addition to acquiring the right knowledge and skills, you will need to change your mindset to become a manager. Management requires a more strategic approach than a technical role like medical writing and is conducted on a larger scale and covers a greater scope of work. Consider how the individual and collective objectives of your team fit in with those for the department or business unit and ultimately the organisation's business objectives.

Because you are taking on a new role where you will have to learn new skills and think a lot more strategically, you will probably be moving into unfamiliar territory. This transition will have to occur quickly because of the inevitable pressure to deal with management issues promptly.

At the start of your career as a manager, you may frequently feel very uncomfortable. You will face new challenges and will have to deal with questions you have never been asked before, some of them with no easy answers. If your organisation has a human resources department, you may find it helpful to consult them. This is vital if an issue requires legal expertise such as dealing with absenteeism, someone whose work performance may be being affected by health issues or if disciplinary procedures need to be implemented. Fortunately, most people involved in clinical research come to work wanting to do a good job, but there are exceptions.

Most of us need training, development and support to become competent in people management

As a manager, sometimes you will need to deal with challenging and complex issues and be prepared to know which procedures need to be followed and who else needs to be involved or consulted. These situations are often stressful and uncomfortable for both managers and team members alike. Look at moving out of your comfort zone as a step in your development. It may feel very awkward but you will be undoubtedly gaining new skills and knowledge. With time, you will find that you will gain in confidence, and the feelings of discomfort will diminish—but they will never vanish! >

Making the transition from operations to management

> Remember a common saying: "The most successful managers have perfected the skill of getting comfortable being uncomfortable".

Learn to delegate

One of the key attributes of a good manager is being able to get the best out of other individuals and teams. In this context, one of the essential skills of being a good manager is the ability to delegate. Delegation is sometimes misunderstood, but it means giving people freedom to carry out work within an agreed framework using their own initiative and in their own way. Perhaps in a previous role you had some experience of delegating. Keep in mind that one of the pitfalls in management is to apply the same universal attention to detail as you applied to your role as a medical writer. This is often called 'micro-managing'. Managers who micromanage their team find life very difficult, and their team quickly becomes demotivated and frustrated.

Delegation is sometimes misunderstood

If you are having trouble with this, think about why. Maybe you have difficulty trusting people and have a fear of losing control. Are you giving your team clear guidance, and do you have realistic performance standards? Use the knowledge, skills and experience of your team. If they are experienced, they will appreciate being consulted and feel valued when you seek their advice. By using the expertise of the team, they will be able to advise, problem solve and take action if you specify when you need to be involved or just kept informed.

Adapt your management style according to the team and situation

You will need to adapt your management style to suit the collective and individual needs of your team members. You may be managing a team of largely inexperienced people. If you have inexperienced people in the team, you will have to play more of a role in directing and coaching them. Another case where you will need to change management styles is when your attention to detail is needed to solve a problem and determine its root causes.

Individual people need and may want to be managed in a particular way. Generally, new staff need a good deal of direction early on in their career, but once they start to gain confidence, you can move to a coaching style of management. This involves giving people the opportunity to do it their way by learning on the job, provided SOPs are followed and performance standards are met. Once people have gained competence and you and they are confident in their abilities, you can move to a more hands-off style, which involves giving them support through some guidance and then eventually delegating work to them.

Sometimes, you will have to adapt your management style to the situation. For example, in a crisis, there is usually not much time for discussion or for reaching a consensus. In this case, you will need to revert to a very direct style. It's a case of "…this is what needs doing so let's just do it." This can be considered military-style management. If the management team in the organisation is competent, these situations should be rare. Sometimes this directing style may be needed if all else has failed, for example, when trying to get someone to perform satisfactorily. Before you get to this point, however, you should give the person ample opportunity to examine their own performance and should agree an action plan, with support if necessary, to get them back on track.

Managing in medical writing

In a technical role such as medical writing, there is a culture of doing everything to perfection. There is a good reason for this. Clinical research is a highly regulated environment, and the rights, safety and welfare of patients are paramount. Clinical studies must be conducted and the results analysed and interpreted with scientific robustness. Protocols and clinical study reports need to be written precisely and unambiguously.

Look at moving out of your comfort zone as a step in your development

Managing people, in contrast, is an imprecise and indistinct environment. There are many more shades of grey. There is no SOP on people management (as far as I am aware!). People are complex, and what works for one person may not be suitable for another. Sometimes a good deal of patience and hard work is required to resolve people issues. Now and again, a compromise may have to be reached which might be less than ideal but is a practical way forward.

A work colleague once said to me if 80% of your team are happy and motivated, things are going really well! And the French historian and philosopher Voltaire is credited with the quotation "Don't let the perfect be the enemy of the good." In other words, no one is the ideal manager in everyone's eyes, so don't feel like you have to be superwoman or superman. Just do your best to get close!

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Practical tips on moving up through the ranks of management

by Virginia Watson

There are plenty of books around on management theory, practice and styles, so when I was asked to write an article on management for *The Write Stuff*, there was a momentary panic. I have worked for many years as a manager, at a departmental, international and global level, and during this time, I have embraced a wide number of activities and responsibilities. After thinking about my experiences, I decided to focus on the more practical side and give those of you hoping to move up through the management ranks some idea of what may be in store.

I tend to think of management as being divided into three key areas: operational, personnel and strategic. However, these activities do not stand in isolation and there is considerable overlap.

The operational level

Departmental level

At the operational level, a departmental manager is responsible for the work of the department, but this is not just ensuring the timely delivery of quality documents by the department. This also means resource planning, resource utilisation and the use of 'metrics' (measurements of an organisation's activities and performance). Project time and costs are important and, if you work for a CRO, you must provide input into business development proposals and attend bid defence meetings.

As a departmental manager, there is considerable interaction with other departmental heads when working on full-service projects. This interaction allows you to follow the progress of the clinical trial-related activities and adjust your department's timelines as necessary. However, there are occasions when you must 'fight your corner' because of compressed writing timeframes due to project delays. It is also essential to write management reports and collate metrics for reporting upwards to your line manager.

European or global level

Activities are much the same when working at a European or global level as when working as a departmental manager, but the responsibilities are proportionally greater. A European- or global-level manager must not only oversee all projects but also must distribute the work across offices according to factors such as availability of resource and staff experience, location of the client and other project-related activities, languages, and time zones.

Also, at this level, there is a lot more emphasis on financial aspects, including pricing levels, cost effectiveness, profit margins, resource utilisation, and long-term forecasting. It can be difficult to accurately forecast resource utilisation more than about 3 months ahead, and a year in advance is well-nigh impossible—partly because timelines change during the life of a full-service project and partly because stand-alone writing projects are so often outsourced at short notice. You must also be able to justify 'gaps' (differences between 'forecast' and 'actual' contracted) and be able to assure your line manager that by the time the third or fourth quarter is reached, the gap will have been filled. This all requires experience, figures from past years, and confidence.

Managing departments remotely also means relying on your team of departmental managers to do their jobs efficiently, keep you updated, alert you of potential problems, and provide you with information for your monthly reports. Therefore, when working at a European or global level, you need to find a way to become comfortable with your departmental managers and with your work with them.

The personnel level

Staff or personnel management works very much in parallel with operational management. You will need to consider many questions, such as do I have enough people to do the job, do they have the necessary experience, and should I involve them in a project to build their experience? If you do not have sufficient resources, you need to consider whether you should outsource the work, and if so, whether you have used the contractor before or need to find a new one.

But managing staff is much more than this. The working environment has noticeably changed in the last 30 to 40 years. Staff are now seen as a resource and not as people. But if you want good staff, you need to respect them as individuals, develop and stretch them, and ideally retain them. Sometimes, you will lose a good staff member. This can be sad, but there is also satisfaction in seeing someone you have worked with and trained move on as part of their career progress.

Staff training is important, yet training budgets are often the first to be cut when financial restraints are imposed. I learned very early on in my management career to book external trainings for staff at the beginning of the financial year.

Laying off or 'making staff redundant' is one of the hardest things for a manager. There is no easy or kind way of doing this. Disciplining employees is also not easy, and you must >

Practical tips on moving up through the ranks of management

> be very careful to follow the procedures laid down by your human resources department. Annual staff appraisals must be done, and these should be a positive experience. However, there are instances when the corporate grading scheme to be applied will be perceived by staff as de-motivational. For example, work of consistently high standard has to be graded as satisfactory. In this situation, it is essential that you maintain staff motivation during and after the appraisal.

Still counting those hours...

A few months ago I wrote about various time tracking systems I had discovered on the web including one called Rachota (http://rachota.sourceforge.net) that I'd only just downloaded at the time (see *TWS* 20 (2) page 91). I've been using it since then to track my working time and I've found it an exceedingly useful tool. My husband also works freelance (in the museum sector) and was immediately converted.

Here's how it works: When starting on a new project, I add the task to the daily tracking page, click 'Select' and then 'Work' and the clock starts ticking. If I have a break, I just click on 'Relax' and the clock switches to timing the 'Idle time'. And if I switch to another project I just have to remember to 'Select' and 'Work' on that one. On days when I'm juggling several projects it's been extremely handy. If I forget to switch I can 'Move time' from one project to another.

The software can analyse your time to tell you how efficiently you're working, but I don't use that function (apparently according to Rachota I don't prioritise my tasks correctly…). It will also give analyses of how much time in total per day, per week, per month or per year you have spent on your various projects and activities, which I have found useful as a double check on total times for invoicing purposes. You can also scan back through the preceding days to see previously tracked time.

My plan was that if I count my working hours, then I would have more hours in my day that really count. I'm not sure Rachota has transformed me into a super-efficient time manager, but I do feel it's an accurate, easy-to-use method to track my time.

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P.S.: A fairly large part of my non-work/family/household time is spent in the garden, and I came across a lovely time-related quote the other day from Dieter Kienast, who was a Swiss landscape architect, "The garden is the last luxury of our time, it requires what has become most precious in our society: time, attention and space." (I hasten to add that I haven't started tracking my gardening time on the computer.)

European or global level

Managing European or global staff remotely can be quite challenging. There are language and cultural differences to be considered, as well as different employment laws, public holidays, and standard working hours. Salary levels per country are related to the cost of living in that country, and it is important to understand this when conducting annual salary reviews. You must be mindful of travel budgets, so it may not be possible to visit staff in other countries as often as you may like. Dropping in for a surprise visit is difficult, so most visits are planned in advance and your staff will be well prepared and likely to be on their best behaviour. For me, it was nice to have a room set aside for my use and to be served biscuits with my coffee, but was I really getting the true picture? Conference calls are useful and keep you in touch, but without seeing facial expressions or watching body language it is difficult to pick up early signals of potential problems.

The strategic level

Being involved at a corporate level can be very enjoyable, but at times it is tough: information is frequently highly confidential, and you may have to keep both good and bad news to yourself until you can release it. For example, I can recall one senior management meeting when no one could leave before we had made a decision on where we would make x% of staff cuts, by country and department; this was not a pleasant experience for anyone. Nevertheless, despite some of the difficult decisions that have to be made, it is at this level where central strategic thinking and debate occur, which is one of the most rewarding aspects of being a manager.

As a manager, you have to rise to any challenge that you are presented with, even though sometimes you have no idea where to start. Neither can you shirk responsibility: whatever the problems within your department, you have to take responsibility and sort things out. You have to make new initiatives work. It is necessary to strike a balance between supporting your staff and supporting corporate ideals. You may not receive specific training for this—I never had any formal management training, unless you count team building courses and a few manager 'away-days'. You must therefore learn by experience, by listening and watching, from your mistakes, and by not being afraid to ask for advice.

The view from here

For the new manager or the manager moving to the European or global level, there's a lot to learn. Managing is immensely challenging at times, but it is also stimulating and rewarding.

I have now been working for myself for over 18 months, and although this is much better suited to my current lifestyle, I have to admit that there are times when I still miss the buzz of management.

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An Interview with Julia-Forjanic Klapproth

On starting and managing a medical writing agency

Many medical writers have thought about branching off on their own or with partners and setting up their own medical writing agency. Making this transition from an otherwise secure position might be appealing to some with an entrepreneurial spirit, but there are also many unknowns. How does one get started? What needs to be considered? What are major pitfalls and how can they be avoided? And how do you manage your company and adjust as it grows?

To answer these questions, *The Write Stuff* (*TWS*) turned to Julia Forjanic-Klapproth (JFK), Senior Partner and CEO of Trilogy Writing & Consulting and former president of EMWA (2001-2002 and 2007-2009). After receiving a PhD in Developmental Neurobiology, Julia started her career as a medical writer at Hoechst Marion Roussel in 1997. She founded Trilogy Writing and Consulting, a specialised medical writing company, with her partners Barry Drees and Douglas Feibig in 2002. Trilogy Writing & Consulting is based in Frankfurt, Germany and Downham Market, England and currently has 20 employees. Trilogy has gone from a start-up to a stable and growing medical writing agency, which makes Julia's experiences directly relevant and invaluable to those wanting to start their own medical writing agencies.

TWS: How and under what circumstances did you and your partners decide to start a medical writing agency?

JFK: I had been working as a medical writer at Hoechst Marion Roussel (now Sanofi-aventis) for about four years when they decided to spin off their medical writing department as a separate business. I knew that this would happen at least a year in advance, so I started planning and carefully considered my options. For me, the logical next step was a position of more responsibility, but I had not found what I was looking for at other companies. I decided that the best choice was to branch out on my own. So, in 2001, I started Trilogy Writing & Consulting. I chose the name Trilogy because two of my colleagues, Barry Drees and Douglas Feibig (who are also senior partners) also expressed interest, although they waited until the business was stable before joining me a few months later (in 2002).

TWS: How did you manage financially to make the jump from a stable job to starting your own business?

JFK: I had been the lead writer for a whole clinical program at Aventis, so I spoke to the clinical head of the project to ask if he would give me the project if I went independent. Aventis was closing down its medical writing department anyway and one way or the other he was going to have to outsource the project. So he preferred having me continue to work on the project. That was my first client. Also, I used the pension plan pay out I received when I left Aventis to help pay start-up costs. Of course, in the beginning, I worked from home, so I had very few overheads. The main costs were for office equipment and set up.

TWS: Why did you decide to start a company rather than go freelance?

JFK: Barry, Douglas and I enjoy writing submission dossiers, and we knew we could only take on bigger dossier projects as a team. Plus, we knew that as a trio we could cover for each other if we got sick or took holidays. That is a luxury freelancers don't generally have. And I definitely wanted partners, just because life is more fun if you share it with someone.

TWS: What did you have to do and how did you organise yourselves to start Trilogy? How long did it take to organise?

JFK: It really took just a couple of months. I started by writing a business plan for the company. I got information about writing business plans and a template off the internet, and made a plan of where I wanted the company to go financially. I also took a course on starting your own company to learn about the administrative and bureaucratic side of running a company, the basics of bookkeeping and accounting, company types and so on. In addition, I bought a basic financial software package for invoicing and bookkeeping.

TWS: Any important lessons from starting up?

JFK: Yes! *Make sure* that you get an accountant who really knows what they are doing. You must be able to trust your accountant because, unless you already have a degree in accounting, you really don't know what they are doing. We were nearly ruined by a bad accountant early on.

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An Interview with Julia-Forjanic Klapproth

TWS: Originally, it was only you and two partners. At what point and after how long were you compelled to hire employees? Was this a difficult decision?

JFK: This was not a difficult decision at all because we were compelled to do it.Originally, we wanted to just work with a network of freelancers to cover any extra resources we needed. But we soon realised that this was impractical. The difficulty with planning large projects around freelancers is that we couldn't control when freelancers work and what they are working on. So if our clients delivered source documents late (which is generally the case) we often found that freelancers who we had planned in for a project had moved on to other projects in the meantime, and we couldn't very well tell them to stop working on their other projects and work on ours! So we quickly realised that we needed to have in-house writers (employees) to better allocate the resources needed for shifting projects. We hired our first employee within a year, in 2003.

TWS: Recruiting good people can be difficult. How did you evaluate and identify good candidates? What have you learned?

JFK: There are a few key skills that we look for in all candidates. First of all, candidates must have excellent English language skills—primarily written but also spoken—or they aren't considered further. If we see spelling mistakes or poorly structured sentences in their applications, they get an immediate rejection. Secondly, they need to have good interpersonal skills. Furthermore, our job ad specifies which qualifications they must have and specifies that they must write a cover letter—in English—describing how they comply with the criteria for the position. Anybody who doesn't fit these criteria and isn't able to explain in their letter how they comply with the criteria also gets an immediate rejection. Attention to detail is essential for the job. We also ask candidates to do writing tests to evaluate their technical writing skills. During the interview, all three of us see the candidate, and we have a set of standard questions we ask. In this way, we evaluate not only their English speaking skills but also their interpersonal skills. Before we make someone an offer, all three of us must be in agreement that the candidate is well-suited to fit into the Trilogy environment.

TWS: Has this changed since you started?

JFK: Our writing tests have changed, and we have them do some of the test before deciding if they are eligible for an interview. Also, for anybody who does not live close and where there would be a significant cost in bringing them in, we first have a phone interview as an initial screen. We didn't do that in the beginning. But we realised that about 80% of people are screened out in the first interview, so if we can save large costs at that stage, it is an advantage.

TWS: What challenges did you face scaling up from three people to having a few employees and continuing to grow?

The biggest challenge was standardisation and developing uniform processes. In a small company, you just talk, but when there is a larger group, you need to find a way of communicating intentions to be sure everyone is doing things in the same way. The most important thing as you scale up is having a way to systematically transfer ideas. This means having standard operating procedures and, even more, developing fail-proof processes. From the beginning, we started with checklists and templates. Then we realised we had to develop documents that communicated company policies and philosophy to the employees. All companies in the world struggle to find effective in-house communication tools, and it takes considerable thought and effort to get it right.

TWS: Losing good employees is very costly to companies. Do you manage to retain employees? How do you do it?

Yes, we do manage to retain employees. First, we try to create a company that is fun to work for. We certainly had some very important learning experiences in the first few years, but fortunately we managed to hone our management skills a little and have tried to create a work environment that people enjoy. For example, we found that open spaces rather than individual offices were actually preferred by our employees. And we have social events together, such as a wine and cheese parties on Friday afternoons and free yoga training on site. But even more important, I think, than the social events is that we respect our employees as colleagues—we never expect them to do something that we would or could not do ourselves. We make sure that they know we are going to help them and

that we're a team; we don't expect people to figure things out on their own. In addition we have an open-door policy and a very flat hierarchy, where the managers encourage their direct reports to come forward with any problem, suggestions for improving things, or whatever. We really encourage this. I tell them that if I don't know there is a problem then I can't fix it!

TWS: How do deal with the need of employees to be trained? What training do you require or offer? How do you include this in your accounting?

Our writers are only as good as the skills they have, so we have a multi-faceted training policy. We start with an induction policy and then have both in-house training, which consists of workshop and seminars, and external training, which includes membership in EMWA and attendance at one EMWA conference per year. We also have a mentoring programme where all writers work with a mentor and discuss questions and problems on a regular basis. We have a training budget that accounts for both time spent on in-house training as well as external training costs.

TWS: Describe your management structure. How did you come up with this structure? What advantages does it have?

We have 4 senior partners and 2 medical writing managers. The managers and senior partners sit on a board and make the decisions by committee, although major decisions are made by consensus between the senior partners. All the writers work in teams of about 5 people with a manager and/or senior partner managing the team. This means that we have a very flat management structure. This structure also helps the managers delegate easily and manage resources because they are only responsible for a small group instead of everyone. This structure arose organically, partly because we wanted to preserve the feeling of a small company even though we were growing.

TWS: What key advice would you have for someone wanting to start a medical writing agency?

Just do it! Most people think about the reasons that they can't rather than focussing on all the reasons they can. Really, the first step is to get yourself a client—you only need one to start. You can do this by going to conferences, talking to colleagues, and generally networking. At least 90% of our clients come through word of mouth. If you can't do this kind of networking and hustling, and if you don't think you have a something to sell, you probably aren't the entrepreneurial type, which is an important thing to figure out about yourself before you decide to open up shop. Being an entrepreneur definitely isn't for everybody, but for those people who have the right skill set and aren't afraid to get out there and make things happen, it's fantastic!

Announcement of a new clinical pharmacology article series

Clinical pharmacology is an integral part of drug development and can form up to 50% of the product label. PK/PD data underpin much of these statements. It is therefore important that all drug development project team members have a working knowledge of this important subject. A new series of articles starting in March's issue of Medical Writing will address, from a PK perspective, emerging technologies and trends within drug development along with any appropriate regulatory guidance. Subject areas to be covered include; drug drug interactions, oncology, obesity, nanomedicine and formulation development.

This series will be authored by **Graham Blakey** who is a pharmacist with expertise in pharmacokinetics and clinical pharmacology. Following a PhD from the University of Manchester he joined the pharmaceutical industry, where he worked as a pharmacokineticist gaining extensive experience with many global project teams developing new medicines in Europe, Japan and North America. Latterly he has worked as an independent consultant through GBPK Consulting Ltd., a company he founded in 2007. Graham has a particular interest in the transition of new chemical entities from the pre-clinical arena into humans for the first time.

The Development Safety Update Report (DSUR): A new regulatory document intended to harmonise periodic safety reports for clinical trials

by Julia Cooper

The regulatory authorities in the three ICH regions (US, Europe, Japan) require sponsors conducting clinical trials to assess the safety of the trial subjects on a regular basis. This assessment includes preparation and submission of a periodic report on the safety data from trials being conducted with an investigational product. The availability of the periodic safety report ensures that the regulatory authorities have the most recent safety information while the product is being used in a 'non-approved' manner in clinical trials.

The timing and content of the periodic safety reports varies considerably between the ICH regions. In the US, the FDA requires an IND Annual Report from the first anniversary of the day the IND went into effect. In Europe, an Annual Safety Report (ASR) is required from the first anniversary of the date of authorisation of the first study site in the European Union; the ASR reporting cycle is therefore unlikely to coincide with that of the IND Annual Report. The required content also differs for the IND Annual Report and the ASR (see Table 1). In Japan, the periodic safety report is different yet again, comprising a table of adverse drug reactions divided into clinical studies performed in Japan and outside of Japan; the reporting cycle is every 6 months, based on the date of the first trial authorisation in Japan.

The Development Safety Update Report (DSUR) is a new document intended to provide a common standard for the periodic reporting on safety of medicinal products under development in the ICH regions. The purpose of this article is to introduce the scope of the DSUR, and to highlight some of the differences between the ASR, IND Annual Report, and the DSUR. The article is written with the medical writer in mind, as the likely author of this new regulatory document and the coordinator of the cross-functional teams involved in DSUR preparation.

The DSUR is described in the ICH E2F guideline *Development Safety Update Report* [1], and was designed to fulfil the requirements currently met by the IND Annual Report and the ASR. Like all ICH guidelines, ICH E2F has to be adopted into regional and national legislation to come into effect. In the European Union, ICH E2F was adopted on 1 September 2010 [2]. This was followed by a one year transition period during which either the ASR or the DSUR were accepted by the European authorities. Full European implementation of the DSUR occurred on 1 September 2011. On 23 August 2011, the FDA announced via the Federal Register that the DSUR may be submitted in the US in place of the IND Annual Report [3]. The implementation date for Japan is yet to be announced. Once adopted, there will be a global standard for periodic safety reports of clinical trials across all three ICH regions. ICH E2F will probably also be adopted outside the ICH regions in the same way that ICH E3 has been used as a global standard for clinical study reports.

To resolve the different timings of the existing periodic reports, the ICH E2F guideline introduces the concept of the Development International Birth Date (DIBD). The DIBD is the date of the sponsor's ***first*** authorisation to conduct a clinical trial with the investigational product in ***any*** country worldwide. The worldwide reporting cycle starts from the DIBD, regardless of where the DSUR is submitted. At the end of the reporting period—one year (or multiples of one year) after the DIBD—the sponsor has 60 calendar days to submit the DSUR to the regulatory authorities. This timeline is not new—both ASR and IND Annual Report were also required within 60 days of data lock point. However, the content requirements for the DSUR are more extensive compared with the ASR and IND Annual Report, so it will be important not to underestimate the effort and organisation involved in compiling the DSUR within the regulatory time window. Once the DSUR is fully adopted, the reporting period will be aligned in the three ICH regions. However, the time point at which the sponsor is allowed to stop submitting DSURs at the end of the clinical trial programme is still governed by regional or national requirements, and these are not harmonised.

The DSUR includes all safety data from clinical trials with the investigational product that were either ***ongoing*** or ***completed*** during the ***reporting period***. This implies that, no matter how many trials the sponsor is performing with the product, or where the trials are located, all the safety data should go into one single DSUR. By including all trials in one DSUR, the sponsor and the regulatory authorities have a proper overview of the safety of the investigational product. This concept of a single DSUR is similar to the European ASR, which required that all trials with the investigational product with at least one site in the European Union were included in a single report. However, in this respect, the DSUR is different to the US IND Annual Report. In the US, trials with the same investigational product are often registered under different INDs for different indications, so the safety data for the different indications are summarised in different IND Annual Reports.

If the sponsor is unable to include all indications in a single DSUR, the rationale for separate DSURs must be explained in each report. It is also advisable to discuss the proposed approach in advance with the regulatory authorities.

The ICH E2F guideline provides a framework that can be used to create a DSUR template. It includes detailed guidance on the content to include in each section of the DSUR, and the structure is shown in Figure 1. The DSUR was designed as a kind of pre-approval Periodic Safety Update Report (PSUR), and the structure is quite similar to the PSUR required for ***approved*** products. Indeed, the content of some sections overlaps with the PSUR. If the investigational product is already marketed for other indications, and the sponsor is therefore required to prepare a PSUR as well as a DSUR, it will be important to ensure that the overlapping sections remain consistent in the two reports.

The data required for the DSUR come from diverse sources, so it will be worth preparing a standard DSUR checklist to distribute to the various contributing groups well ahead of the data lock point. Based on experience when the ASR was introduced in 2004, clear templates with example text will be important for successful DSUR preparation. The cross-functional teams responsible for these documents will need guidance on what to include, especially as the regulatory authorities have made clear they do not want the DSUR to be used as a data dump. Transparency is essential and the DSUR authors should clearly explain which data are included, why the data are presented in a particular way, and the reasons for any omission of data. An example DSUR for a fictitious product is available on the ICH website [4, 5].

Some aspects of the DSUR that are likely to be challenging include:

- **Estimated Cumulative Exposure (see Figure 1, section 6)**. The sponsor must include a table of cumulative exposure to the investigational product and comparators since the DIBD. This will often be presented as the number of subjects exposed, although other measures such as subject-days may be more appropriate for some treatment regimens. If the blind has not been broken for ongoing trials, exposure will have to be estimated based on enrolment numbers and the randomisation plan, and this will affect accuracy of the table.
- **Listing of Serious Adverse Reactions (SARs) and Table of Serious Adverse Events (SAEs) (see Figure 1, section 7.2 and 7.3)**: The difference between SAEs and SARs sometimes causes confusion, especially if the team's previous experience was limited to IND Annual Reports (which only present SAEs) or to ASRs (which only present SARs). The definition of SAE and SAR can be found in ICH E2A [6]. Note that the SAR listing required for the DSUR only covers data for the ***reporting period***, whereas the SAE table is ***cumulative*** from the DIBD.
- **Blinded data**: Although the treatment group should not be identified specifically for the DSUR, serious events (usually potential SARs) may have been unblinded during the reporting period, e.g., at the investigator's request. In the DSUR, such SARs should be reported with the actual treatment group. Distribution of DSURs containing unblinded data must be carefully controlled to ensure relevant study personnel remain blinded to treatment allocation.
- **Overall Safety Assessment (see Figure 1, section 18):** The DSUR must include a concise integrated discussion of all new relevant clinical, non-clinical, and observational information obtained during the reporting period and pertaining to safety**.** This kind of comprehensive overall synthesis was not required in the IND Annual Report. It was required for the ASR, although the guidance on what to include was less detailed**.** In the DSUR, the sponsor is also required to make a statement on whether the benefits of the product outweigh the risks, based on the data seen so far. The regulatory authorities expect the sponsor to review their own safety data regularly and take action when necessary to protect the safety of trial subjects. If anything seen in this reporting period changes the balance between the benefits and risks, the sponsor must report on the actions being taken, or that the sponsor proposes to take, to address the change**,** such as introducing restrictions/exclusions via protocol amendments. The medical writer can prepare a draft text for this section but will need substantial input from a physician who is aware of the drug safety and efficacy profile. Key stakeholders for this section should be involved as early as possible to avoid conflicting opinions which may delay finalisation.
- **Summary of Important Risks (see Figure 1, section 19)**: This is a new concept not required in the previous periodic safety reports for clinical trials. The sponsor should provide a cumulative list of known risks or safety concerns associated with the product in this DSUR section. The list will include risks identified in ***all*** previous DSURs as well as new risks identified during the reporting period. For each risk, the sponsor should include a summary of the issue, a description of what has been done so far to address it, and any other actions planned to manage the risk. It essentially provides a checklist to help the regulatory agencies keep track of safety concerns, and is likely to be helpful to the sponsor as well. It may be prudent to take a conservative stance when deciding whether to include a risk in this section.

Once the DSUR format is adopted across all regions, it will harmonise the content and timing of periodic reports for clinical trials, and will reduce the number of such reports that sponsors must prepare when conducting multinational clinical trial programmes. Adoption of the DSUR will also allow the regulators to share assessments, as is the case with the PSUR work-sharing initiative already in place in Europe.

Although the DSUR has only recently been implemented, it is already obvious that these important safety documents will need skills in clear presentation and analysis of >

DSUR: A new regulatory document

> data, as well as in project management of multidisciplinary teams to produce quality reports within the regulatory timelines: medical writers are well equipped to deal with these challenges!

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Table 1 Summary of content: ASR, IND Annual Report, and DSUR

ASR	IND Annual Report	DSUR
Covers all ongoing trials with the product with at least one site in Europe Union	One report per IND (often a single trial)	Covers all ongoing trials with the product worldwide
Global analysis of safety	Study level summaries of safety	Global analysis of safety for the reporting period and cumulative since DIBD
Data displays of SARs and SUSARs	Data displays of SAEs, deaths, and discontinuations due to AE	Data displays of patient/subject exposure, SAEs, SARs, deaths, and discontinuations due to AEs

AE = Adverse Event; ASR = EU Annual Safety Report; DIBD = Development International Birth Date; DSUR = .Development Safety Update Report; IND = Investigational New Drug Annual Application; SAE = Serious Adverse Event; SAR = Serious Adverse Reaction; SUSAR = Suspected Unexpected Serious Adverse Reaction

Figure 1 Table of Contents for the DSUR

Executive Summary

1. Introduction
2. Worldwide Marketing Approval Status
3. Actions Taken in the Reporting Period for Safety Reasons
4. Changes to Reference Safety Information
5. Inventory of Clinical Trials Ongoing and Completed during the Reporting Period
6. Estimated Cumulative Exposure
   - 6.1 Cumulative Subject Exposure in the Development Programme
   - 6.2 Patient Exposure from Marketing Experience
7. Data in Line Listings and Summary Tabulations
   - 7.1 Reference Information
   - 7.2 Line Listings of Serious Adverse Reactions during the Reporting Period
   - 7.3 Cumulative Summary Tabulations of Serious Adverse Events
8. Significant Findings from Clinical Trials during the Reporting Period
   - 8.1 Completed Clinical Trials
   - 8.2 Ongoing Clinical Trials
   - 8.3 Long-term Follow-up
   - 8.4 Other Therapeutic Use of Investigational Drug
   - 8.5 New Safety Data Related to Combination Therapies
9. Safety Findings from Non-interventional Studies
10. Other Clinical Trial/Study Safety Information
11. Safety Findings from Marketing Experience
12. Non-clinical Data
13. Literature
14. Other DSURs
15. Lack of Efficacy
16. Region-specific Information
17. Late-breaking Information
18. Overall Safety Assessment
    - 18.1 Evaluation of the Risks
    - 18.2 Benefit-risk Considerations
19. Summary of Important Risks
20. Conclusions

Appendices to the DSUR

1. Investigator's Brochure (if required by national or regional laws or requirements)
2. Cumulative Table of Important Regulatory Requests
3. Status of Ongoing and Completed Clinical Trials
4. Cumulative Summary Tabulations of Demographic Data
5. Line Listings of Serious Adverse Reactions
6. Cumulative Summary Tabulation of Serious Adverse Events
7. Scientific Abstracts (if relevant)

Regional Appendices, as appropriate:

- Cumulative summary tabulation of serious adverse reactions
- List of subjects who died during the reporting period
- List of subjects who dropped out of studies during the reporting period
- Significant Phase I protocol modifications with respect to a US IND
- Significant manufacturing changes
- Description of the general investigation plan for the coming year with respect to a US IND
- Log of outstanding business with respect to a US IND.

Impact of the new European pharmacovigilance legislation on medical writing

by Alison Rapley

For those of us involved in preparing drug safety documents the next 12 months are going to see some major changes. Legislation to rationalise pharmacovigilance in Europe first proposed in 2008, was finally published at the end of December 2010 [1]. The revised regulation will come into force in July 2012 and the directive will be transposed into national law in each of the European Union (EU) member states during this period. Changes are wide ranging and impact on all personnel working in pharmacovigilance. They aim to increase transparency, communication and patient involvement, and will:

- simplify the current procedures and decrease the administrative burden on the Competent Authorities (CA) by increased cooperation and worksharing by the EMA and the EU member state competent authorities
- consolidate EU decision making on drug safety across the EU
- provide clearly defined responsibilities for the Marketing Authorisation Holder (MAH) to ensure high quality data are collected, safety is continuously monitored and a pharmacovigilance system is documented and maintained.

It is expected that Volume 9A [2], the current pharmacovigilance bible, will be replaced by other guidance. Timelines on the development and introduction of this guidance are not yet available but a number of changes have already been spelt out and companies and individuals need to prepare for the changes now. What follows is by no means a complete review of the new legislation. I will concentrate on those changes which are relevant for medical writers, in particular on those which relate to the preparation of Periodic Safety Update Reports (PSURs).

PSURs

PSURs will no longer be required for all products and there will no longer be a standard reporting frequency. Requirements will become proportionate to the risks posed by the product and the frequency of submission will be specified at the time of marketing authorisation approval. Reports will continue to be required for newly authorised products but should not be necessary for generic, well established products. A list of those generic products not requiring PSURs is not yet available. Although regular PSURs for generic products will no longer be required it is not clear whether PSURs to support licence renewal will be required for these generic products. The timing for renewal PSURs will, however, change. They will need to be submitted at least 9 months before the renewal date rather than the current 6 months.

As all adverse events will now be reported to Eudravigilance, the scope of the PSURs will change. Detailed line listings will not need to be routinely included as these will be available to the CA for analysis from the Eudravigilance database. The focus of the document will move from data presentation to structured evaluation. PSURs will be required to present a thorough analysis of the benefit-risk balance of the product rather than the current line listings plus review of the product risk profile. The directive specifies that the PSUR must contain:

- Summaries of data relevant to the **benefits** and risks of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation
- A scientific evaluation of the risk-benefit balance of the medicinal product, which shall be based on all available data, including data from clinical trials in unauthorised indications and populations
- All data relating to the volume of sales of the medicinal product and any data in possession of the MAH relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.

How does this differ from what we are already providing? The main difference is the requirement to provide data relating to the benefit of the product as well as the risk. There is no new PSUR template yet available but we do know that the document will have a modular structure. Preliminary advice from the EMA suggests that the structure of the Introduction and Data Analysis sections will remain basically the same.

- Introduction
- Worldwide Marketing Authorisation
- Actions taken in the reporting period for safety reasons
- Changes to the reference safety information
- Population exposure
- Summary of data from studies (interventional, non-interventional, non clinical data, literature)
- Summary of data from marketing experience

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Impact of the new European pharmacovigilance legislation

> Key changes will be the inclusion of a risk evaluation module which will include:

- Safety specification
- Signals (newly identified, ongoing or closed in the reporting period)
- Newly identified important risks/new information on existing important risks
- Effectiveness of risk minimisation

A benefit evaluation module which will include:

- Important efficacy/effectiveness information
- Strength of the evidence and limitations of the data
- Newly identified efficacy/effectiveness information

and a module covering integrated benefit/risk analysis for the approved indication which will include:

- Introduction (perspective)
- Importance of the benefits and risks
- Discussion of the benefit-risk balance.

What the CA expect to see in each of these sections should become clearer over the next 12 months. Until then we should prepare as much as we can and ensure that we consider benefits as well as risks.

There will also be administrative changes. PSURS will be submitted to the EMA and assessment will be shared amongst member state CAs. There will be a single assessment of PSURs for all different medicinal products containing the same active substance by the CA and PSUR safety assessment conclusions will be reviewed by a Pharmacovigilance Risk Assessment Advisory Committee (PRACC) which replaces the Pharmacovigilance Working Party (PVWP). Following the single assessment of the PSUR any planned changes to product labelling will be adopted through a single EU-wide procedure providing a harmonised process for label changes.

PSURs will be submitted electronically although again details of how this will work have not been provided.

Summary of Product Characteristics (SPCs) and Patient Information Leaflets (PILs)

SPCs and PILs for all medicinal products will contain standard text requesting that all ADRs should be reported by healthcare professionals and patients/consumers.

SPCs and PILs for medicinal products subject to additional monitoring will be identified by a specific black symbol warning that "This medicinal product is subject to additional monitoring".

There will be a "Key Information Section" for essential information as with the current US labelling requirement [3].

Medical Literature

The EMA will monitor medical literature for Individual Case Safety Reports (ICSR) but only for selected medical publications and selected active ingredients. There are no details as to how this will be done or for which products but it is likely to cover certain generic products and will decrease the burden on those companies who market these products. The MAH will not be required to expedite ICSRs from these publications but will need to discuss and include them within the PSUR.

The next 12 months should see clarification about exactly what is needed and will be a busy time for those of us involved in pharmacovigilance writing.

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What do beetles exhausted from misplaced copulation, flattened luxury cars and procrastination have in common?

The Ig Nobel Prizes for 2011 were announced at the end of September. It was the Biology Prize that primarily caught the imagination of the general media with the finding by two Australian zoologists that one of their native beetles tries to mate with a particular type of beer brown bottle which has bobbly bits on it. Of interest to any managers reading this issue of *TWS* with its theme on managing people will be that this year's Ig Nobel Prize for literature was awarded to John Perry at Stanford University for his Theory of Structured Procrastination. The theory is that to become a high achiever you should always work on something important to avoid working on something that is more important. My favourite though was the Peace Prize awarded to the enterprising mayor of Vilnius, Lithuania. He solved the problem of illegally parked luxury cars by having them run over by an armoured tank.

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Source: http://improbable.com/ig/winners/

The European Marketing Authorisation process: Responding to regulators' questions

by Maria Fernandez-Piera

Over the last couple of years, a large proportion of my work has focused on preparing clinical dossiers for European Marketing Authorisation Applications (MAAs) and, afterwards, as part of the team who addressed the clinical questions received from the regulators. These applications were for two different companies, and two different application procedures were followed, one decentralised and the other centralised. This article describes the different procedures and provides some advice on how to plan for and deal with regulators' questions.

Different MAA procedures

For those not very familiar with the European MAA, the Decentralised Procedure is used for applications for marketing authorisation in several European Member States for medicinal products which have not yet received a marketing authorisation in any European country at the time of application. The applicant requests one country to be the Reference Member State (RMS) in the procedure, and the dossier is submitted to this RMS. The other Concerned Member States (CMS) participate in the authorisation process by contributing to the assessment report on the application, and a coordination group is set up to examine questions relating to the marketing authorisation and to consider points of disagreement raised by Member States. In the Centralised Procedure the dossier is submitted directly to the European Medicines Agency (EMA) to obtain marketing authorisation in all European countries simultaneously. In this procedure marketing authorisations are granted under the responsibility of the European Commission. Some medicinal products must follow this procedure (such as orphan medicinal products and new medicinal products intended to treat cancer, AIDS, neurodegenerative diseases and diabetes). For the Centralised Procedure, a team of assessors, which prepares the assessment reports, is assigned by the Committee for Human Medicinal Products (CHMP). Prior to the formal application, a rapporteur is assigned to coordinate the MAA evaluation. The CHMP concerned may also appoint a second co-rapporteur, if required.

There is also the Mutual Recognition Procedure, which is similar to the Decentralised Procedure, but for this procedure the medicinal product must have already received a marketing authorisation in a Member State, which then acts as the RMS. Finally, it is still possible to seek national authorisations for medicinal products to be marketed in one Member State only. Detailed information on these procedures can be found at the following locations:

- http://www.hma.eu/91.html
- http://www.ema.europa.eu/ema/
- http://ec.europa.eu/health/authorisation-procedures_en.htm.

Timelines are different in each of these procedures (see Tables 1 and 2), but in both the Centralised and Decentralised Procedures, an assessment report is prepared and sent to the applicant. The applicant has then to submit responses to the assessment report, which the assessors may accept or they may submit a new assessment report, with a new deadline for the applicant. Companies can also give verbal explanations relating to the dossier they have submitted.

Table 1: Timeline for the Centralised Procedure

Day	Action
1	Start of procedure (MAA is submitted by applicant)
80	Assessment Report sent to applicant (containing preliminary conclusions)
120	From Day 80 to 120: Rapporteur/EMA receive comments from other CHMP members On day 120: a list of questions is sent to the applicant Clock stops (submission is on hold, awaiting responses)
121	Applicant submits responses to the questions, including a revised Summary of Product Characteristics (SPC), labelling and package leaflet text (if required) Clock restarts
150	Preliminary conclusions sent to applicant
180	List of outstanding questions sent to applicant
181 to 210	From 181 to 210, applicant submits responses to outstanding questions
210	Final CHMP opinion and Assessment Report

>

Regulators' questions

Table 2: Timeline for the Decentralised Procedure

Day	Action
-14	Submission of the MAA to the RMS and CMS(s) Validation of the application
0	RMS starts the procedure
70	RMS sends a Preliminary Assessment Report (PAR) to CMS(s)
Until 100	CMS(s) send their comments to RMS
Until 105	Consultation between RMS and CMS(s) and applicant If consensus is not reached, RMS stops the clock and allows applicant to supplement dossier and prepare responses to any questions
106	Response is submitted. RMS restarts the clock
106-120	RMS updates PAR to prepare draft Assessment Report (AR), draft SPC, draft labelling and patient information leaflet (PIL) to CMS(s)
120	If consensus is reached, the RMS may close the procedure If consensus is not reached RMS sends the draft AR, draft SPC, draft labelling and draft PIL to CMS(s)
145	CMS(s) sends final comments to RMS
150	RMS may close the procedure if consensus reached Proceed to national 30 days step for granting Marketing Authorisation (MA)
Until 180	If consensus is not reached by day 150, RMS communicates any outstanding issues to the applicant, receives any additional clarification and prepares a short report for discussion by the coordination group
Until 205	Involved Member States must reach consensus
210	Procedure closed, including CMS(s) approval of AR, SPC, labelling and PIL, or referral to the coordination group Proceed to national 30 days step for granting MA If consensus is not reached at day 210, points of disagreement are referred to the coordination group for resolution
270 (at the latest)	Final position adopted by coordination group with referral to CHMP for arbitration in case of unsolved disagreement

The Assessment Report

The Assessment Report prepared by the regulators includes a Recommendation, an Executive Summary, a Scientific Overview and Discussion, a Benefit Risk Assessment, a List of Questions, and the Recommended Conditions for Marketing Authorisation (see Table 3 for typical standard content). The questions cover quality aspects, non-clinical aspects, and clinical aspects. Therefore, different teams should be organised by the applicant to address each set of questions (i.e. separate clinical and non-clinical teams). As an example, the clinical team usually includes regulatory experts, content experts responsible for efficacy or safety, statisticians, clinical trial managers or leaders, and medical writers.

In the Decentralised Procedure, the different CMS(s) prepare a document with their comments on the assessment report, in which they may "fully endorse the RMS assessments and have no further comments", they may "endorse the RMS assessment, but also have additional comments", or they may "not fully endorse the RMS assessment, and have other comments". This means that additional questions from the CMS may be sent to the applicant.

Table 3: Assessment Report: Table of Contents

I	**Recommendation**
II	**Executive Summary**
II.1	Problem Statement
II.2	About the Product
II.3	General Comments on the Submitted Dossier/Development Programme
II.4	General Comments on Compliance with GMP, GLP, GCP and Agreed Ethical Principles
III	**Scientific Overview and Discussion**
III.1	Quality Aspects
III.2	Nonclinical Aspects
III.3	Clinical Aspects
IV	**Benefit Risk Assessment**
V	**List of Questions as Proposed by RMS/CHMP**
V.1	Quality Aspects
V.2	Nonclinical Aspects
V.3	Clinical Aspects
V.4	Pharmacovigilance System / Risk Management Plan
VI	**Recommended Conditions for Marketing Authorisation and Product Information**
VI.1	Commitments/Conditions for the Marketing Authorisation
VI.2	Summary of Product Characteristics (SPC)
VI.3	Package Leaflet (Pl) and User Testing
VI.4	Labelling

Organising the teams

Ideally the process for addressing any questions (and responding to the assessment reports) should be coordinated by a single contact person. This should be someone within Regulatory Affairs who has experience with application procedures. This coordinator should provide the different teams with the assessment reports, along with the templates to be used for the responses, and should clearly inform each team of the deadline for any responses. Some questions may need the coordinated effort of different teams, and some responses may lead to changes in the proposed SPC; all of these activities need to be supervised by the coordinator. However, it is the responsibility of each team to formulate the responses to their specific questions; and to keep the coordinator informed of their progress.

Initial planning meetings need to be set up by the coordinator, and the individual teams need to hold regular meetings to ensure that their work is on track. The teams need to discuss different possible strategies to answer each question, and there should be one team leader assigned who is responsible for coordinating any final decisions, and for reporting back to the global coordinator. Once the strategy is agreed, the medical writer should prepare a draft

response for each of the questions in as timely a manner as possible. These should be reviewed by the team, and after several review steps, the responses are considered final. Alternatively, the responses can be drafted by different team contributors, and the medical writer can support the team by editing the responses and by ensuring that the appropriate template and styles are applied. The final steps of any approval process should include an executive review, and a thorough check should be made to ensure that the responses are consistent across all of the different teams, and are 'on message'.

The responses to the regulators

The responses prepared by the different teams need to be consistent in formatting and style, and therefore it is key to have good templates and clear style guidelines that all teams/writers should follow. This is also a key area where the medical writer can contribute, as they can provide quality control for each response. All questions need to be answered. Normally a separate response must be provided for each question, but as some answers often contain similar or identical information or touch on the same topic you can cross-reference between responses. For each response, the corresponding question should be pasted at the beginning of the response document, indicating the question number and/or the CMS who sent the question as applicable. It is recommended that the responses start with a polite acknowledgment of the question, followed by an appropriate explanation. Sometimes, the applicant may need to accept the assessor's concern and explain, for instance, that the SPC will be changed to address this concern. For some responses, additional statistical analyses of the available data may be needed and additional tables or graphs may be prepared. If any references are quoted in the response, these should be listed at the end of the response, and the corresponding papers will need to be collated and submitted. Once all the responses are final and approved, they should be compiled and published ready for submission. This is normally a task for Regulatory Affairs.

Some tips

It is paramount that clear leadership is provided during the process and that individual team members are aware of their responsibilities. As responses are often time critical, a process for tracking and following up outstanding questions needs to be in place. Executive oversight is recommended, with a clear path to escalate any delays or lack of progress. Contingency plans for difficult questions, or questions which may involve lengthy reanalysis need to be agreed upon and put in place. Fluent communication with the regulatory authorities is essential. It may be useful to initiate informal discussions with the regulators or request clarifications when formulating answers, which could be vital to achieving successful authorisation. Alternatively, advisory meetings can be organised with key opinion leaders/experts to discuss the best approach to the responses. Applicants may also wish to request formal meetings with the regulatory authorities to discuss their application.

Conclusion

Making a successful MAA is a complex and lengthy procedure, with many different factors to consider. After the initial application has been submitted plans need to be in place to deal with the responses raised by the reviewers. This is a team effort that will involve multiple players, and the medical writer can be pivotal in ensuring that timelines and quality are maintained. The goal is to clearly communicate to the reviewers the ideas and arguments of the applicant, in a style that is succinct, and scientifically and medically accurate. Performing this in a professional and consistent manner will only add to the likelihood of a favourable outcome, and the key skills of a medical writer can be invaluable during this process.

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Another word order challenge

to be treated - in Switzerland - present - with injuries - about 1,000 alpine skiers and snowboarders - in hospital - per day - during each skiing season - serious enough - all over the country

Your task: without changing any words, rearrange the elements above to create an intelligible, easy-to-read opening sentence for a publication with the different ideas in the sentence in the appropriate order. One of the elements is redundant and should be deleted.

See if you agree with my solution on page 243.

Alistair Reeves
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Tricky terrain: Healthcare and social media

by Ursula Schoenberg

The Internet has evolved from a passive information tool ('Web 1.0') to a more social medium that enables and fosters interaction between its users ('Web 2.0'). Twitter, YouTube, blogs or social networks like Facebook and Google+ are changing and influencing the way society, business and policy makers communicate with one another. In healthcare, these three fields intersect in a unique way. The needs and interests of patients, physicians, healthcare companies and regulators are inextricably intertwined. But in the fast-paced world of social media, each group is faced with a special set of chances and challenges.

Chances for patients: improved access to information and care

The Internet has given patients access to a broader range of medical information than they have ever had before. Websites like WebMD in the US, NHS Direct in the UK, Netdoktor in Germany or Doctissimo in France have often become the first 'ports of call' for patients searching for information on health issues [1]. The anonymous character of the web also encourages patients to seek information on topics they may hitherto have avoided mentioning to their physician, like sexual problems, hemorrhoids or miscarriages [2].

With the growth of the social web, this mainly passive usage of the Internet has morphed into something more dynamic and interconnected. Platforms such as PatientsLikeMe have emerged that allow patients to connect to and share information with other patients suffering from a similar condition [3]. Blogs and specialised forums give individual patients an independent voice that can be heard globally. This can be particularly empowering for people suffering from rare or chronic diseases, as popular patient blogs on multiple sclerosis and diabetes show [4].

Patients can also take an increasingly active role in improving their health by using new technologies to manage their condition or liaise with physicians. In this, they are being supported by some public and corporate entities. The UK National Health Service is giving patients access to GPs via Skype with the aim of enabling 24/7 doctor availability, regardless of geographical location [5]. Merck has developed smart phone apps like iManage Migraine or iChemoDiary to help patients better manage their diseases [6]. Roche is offering UK patients on long-term warfarin an online training tool to help them learn about anticoagulation self-monitoring [7]. Where the channels of communication have been opened, patients can now also talk directly to companies. AstraZeneca, for example, has a dedicated Twitter account that patients can use to report side effects [8].

Challenges for patients: whom can you trust?

Because the web in general and the social web in particular is still a largely unregulated environment, navigating and using it is challenging for patients and not without certain risks. Patients are left very much alone when finding their way around the web and forming judgments on what they find online. Patients' ability to access pertinent healthcare information depends directly on how web-savvy they are. And their ability to form an opinion on the veracity of that information depends on their level of sophistication in assessing various sources. That doesn't come easy to everyone: according to a survey conducted by the British Department of Health in 2007, almost three out of four people expressed difficulties in identifying whether information provided on health websites is trustworthy or not [9].

In addition, the sheer volume of web and social content is already mind-boggling, and it is growing daily. Even for experts it can be challenging to keep abreast of developments online. This not only makes it increasingly difficult for patients to find pertinent, accurate and up-to-date health information. It also heightens the need for search technologies which may be open to manipulation [10]. Plus, patients may become targets for direct-to-consumer advertising by healthcare companies or other third parties with an economic interest. One case in point is Sharecare, a WebMD spinoff that styles itself as 'a social networking site dedicated to health' [11]. It not only gives its corporate sponsors the opportunity to provide content for the site, but also provides them with information on which content users prefer [12]. Other examples of the grey area between industry and patient interests include paid bloggers, 'unbranded' websites or seemingly interactive moderated forums that operate without full disclosure of who is sponsoring them [13].

Some patients may not bother to carefully assess what they are finding on the web. One study showed that only about one quarter of health information seekers thoroughly check the sources and timeliness of online information [14]. This is cause for concern because nearly half the people who use the web to find out about health (46%) do so to self-diagnose [15]. If the information patients receive is misleading or inaccurate, it may lead to misdiagnosis

and prevent people from seeking treatment out of fear or confusion. Patient harm may also result from counterfeit drugs purchased via rogue online pharmacies [13]. This issue has become so relevant that the healthcare industry has been forced to become active. For example, the Pfizer-sponsored 'Real Danger' campaign uses social media channels to educate patients on the risks of purchasing drugs online [16].

Chances for doctors: offering better patient care, faster

While the 'old' web benefited doctors by allowing them to stay abreast of current medical knowledge via sites like Medscape, PubMed or UpToDate, the social web is intensifying and speeding up the exchange of specialised information [17]. This exchange is being mediated by online physician communities like Sermo in the USA, Doctors.net.uk in the UK, Coliquio in Germany and Egora in France. The three latter groups have recently formed an international alliance called Networks in Health to further extend their reach [18].

Since a physician's most valuable resource is time, one of the greatest advantages of the new technologies is that they allow doctors to access information on their own schedule. Merck and Novo Nordisk, for example, offer physicians on demand phone or web conferences or online sampling, removing the need for a time consuming visit by a drug rep [19]. A strongly emerging trend is the growth in the use of mobile devices. Companies like Epocrates have successfully crafted a business model around optimising the accessing of information via online and handheld devices for healthcare professionals [20].

Mobile devices like smart phones or iPads can be used directly at the point of care, thus increasing flexibility and speeding up decision making. In developed countries like the USA, about 3 out of 4 physicians own a smart phone, and 30% of these doctors report that they use medical apps professionally [21]. These apps range from diagnostic and dosage tools to sources for patient assessment and education, disease education and medical information. Doctors can also use sophisticated e-detailing sites like Lilly's oncology site to teach patients about their illness [22].

Challenges for doctors: information overload and social media savvy

Some of the challenges that doctors face with regard to the web are similar to those faced by patients. The sheer amount of information and speed of change, exacerbated by limited time budgets, can be overwhelming to physicians seeking to use the web effectively. Not only are there millions of websites, there are also thousands of medical apps on the market, and new ones are being launched daily. In this kind of environment, relying on already trusted medical sources (and their digital counterparts) or listening to recommendations by respected colleagues may be a strategy that many doctors are most willing to embrace.

Doctors who want to enter the social media dialogue should be aware of some basic facts. Firstly, with Twitter, Facebook and Co., it's no longer a question of one-on-one conversations, but one-on-many broadcasting. And secondly, social media platforms make it very easy to blur the line between the professional and the private. Should doctors twitter, blog or post on Facebook? There are doctors that do [23]. But physicians wishing to use social media channels need to educate themselves about how they work, not least in order to protect their own reputation and patients' confidentiality. Otherwise they may end up facing the consequences, as in the case of an ER doctor in the USA who got fired for posting patient information on Facebook [24].

Chances for industry: improve products and win (back) trust

The healthcare industry has been plagued in recent years by an erosion of trust that has impacted the public's perception of what it does and how it operates [25]. Using social media can be a way forward out of this dilemma, provided companies are able and willing to allocate or shift resources into this arena. Social media can give them the chance to show their willingness to and capability of interacting with patients and taking them seriously. One example is EMD Serono which has put up a sponsored site >

called 'How I fight MS', where it cooperates with bloggers suffering from multiple sclerosis and seeks to educate patients about living with the disease [26].

It has been pointed out that the new world of social media will force industries to think more like publishers than like marketers [27]. The give-and-take approach that is necessary to make social media work is a particular challenge for the healthcare industry, which is knowledge- rather than consumer-driven. Healthcare companies must get used to the idea that they no longer have total control over messages that are circulating the marketplace. However, they can influence opinion building by strategically utilizing the synergies that multi-channel social media offers. Boehringer Ingelheim shows how it's done with 'Drive-4COPD' which uses virtual tools like Twitter, Flickr, YouTube and Facebook to amplify and enhance real life events with celebrities in a public health initiative that is planned to run for several years [28].

Social media allows companies to reach millions of people directly and on a more personal level. This can help improve corporate and brand perception with established audiences, but can also extend a company's reach to new audiences. On average, every second person seeking health information online watches a video [29]. GSK took advantage of this fact and specifically targeted a younger audience with a viral YouTube clip to heighten awareness for restless legs syndrome; the video has been viewed by more than half a million people to date [30]. Johnson & Johnson uses its dedicated YouTube channel to show real-life patient testimonials and address the concerns of carers faced with a loved one suffering from Alzheimer's disease [31].

Twitter can be a valuable tool with which companies can watch the competition or mine the collective intelligence of patients and healthcare providers with a view to improving products. It also allows companies direct access to previously hard-to-reach audiences, as in the case of Boehringer Ingelheim UK, which has begun to tweet British politicians about atrial fibrillation and stroke risks [32]. Pfizer is using smart phones and web technology to conduct the first ever 'virtual' clinical trial for patients suffering from an overactive bladder [33], and Novartis is educating patients about clinical trials under a restricted Twitter account [34].

Challenges for industry: how far can you go and what's your goal?

The healthcare industry has been slower than other industries in adopting social media. The reasons for this can be characterised twofold: as regulatory and as psychological. Currently, social media usage is operating in a regulatory 'grey zone' which has been making healthcare companies leery of investing too much or forging too far ahead. To date, clear guidance from the American Food and Drug Administration (FDA) on the topic is lacking, a core concern being the difficulties in ensuring the principle of 'fair balance' (i.e. neither over- nor understating the risks and benefits of a drug) in the dynamic social media environment [35]. In the UK, the Prescription Medicines Code of Practice Authority (PMCPA) has issued some, albeit basic, guidance on how the industry may use social media and other digital communications tools [36].

The fact is that social media demands an openness that even more consumer-oriented industries may find challenging. In a poll of communications managers in Germany on the barriers of professional social media use, only about one in three managers said their company had a participative and open communications culture [37]. 55 percent admitted to being afraid of losing control of communicative processes. This seems a tad naïve in view of the fact that with the advent of tools like Google's 'Sidewiki', with which registered users can post comments on any site on the web, companies have effectively lost control of certain aspects of their digital presence already [38].

Considering these data, it is hardly surprising that the healthcare industry, conservative at best and already hampered by regulatory limbo, should be hesitant about how to engage with stakeholders via social media channels. Like other industries, healthcare finds itself in a Catch-22 situation, because not participating in social media just isn't an option—people will talk about you whether you like it or not. But the 'control of messages' issue is a real one, and companies active in social media need to be aware that they only have limited power. For example, after Sanofi-Aventis had posted a commercial for a sleeping pill on YouTube [39], one online parody had a boy bludgeoning his little sister to death after taking the medication [40]. There is also the risk that an outdated web presence may not be enhancing your image, as in the case of Amgen's rather lackluster online community for patients suffering from a rare blood cell disorder [41]. Participants in social media demand to be heard and taken seriously, or as one blogging patient put it: 'Talk with us. Not at us.' [42].

Social media is a fast-paced and technology-driven environment, as Pfizer found out when its Facebook page was hacked [43]. In spite of the challenges this poses, healthcare companies need to invest in a coherent strategy for engaging with specific audiences via the appropriate channels if they are going to make social media work for them. They need to allocate resources and set up a realistic budget, because social media doesn't come cheap. And companies need to train employees to use social media tools correctly. Otherwise they may end up like Bayer UK, whose Twitter account was found to be in breach of the ABPI Code of Practice because it sent out product-related tweets [44].

Conclusion

The social web is here to stay. It can empower patients and their caregivers to actively seek advice and support in online communities, but remains a thinly regulated environment in which it can be difficult to know whom one can trust. Doctors can use social media and mobile technologies to deliver better care in a more timely fashion, but need to be aware of how social media may impact patient confidentiality. The healthcare industry can use social media to (re)

establish its reputation with patients and healthcare professionals, but is in the difficult situation of needing to forge ahead in spite of inadequate regulatory guidance.

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43. www.inpharm.com/news/163037/digital-pharma-pfizer-facebook-page-hacked
44. www.inpharm.com/news/164975/digital-pharma-bayer-twitter-abpi-code

Solution to word order challenge on page 239

Original word order:

About 1,000 alpine skiers and snowboarders present per day all over the country with injuries serious enough to be treated in hospital during each skiing season in Switzerland.

The author here opted for the classic S(ubject)-V(erb)-0(bject [no object in this case]) approach with the adverbial order P(lace)-M(anner)-T(ime) as expected for a sentence in English where no elements are stressed. M-P-T is also commonly used. The order is acceptable, apart from the position of 'per day' (see below)—but is this really the best order for ease of reading and for the first sentence in your paper?

This sentence is teeming with adverbials modifying different things all over the place, in addition to the subject 'About 1,000 alpine skiers and snowboarders' and the verb 'present'.

What is important here? For me it is the number of injuries and that it occurs in each season in the whole country. So, as your first sentence in your paper, you have every reason to deviate from the classic SVO-MPT or PMT approach. 'During each skiing season in Switzerland' here modifies the number of skiers and snowboarders. It would be inappropriate to place it after S because it also modifies the whole sentence and underlines the gravity of this statement. So, contrary to the unstressed approach of having T at the end of our English sentence, we pull the time idea forward to stress it, combine it with the associated secondary idea of place 'in Switzerland' (p), and show that this as a whole modifies the whole sentence and is our most important idea.

The primary time idea in this sentence is 'during each skiing season'. We also have a secondary time idea (t): per day'. The author originally placed this after the verb—but it does not modify the verb 'present', it actually modifies the subject 'About 1,000 alpine skiers and snowboarders' and is therefore better at the end of this phrase before the verb.

So we have T(p)-S(t)-V and have M and P left. Obviously, we have to write 'present with injuries' and 'with injuries' here is M (how the patients present). 'Serious enough to be treated' modifies the word 'injuries' and is therefore also part of M, and 'in hospital' (P) modifies the verb 'treated'. So our final word order is T(p)-S(t)-V-M-P:

(T) *During each skiing season* (p) *in Switzerland*, (S) *about 1,000 alpine skiers and snowboarders* (t) *per day* (V) *present with injuries* (M) *serious enough to be treated* (P) *in hospital*.

As you see, what I deleted was 'all over the country' as this is implicit in 'in Switzerland'.

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Webscout

Team management or how to communicate with your team

by Karin Eichele

Team management is not as easy as it seems. Indeed it is a lot about finding the right way to communicate with your team. But this is where the trouble begins. What is the right way to communicate? Is there a one and only solution? Definitely not! The solutions are as numerous as the character traits and attitudes of the individuals in your team. Team management is knowledge of human nature and to a certain extent it is psychology. And as said before, management is communication. You might say fine, we are all communicators, so this will be easy. No, it is not that easy. In our daily business, we are rather used to communicate in order to distribute information, so to say, most of us are one-way communicators. When communicating with your team, you need to communicate differently. For sure, you inform – about projects, about timelines, about contents, about challenges etc. But what you want from your team is an answer, and the answer should come in the form of productivity, dedication and commitment. The following websites introduce you to different facets of 'productive communication' and the psychology behind it.

http://www.exforsys.com/career-center/team-building/team-behavior.html
A team member's behaviour may be categorised as acceptable, unacceptable or destructive. Some examples are given here. The following links will provide you with some ideas on where to get advice and on how to deal with some distinct team behaviours.

http://www.humannatureatwork.com/_Articles.htm
To understand human nature will help you to get the best out of the team. Improve your ability to motivate and you will increase productivity. And with that you will indeed reduce costs. Have a look at the articles under 'Employee Morale and the Bottom Line' and 'Workplace Stress and Its Cost'. Reading through the articles I felt that their content was common sense. But do you follow these rather simple principles in your fast-paced daily business life? We all should be aware of the things they recommend, all the time. But unfortunately, our daily business is not always love and peace. You will have a lot of discussions even if you follow the above recommendations. What to do about it? To make these discussions fruitful, I recommend you read through 'Turning Difficult Discussions Into Constructive Conversations'.

http://www.mindtools.com/pages/main/newMN_TMM.htm
Mindtools.com is a resource for all aspects of management: project, time, stress and of course team management. Unfortunately for many contents you have to subscribe, however, around 30% are available for free and they are a good start. Do you have difficulties in delegating projects? You are not alone. As a team leader, you have to see the big picture and need to avoid getting lost in details. This does not only cost valuable time – your time – but also thwarts the creativity and productivity of your team. Learn to delegate effectively, read about it on this page, especially the section 'Successful delegation', which contains useful tips on how to delegate. I would also like to warmly recommend the sections 'Motivating your team' and 'Rewarding and engaging your team'.

http://www.askamanager.org/category/good-management
This a question and answer blog, also available on Twitter: http://twitter.com/#!/AskAManager. The questions dealing with in the category 'Good management' are more or less examples of what can happen to you in your team management career. Try to profit from other managers' experience. Of course, these are subjective pieces of advice, but consider it as the start of a thinking process. In the end, you may come up with your own solution, or you may follow the advice. But this blog is nice to read anyway.

http://everyjoe.com/work/three-minute-management-course-humour-169/
Humorous, but in the end, you will find a lot of truth in it. Read, enjoy and think about it.

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

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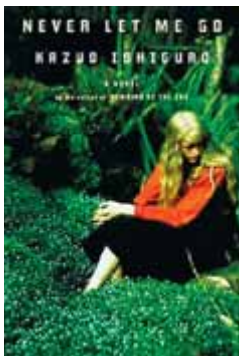
In the bookstores ...

A futuristic solution to a medical need



Kazuo Ishiguro. Never Let Me Go, 2005, ISBN-13: 978-0571258093, 7.99 GBP. 304 pages.

Some may be familiar with another book by this author 'The Remains of the Day' but the setting for this tale is very different from previous books by Kazuo Ishiguro. Set in England in the late 1990s, it is a country we know but don't quite recognise as normal. The story is told by Kathy H, a carer reminiscing about her own life and those of friends from her much loved school Hailsham and we follow their exploits through school and beyond.

Initially we find out how the children coped with life at the school. Familiar scenes are depicted with undercurrents and a certain degree of strangeness. The children are boarders with assigned guardians and vie to have their art work selected to be viewed in the gallery. Earning tokens from the sales and exchanges that take place several times a year allows the children to make small purchases for themselves. When they become older and leave the school they move into "the Cottages" and come into contact with "veterans". At this stage they are encouraged to attend seminars in preparation for the next part of their lives and rumours abound about what this will be.

At first, the story has the feel of an ordinary tale about young people growing up, however, as it progresses there is an undertone of things not being quite as they seem. It appears that the children know nothing about life outside and have no family or memories of life before the school. The words used in the book to describe roles the young adults are expected to undertake are words we would recognise from society today: carer, donor, completing, guardian, donations. However what becomes clear is that their meaning in the society depicted in this fictional world is entirely different from what we might expect in our own lives.

One rumour the young people really believe is the ability to have a "deferral" if you can show you are in love; Kathy and her two close friends search desperately for a deferral. In doing so, they discover the truth about themselves. What emerges is that the children are clones designed to be used as living donors with their beloved Hailsham described as a failed experiment. They are told by one of the school founders:

"...How uncomfortable people were about your existence, their overwhelming concern was that their own children, their spouses, their parents, their friends, did not die from cancer, motor neurone disease, heart disease. So for a long time you were kept in the shadows, and people did their best not to think about you. And if they did they tried to convince themselves you weren't really like us..."

"…we demonstrated to the world that if students were reared in humane, cultivated environments, it was possible for them to grow to be as sensitive and intelligent as any ordinary human being. Before that, all clones—or students, as we preferred to call you—existed only to supply medical science…."

In calm and pseudo-scientific terms an explanation is given as to how they came about

"….when the great breakthroughs in science followed one after the other so rapidly, there wasn't time to ask sensible questions. Suddenly there were all these new possibilities laid before us, all these new ways to cure so many incurable conditions…..people preferred to believe these organs appeared from nowhere, or at most in a kind of vacuum…"

Beyond the donation processes, where the living donor obtains "completion," still more possibilities for harvesting useful parts are described. This is one scenario of how technology might advance to make organs and treatments for incurable disease more available to all who need it. I hope reality never imitates this fictional account.

I read this book when it was first released and I often find myself thinking back to the premise of the book and wondering if we will ever go that far. Some of the more disturbing stories that emerge about the trade in human organs can be regarded as urban myths but not all. One recent report that had wide coverage involved a teenager from China who was reported to have sold a kidney because he wanted to buy a new iPAD (see http://www.bbc.co.uk/news/world-asia-pacific-13647438). One thing is sure, that organ was sold on for a lot more than the cost of an iPAD.

Ask yourself: if necessary, how much would I be willing to pay for a kidney, a heart, or a liver and would I question where it had come from?

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"You live and learn.
At any rate, you live."

Douglas Adams, English humorist & science fiction novelist (1952 - 2001)

Journal watch

Revisiting ghostwriting and authorship

by Nancy Milligan

In this issue, we look at two articles, one on ghostwriting and the other on authorship, which also touches on the ghostwriting issue.

The first article, authored by the *PLoS Medicine* editors, takes another look at the issue of ghostwriting and claims that attempts to reduce the practice of ghostwriting are not working [1]. They started the article by referring to the legal action relating to publications for the menopausal hormone therapy Prempro, previously reported in *PLoS Medicine* and *The New York Times* (and Journal Watch); the story has been put forward as evidence of how pharmaceutical companies use ghostwriters to introduce potentially misleading or unproven marketing messages into manuscripts published in medical journals [2, 3, 4].

The editors discussed three recent *PLoS Medicine* articles, also examined in more detail in the previous Journal Watch. The first (Stern and Lemmens) essentially suggested that ghostwriting raises serious ethical and legal concerns and that the imposition of legal fraud liability could be applied to ghost authors, guest authors, and their employers [5]. The second (by medical writer Alastair Matheson) revaluated the International Committee for Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts authorship and contributorship criteria. Matheson suggested that industry publications have undermined the authorship standards to the point that ghostwriting is now seen as almost legitimate and argued that the ICMJE guidelines need to be fundamentally revised, including the idea that writers who work on industry publications should be listed as byline authors [6]. The third was a personal account of another medical writer (Linda Logdberg) who participated in ghostwriting for many years until she was asked to work on a project that conflicted with her personal beliefs [7].

The editors went on to provide a couple of examples of *PLoS Medicine* being inadvertently involved with ghostwriting: the first was an assertion from an anonymous ghostwriter who claimed to have written articles for a number of leading journals including *PLoS Medicine* [8]; the second was a report of a study which showed that 7.8% of authors from 630 articles in six top medical journals (including *PLoS Medicine*) had lied in their authorship statements including listing guest authors and omitting ghost authors [9]. The editors proposed that "such anecdotes add to the body of evidence that the medical literature continues to be systematically manipulated to promote specific products". However, it is debatable whether anecdotes can really provide evidence of something happening 'systematically'. In addition, a major downfall of the article is that the editors fail to provide their definition of ghostwriting. Do they consider a writer who has not been mentioned as contributing to the manuscript at all (i.e. invisible) a ghost?

Or would they still consider a writer whose role is clearly accredited (such as in the acknowledgements section) a ghost? Most people (including the ICMJE) would consider the practice of the first definition (i.e. a writer whose contribution is not mentioned) unacceptable, but probably not the second.

The second article discussed in this issue of Journal Watch is a commentary piece by Anna Lok, a senior associate editor of *Gastroenterology*. The article also considers the ICMJE criteria for authorship [10]. Lok questions who should be included as an author and how should it be determined, and splits her advice into increasingly complex study situations: single-centre studies, multicentre studies, and industry-funded multicentre studies. On the face of it, the author list for a single-centre study should be the simplest, but it can still be challenging to determine who has made substantial and critical contributions to the study and therefore warrants authorship. Determining authorship for multicentre studies can be more complicated: they may involve a publication committee and the stage of manuscript writing may involve a large amount of people with varying thoughts and comments. She suggests having ground rules from the beginning to avoid later problems. Lok admits that determining who should be an author in industry-funded multicentre studies is a mystery to her, sometimes involving a large number of people. Lok argues that, for her, "authorship is not important; what matters is making sure the results (positive and negative) are shared with the scientific community and presented objectively".

Lok also talks about a major concern with industry-funded studies, the involvement of ghost authors. She acknowledges that medical writers can be a great help in developing a manuscript outline; collecting and compiling author comments; formatting text, tables, and figures; and collecting author disclosures. Lok finishes by saying that the role of medical writers is justifiable when their role and funding source are declared and when authors are fully involved in data interpretation, critical review, and approval of the final manuscript, but she believes that medical writers also tend to put a positive spin on results and they often have limited knowledge about the disease they are writing about.

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Whether to insert a hyphen between two words, e.g. time-point, is primarily a matter of stylistic taste. Most shop signs in Nepal are written in English and the Nepalese put hyphens in some novel places. For example, welcome is often written wel-come. The above is a sign outside a lodge in the middle of nowhere a few kilometers' distance from Jomsom.

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Good writing practice

Writing for the audience (1)

As part of the EMWA subgroup that is looking at Good Writing Practice, this article focuses on writing for the audience. It might seem obvious, but the first thing you need to consider before you start writing any document is who the document is being written for. The immediate person you are writing the document for may be your boss, but they are less important than the final end audience of a regulatory reviewer, a journal subscriber, or a lay person. So the first step is to identify the key audience for your document and keep that person in mind while you are writing. Then you need to consider the following points:

- What does the audience want to know?
- What does the audience need to know?
- What is the audience likely to understand?

These three questions are more important than what you want to tell the audience. For example, there is no point writing a comprehensive document covering all aspects of a drug development programme if the person you are writing it for only wants a series of key bullet points to use at a meeting. You also do not want to be writing a document for review by an expert in a regulatory authority that includes a huge section on the basics of the therapeutic area that is well known to them. This point is particularly important when writing a document for a lay person, such as a patient information sheet—the patient wants to know what is involved in terms of their time, possible side effects, possible outcomes etc. as a result of taking part in a clinical trial and they don't need to know about the disease or the pharmacology of trial drug in any great detail.

The next step is to then consider the depth of knowledge the reader has and also how much time they can afford to read the document. You also need to consider how important the document is for the reader to reach any decisions they need to make—will a doctor be making a decision to prescribe for a patient based on the information, or will a regulatory reviewer be approving a drug based on the document?

Once you know your audience then you can consider the following:

- What is the aim of the document?
- What are the key messages?
- What is the target word length?
- What is the best format of the document? (Word text document, glossy brochure, Powerpoint slides etc.)

It is important to consider all these points BEFORE you start writing—after all if you don't know where you are heading, you are unlikely to get there….

Another important aspect of writing for the audience is the dynamics between the scientific information you are trying to convey, the communication method (e.g. oral, plain text, glossy brochure etc.) and the presentation (i.e. the way you write or speak it) (see figure below):

Spelling, grammar and punctuation are important since mistakes can be misleading and impact on the presentation, and a negative presentation can create an impression that the information is incorrect as well. Communicating effectively with an audience is about them understanding the message that you want to convey. But remember, it is not about what *you* think you have communicated, it is what the *reader* thinks you have communicated.

In summary, before you start writing any document, think about the true audience for the document so that you can tailor the document to their needs. In this way you will end up with a document that is fit for purpose.

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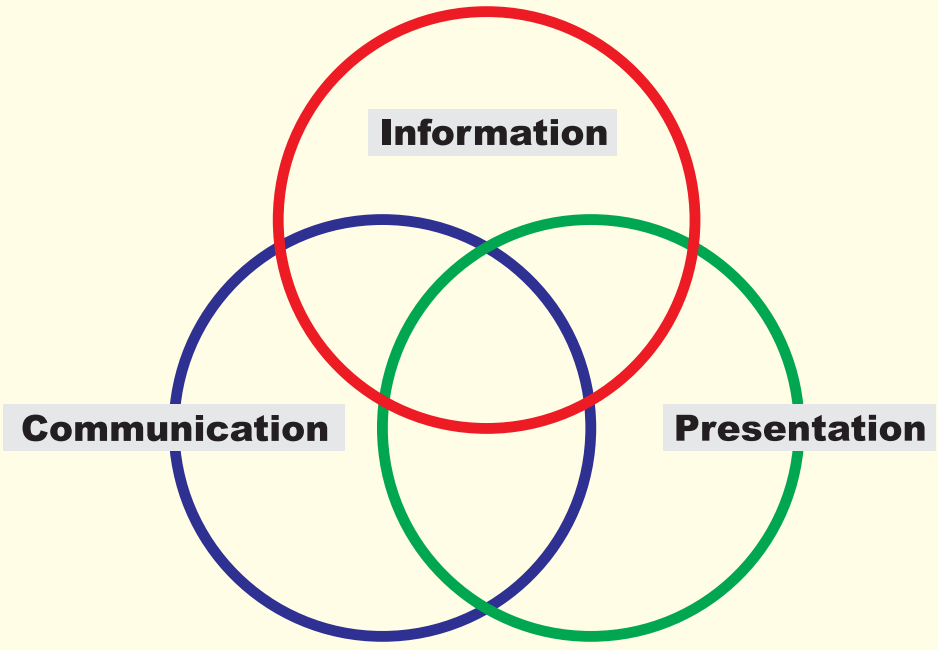

Welcome to our rather festive and final 'Out On Our Own' (OOOO) of 2011. It was wonderful to share news and exchange views with so many familiar faces and new colleagues at the London Freelance Business Forum (FBF) last month. We have a round up of the FBF minutes in this issue on page 252. As usual, we will archive the FBF minutes in the Freelance Resource Centre on the EMWA website.

We end the year on a light-hearted note with a handwriting competition—can you match the handwriting to the well-known EMWA member? The winner will be interviewed for OOOO: no better prize! Anu has devised the first in a new series of Word Jumbles for your entertainment—unjumble them to give medical writing-related words. Have fun!

At this (extra) busy time of year, staying grounded and maintaining life balance can be a challenge. The informative and thought-provoking article on freelancing and life-coaching by Kathryn is therefore particularly relevant. Plus, Raquel tells us about writing a different kind of annual report at this time of the year in our 'Out of Hours' series.

With a year of issues under the Freelance Team's collective belt, we hope that you have enjoyed the material we have shared with you as much as we've enjoyed preparing and gathering it.

In 2012, watch out for more articles on the business side of freelancing, and we will continue to cover life-coaching from the perspective of a professional life coach.

We love to hear from you, so keep the articles coming, and if you have an idea for one, please step forward and talk to us. This is how we keep your column fresh and full of material that interests you!

Happy holidays!

Sam Hamilton
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Raquel Billiones
medical.writing@billiones.biz

Medical Writing Jumble

1. Re-arrange the jumbled letters to get a meaningful word related to medical writing.
2. Next, take the circled letters from each word and make a new word(s) that will answer the riddle in the cartoon. Hint: The answer is probably a pun.
3. Use British English.

Jumble #1

RIXCEV

RODCOT

PERESH

GODSAE

She went from practising Christianity to Buddhism.
For her it was a "_ _ _ _"-_ _ _ _.

answer:

by Anuradha Alahari | illustration: Anders Holmqvist

See page 257 for the answers.

A fun competition...

... that will test your intuitive skills! Given below are handwriting samples of the people you see in the photographs, except that the pairs are not matched. All you have to do is to guess which handwriting belongs to whom. Hint: some say personality traits and cultural influences are reflected in one's handwriting and doodlings. The first person to send all/maximum correct answers will be the winner. If you win, you will get a FREE interview published in the OOOO section of the *TWS*, which means that in the interview you can speak freely on your favourite topic (yourself, perhaps?). So hurry, match the following pairs and send your entries to Sam [sam@samhamilton-mwservices.co.uk] and Raquel [medical.writing@billiones.biz] by the 31st January 2012. Season's greetings and best wishes for the New Year 2012 from the Freelance Support GroupTeam!

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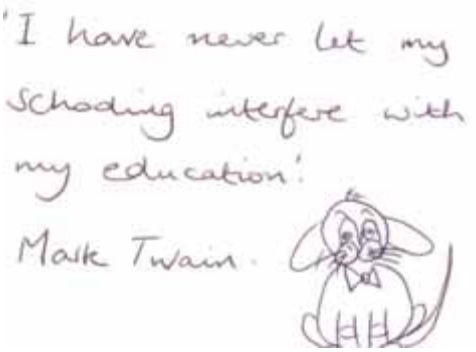
Art Gertel

A

2

Stephen de Looze



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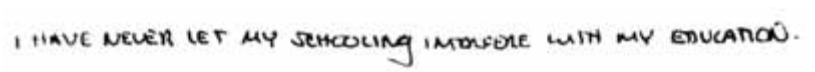
Elise Langdon-Neuner



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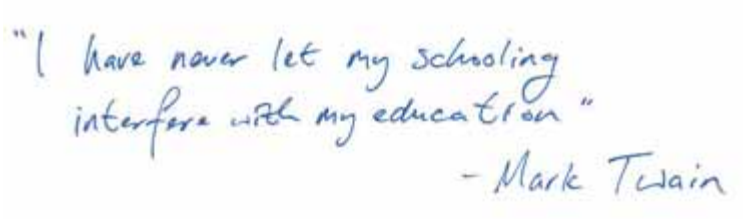
Alistair Reeves



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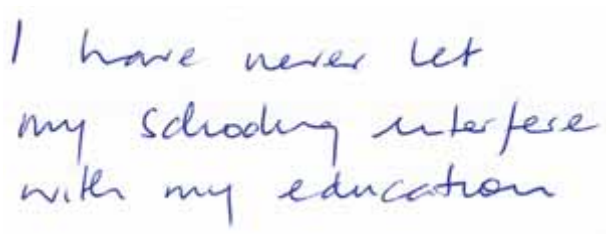
Sam Hamilton



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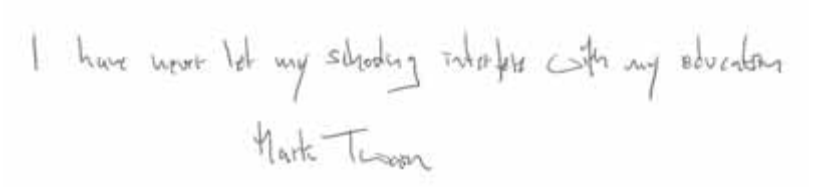
Julia Forjanic-Klapproth



F

A leap of faith—The power of life-coaching

by Kathryn White

In 2009, Kathryn White embarked on a journey that would take her from the 'safety' of a salaried job to the roller-coaster world of freelancing. Kathryn describes how the power of life-coaching helped her to make the transition.

My journey began in late summer 2009. I was enjoying my role as a medical writer with a large pharmaceutical company, where I had worked for over 8 years. I had considered going freelance a few years before, but the business aspect hadn't appealed at the time. After 15 years in the pharmaceutical industry, being my own boss and being able to work at home became too appealing to ignore. I relished the challenge of developing my business acumen. When I look at the path I have taken through life, it is not really surprising that writing has become my way of living because it has always played a significant role since I was a child. In recent years I have gained immense satisfaction from equestrian journalism, which I have pursued as a hobby.

Although it felt the right thing to do, making the leap from regular salary to the 'feast or famine' world of freelancing was too big a decision to make alone. I felt I would benefit from support from someone who was neither colleague, friend nor family; someone who was independent. I had just finished reading an inspirational book by Elizabeth Turner who was widowed following the 9/11 attacks. She had been pregnant with her first child at the time and the book described how she had raised her son and got back on her feet following the tragic loss of her husband. Her journey took her from being a corporate human resources (HR) executive to life-coach and she set up her own life-coaching consultancy. Having been widowed myself, the book and Elizabeth's story immediately struck a chord. If anyone knew how to help me realise my dreams, then Elizabeth would. I contacted her company and was put in touch with her associate and life-coach, Kevin Watson (www.myown-coach.co.uk).

Over the subsequent coaching sessions, Kevin and I built a good rapport—despite the fact that our sessions were over the phone. It was fantastic to have someone to whom I could pour my heart out about the past and describe my hopes and dreams for the future. He listened—I mean, really listened—and took on board what I had said without judgement. At this point, I will handover to Kevin to let him tell you what his thoughts were as a coach and how he feels that coaching has helped.

"As I listened to Kathryn at our first session, I began to be curious as to what was getting in the way of her achieving the life she wanted. Together we explored what her passions were, what she valued most in her life and what limitations she was placing on herself. It emerged that Kathryn was an ultimate planner and, despite everything that had happened in her life, she still felt a need to control her future. It was almost as if this strength was closing down her imagination, the ability to dream of what could be... without limits! So, recognising her love of writing, I invited her to dream of her ultimate future, the life she would love to live, and write it down anytime the urge took hold: the sights, the sounds, the feelings and even the smells.

At the heart of life-coaching is the belief that the coachee has the answer—but may just be stuck right now! So the coach helps to provide an understanding of what the answers are by asking questions—non-leading, non-judgemental open questions. By asking these, listening deeply to the response and offering insights as appropriate, a coach is able to provide different perspectives, revealing the coachee's answers to themselves."

To say I was 'bouncing off the walls' following that first session would have been an understatement. The confidence that life-coaching gave me to move forward with my life and plans was quite incredible. I went to bed the night of the first session and couldn't sleep. Words were tumbling from my head and I had to capture them on paper—to describe the life I wanted to lead as if I was actually there. Despite the lack of sleep, I awoke the next morning feeling more refreshed than I had felt for a long time.

Through my continuing sessions with Kevin I learned to trust my gut instinct and to 'go with the flow'. I absolutely knew that starting my own business as a freelance writer was what I wanted to do. Not only did it enable me to pursue something I was passionate about for a living, it opened up the possibilities of me working from home, relocating to Norfolk to be with my partner Henry, and to realise a long-held ambition of having my horses at home. I even had a mug printed with "What Plan?" emblazoned on the side alongside a poignant photograph of my horse.

My dream began last July (2010) when I left employment to become a freelancer. I haven't looked back since, although it has been somewhat of a rollercoaster ride. Life-coaching continues to play an important part in my personal development. Indeed, only a few weeks into my life as a freelancer, I suffered a really low point—I started to doubt my ability to make it work. I rang Kevin, and as always, the life-coaching session rejuvenated my enthusiasm, motivation and optimism. It reminded me to listen to and trust my instinct; to realise that I was investing rather than spending my savings to give me the life I wanted and >

A leap of faith—The power of life-coaching

> to recognise that the positive feedback and repeat business was confirmation that I was good at what I did! Since then, business has continued to grow. Not only that, but I've expanded my equestrian journalism to include top national, equestrian publications. My advice is not to under-estimate the power of life-coaching. It can be a very effective tool to help you realise your potential and is something I would highly recommend as part of your continuing personal and professional development.

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Join the debate

An editorial on the EMWA website is causing quite a stir. The article *Evading responsibility to readers and third parties: how an international bioethics journal failed to correct the record of publication* by Karen Shashok follows up on Adam Jacob's article in *TWS* (vol 20 (2):108-9). See http://www.emwa.org/Home/Webeditorial-7.html and post your views on the EMWA LinkedIn page.

Summary of the Freelance Business Forum, London, Thursday 3rd Nov 2011

(A full version of the meeting minutes is posted on the EMWA website in the Freelance Resource Centre).

Freelance Resource Centre

- Anu Alahari (AA) is taking over responsibility from Ingrid Edsman (IE) for updating the FRC with help from Shanida Nataraja, the EMWA website manager. Thanks to IE for all her sterling work to date.
- Debbie Jordan (DJ) suggested the addition of a regulatory section to collate guidance documents. This was agreed by the FBF and documents will be emailed to AA, Sam Hamilton (SH), Raquel Billiones (RB) or Kathryn White (KW).

LinkedIn

- EMWA LinkedIn page is used to keep members updated on all matters freelance. Join if you haven't already. There are no plans to make the LinkedIn page restricted to members.

Out On Our Own

- We encourage the membership to contribute with business tips; useful and practical tools for freelancing—a piece of hardware, software, a website, a phone app, a book; or do you have a fresh spin to an old freelancing story? Send your submissions to medicalwriting@billiones.biz.

Contracts and Work Orders

- List/table of points to be included in contracts/work orders is under development. Members Amy Whereat-Terdjman, Rosie Bischoff and Corinne Swainger volunteered to provide information and work with KW. This will go on the FRC and will be a living document to be updated on an ongoing basis.

Qualifications Clarification

- Jo Whelan (JW), EMWA's Education Officer, explained it is important that members are aware that once an EMWA certificate is awarded they cannot state that they are EMWA accredited. Members can state that they are part of the EMWA organisation and that they have an EMWA certificate following completion of the necessary workshops.

Freelance Business Survey (FBS) 2012

- The next FBS is planned for the first half of 2012. Survey will collect anonymous information from freelancers on charges for medical writing services; a report will be published in *TWS*. The more people who contribute, the more accurate it will be.
- Member Gina Dungworth offered to enquire about how other organisations have done this as she knows someone who has done it for ABPI.
- A question was raised as to whether the survey needs to ask in which country the freelancer resides given this may not be where the freelancer conducts their work; many freelancers work outside of their own country and across Europe and the rest of the world. The survey organiser also needs to be aware that if the country of residence is requested, then some freelancers may lose their anonymity because they may be the only freelancer in that country.

Cyprus 2012

- The next EMWA conference will be held in Cyprus. SH requested that all members who attend the conference should make every effort to attend the AGM which will be held on the Tues afternoon.

Out of Hours

Writing an annual family report

by Raquel Billiones

Long before I published my first scientific paper or wrote my first clinical study report or heard of (much less considered) medical writing as a job, I was writing it.

My husband and I started doing it even before we got married, continued through 5 years of childless marital togetherness and somehow managed to fit it in between nappy-changing and breastfeeding when our twins arrived.

I am talking about our tradition of preparing an annual family report, of course! It is a yearly update of what's new in our life and what we've been up to. Actually, many would call it a Christmas letter, but the term 'report' is preferred by a corporate husband and this not-so-religious family. When we were still dating we wrote our separate reports; once we got married we decided that one common letter would suffice for a family. Now we split the workload: I write and he provides the QC.

Lately, I find that Christmas is getting more hectic and busier and I always ask myself, amidst the tight deadlines, decorating, baking cookies and gift wrapping: "*Must I?*" "*Do I really have to*?" And the answer is always a resounding "*Yes!*".

So why do we do this, year after year, between Christmas and New Year, in whichever country or continent, mountain or ocean we might be in/on? The three reasons are:

To keep in touch

We are a multicultural family. I've lived in 5 different countries on 2 continents, while my husband has lived in 4 countries on 3 continents. We have family and friends scattered all over the globe. My husband abhors Facebook and we just don't get the time to write long, detailed e-mails. But all those we hold dear, wherever they are, receive our annual report.

To look back and look forward

We don't keep diaries or personal blogs. But at the end of each year, we sit down and look back at the year that was. What were the highlights and milestones reached? What have we achieved? What could we have done better? And then we look forward to the upcoming year and put down on virtual paper our plans. What are our goals? Which country do we want to visit next?

To preserve the memories for our kids

Our twin boys are now eight-and-a-half years old. Although they seem to have amazing memories, there will be lots of things they may forget or have already forgotten, growing up. The reports will preserve those memories for them. When they are old enough, they'd be able to read about their parents' love story, the DINK[1] period, their babyhood years… Maybe I'd even get them to write parts of it someday. In other words, the annual reports tell the story of our lives.

It's not only what was written but how it was written that tells a story.

Anybody who would brave the task of reading the reports of the last 15 years would be able to trace from the writing style and quality how my career has evolved as a scientist and then as a medical writer. The early reports were long-winded 10-page narratives of 12 months worth of trials and tribulations (how could anybody have gone through them?). Last year, we produced a 3-page concise and structured document, complete with an executive summary, headings and subheadings. As my husband puts it, the report gets shorter—and better—each year, and adds, "Just don't dare to use bullet points!" Like the writers of the reports, the target audience has also matured and reproduced, not to mention become busier and thus, much appreciative of the shorter, better written updates.

The distribution system used to be 80% snail mail. We are now completely paperless.

And every year, we get feedback from family and friends all over the world, and get a couple of Christmas letters in return, too.

So excuse me, everyone, it's out of hours and I have an annual report to write.

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1 DINK=double income, no kids.

Going freelance: The last of a series of interviews

by Diana Raffelsbauer

Medical writing is a female-dominated profession. Most EMWA members are women, and everyone who has ever attended an EMWA conference can confirm the higher proportion of female colleagues. In the December 2010 Issue of *TWS*, which was devoted to the theme 'a feminine workforce', various arguments were provided to explain this phenomenon. One of them was that medical writing is a service profession, a sector dominated by women throughout all business areas. Women are better equipped to compete with men in professions that require high educational levels. Most medical writers have degrees in science, but women are more likely to leave the highly competitive research environment. Besides the scarcity of opportunities in the academic labour market, other reasons for this choice might be gender-specific. For example, the cooperative and intuition-oriented behaviour typical of women doesn't fit well into the ego-oriented and logical scientific métier. The decision to have children may also influence career choice. In this respect, the medical writing and translation professions are particularly suited to home-based working and provide flexible working hours that presumably ease the balance between career and family.

In the last part of this interview series, we present four women who are successful freelance medical writers: **Gillian Pritchard** (G.P.) and **Debbie Jordan** (D.J.) are regulatory medical writers from the UK who also provide training and consultancy services. **Annick Moon** (A.M.) is a medical communications specialist from the UK, and **Anne Bartz** (A.B.) is an experienced medical translator from Germany. Did their feminine skills and intuition help them find a niche and achieve success? Maybe... Read what they have to tell us about their career development and find out.

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

G. P.: These fall into three areas:

1. Writing regulatory documents: clinical study reports, clinical overviews and summaries for regulatory submissions (CTDs) and literature reviews as part of CE mark applications for medical devices.
2. Conducting market assessments: helping academic groups or small companies evaluate products or services through a combination of desk research and telephone interviews with experts to identify commercial potential and thus inform development plans or business strategies.
3. Delivering training courses, e.g. pharmacovigilance training for clinical research staff and investigators.

D. J.: I provide medical writing, consultancy, training and project management services to pharmaceutical companies, CROs, medical communications companies and in some cases directly to doctors carrying out their own research projects. I therefore get involved in writing or reviewing quite a broad range of documents, from protocols, clinical study reports, clinical summaries and overviews for regulatory submissions (which accounts for about 70% of my time), through to posters for conferences and manuscripts for journal publications (which takes up about 15% of my time). The remaining 15% of my time is either taken up with training or consultancy work and the oddments that don't fit into any of the categories above.

A. M.: I provide freelance services to agencies and pharmaceutical industry clients, including medical writing and editorial support, strategic communications planning, positioning, key message development, competitor analysis, and bespoke training programmes. I don't have any regulatory writing experience, but cover all other aspects of medical communications, sometimes providing consultancy such as messaging and publication strategy, although often I am needed only to write. In medical communications, your area of expertise tends to be dictated by the types of projects you are involved in. In the early days, I did a lot of infectious disease work and several conferences, but now after a decade in the business, I've covered every type of project and most major therapeutic areas so many times that my expertise is broad. Having said that, my early infectious disease experience has developed into a specialty, and recently I've written lots of manuscripts about influenza vaccines. In terms of types of writing, I enjoy developing scripts for medical animations: an ex-partner was a 3D animator who used to chat about his job constantly ("very interesting dear, now shut up and let me watch Toy Story"), and I suppose this knowledge was useful when asked to write my first script. I've now done quite a few, and some of the animations I have worked on have won awards. Getting recognition was very exciting, even if it was just a wafer-thin certificate (although not as exciting as getting published in a dictionary of swear words, which I had best not discuss in the EMWA journal).

A. B.: Basically, I translate any documents concerning medical or pharmaceutical topics for the pharmaceutical industry, publishing companies, health care institutions

The last of a series of interviews

etc., with a focus on regulatory affairs and publications. I also proof-read and edit texts for publishing companies and adapt texts to current templates or (publishing) guidelines. I have been writing package leaflets for some time and I'm about to do more writing in the near future.

How did you become a medical writer?

G. P.: I've been 'medical writing' all my professional life. My first major writing task was a dissertation for an MSc in clinical pharmacology. This was memorable because it was also the first time I used a computer to write a document myself – yes, it was a long time ago! During my time in clinical medicine I conducted phase II clinical trials which involved writing patient information sheets, preparing ethics submissions, and subsequently drafting manuscripts for publication – which were all much simpler than nowadays! Then I moved to a phase I research unit and spent a considerable amount of time planning studies, writing protocols, designing case report forms, writing informed consent forms, preparing ethics submissions and study reports. This was a good opportunity to work with numerous sponsors across various therapeutic areas and to learn more about drug development. Working in clinical development for a global pharmaceutical company gave me a fantastic opportunity to plan and run the European part of their phase III diabetes programme. This meant overcoming the challenges of designing studies to accommodate differences in medical practices within Europe and between Europe and the US, whilst complying with all the regulations and still adhering to the development plan. It was also a chance to learn more about different countries, cultures and languages. Pharmaceutical and medical device consultancy work also involved a lot of medical writing: clinical study documentation, standard operating procedures, study reports, literature reviews and market assessments. I also developed and delivered training courses to companies and clinical researchers.

D. J.: I started my career in animal conservation research work, but moved into the pharmaceutical industry due to lack of funding in the conservation field. My initial job within a pharmaceutical company was as a data assistant, and I worked my way up through the roles of CRA (both in Europe and in the Far East), to project manager of global antibiotic and oncology projects. I moved into medical writing at a CRO when I had my first son since the travel involved in my previous role as a project manager did not work with family life, and after my second son was born, I decided to set up on my own providing freelance medical writing services.

A. M.: I was always interested in writing, and as a schoolgirl, I regularly published in the local newspaper's Young Reporters' Club. During my doctoral studies, I was on the editorial committee of the Physiological Society Magazine (now called Physiology News). This was a voluntary position which I was delighted to get after responding to an advert. During my second post-doc, I realised that it was time to bow out of academia, so I applied for jobs which had the word 'editorial' or 'writer' in the advert. I ended up in a medical communications agency, although I didn't know what "med comms" was about until I started the job. I worked at various agencies, in editorial roles: project manager/editor, senior project manager/editor, medical writer/editor, senior medical writer. After five years, I decided to set up on my own and have been freelance since 2006.

A. B.: I have a degree in applied linguistics with specialisation in medical translation from the University of Heidelberg. I started medical writing in April 2011 thanks to some clients who encouraged me to do so and to EMWA.

Why did you choose to work as a freelancer?

G. P.: I became freelance, like so many do, because I was made redundant and saw an opportunity to continue doing consultancy work. I knew how to write proposals and to cost projects and what to include in contracts, plus I already had a network of other freelancers to work with and former employers and clients for sources of work. Also, with two young children and being located in north-east Scotland, I knew that finding part-time work locally was going to be difficult. So setting up my own company seemed a logical step which has worked out very well.

D. J.: I initially decided to become a freelancer about 12 years ago due to family reasons, since I wanted to work from home so I could spend more time with my kids as they grew up. I also wanted a bit more flexibility in my working day so I could manage my work and home life with more flexibility.

A. M.: As a writer in a medical communications agency, I worked with some fabulous people and travelled the world. "– Anything to check-in? – Just these eight trolley loads." From senior writer I could have gone in an editorial team-leader direction, or a principal medical writer direction. Instead, I decided to define my own 1) job, 2) job title, and 3) working conditions i.e. 1) writing whatever comes my way, 2) communications consultant & writer, and 3) lap-top on my kitchen table in my pyjamas. Succeed or fail, it was all down to me. Success was measured by the amount of new and return business I was offered, and ultimately by the invoice total box on my spreadsheet. No managers, no timesheets, no appraisals, and only one cup of tea each time I boiled the kettle. Moon Medical Communications has been in business now for over five years, and I wouldn't change a thing.

A. B.: Basically because there are not many opportunities to work as an employed translator in the medical or pharmaceutical industry. When I started my career back in 1989, pharmaceutical companies were about to close down their translation departments ("Sprachdienste") and to start outsourcing translations. At that time I did not want to work for an international organisation that employ specialised translators, such as the EU commission or the United Nations. >

The last of a series of interviews

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

G. P.: 1) Knowledge and practical experience; 2) Being aware of what you don't know and knowing where to find information; 3) Business skills, networking and training are also important – of course, the EMWA conferences provide all this; 4) Finally, enjoy your work!

D. J.: I think you need to have good organisational skills so you can manage projects and timelines effectively, since keeping to deadlines is very important when you are working as a freelancer. Good people skills are important as well, because you are dealing with clients directly so need to establish a good rapport with them in the start-up phase of the project (which is often long before you actually get to meet them face to face), and they need to view you as a professional person who is reliable and is going to do a good job for them (which also means you need to have a fair degree of confidence in your own abilities to achieve the set goals). You also need to be very flexible since, like all things, nothing goes to plan and so you have to be prepared to put in the extra effort to keep the client happy, even if that means working all weekend to meet a suddenly urgent deadline!

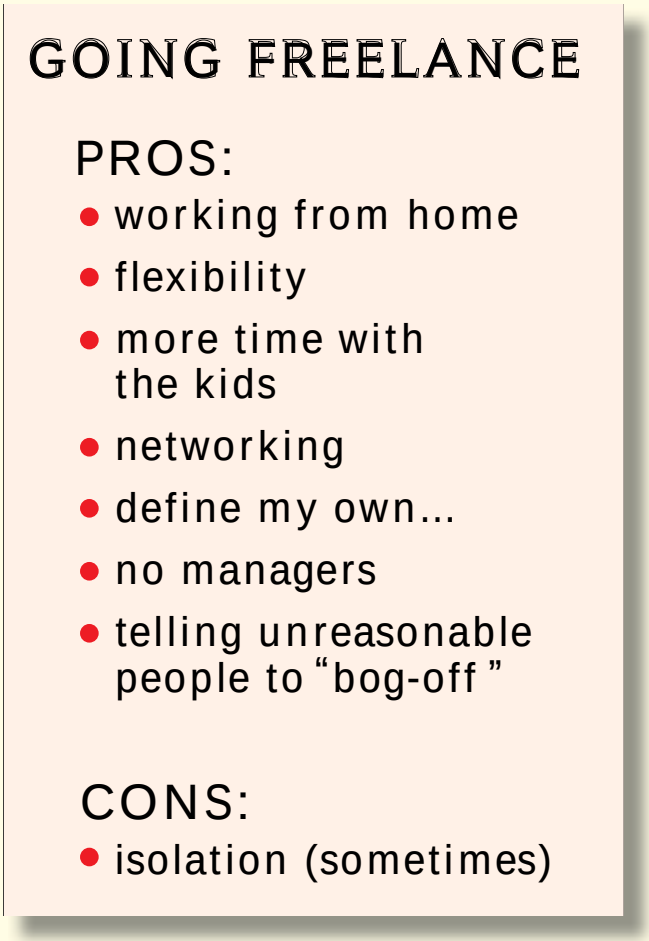
A. M.: Job descriptions often include skills such as attention to detail, excellent communication skills, and creativity. Above all, I think the most important skill is the ability to research a topic using sources in the public domain, and to absorb huge amounts of complex information quickly. The audience for much of my work are global leaders, and regardless of my knowledge in the area, as a 'Jack-of-all-therapeutic areas' I can never be a true clinical expert in a given field. But if I do my research properly, and listen to the views of the opinion leaders and the needs of the client, I can construct convincing arguments and technically accurate copy.

A. B.: Eye for detail, good command of the source and target languages, willingness to learn something new every day, patience, perseverance and for freelancers, the flexibility and willingness to work when everybody else does not.

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

G. P.: Getting the right work-life balance!

D. J.: Moving timelines are the biggest challenge, particularly when you are working for several clients, since however much you plan for one project to finish before another project starts, the timelines always seem to move so that you need to work on both at the same time. Also another big challenge is the 'mushrooming' project—you agree to take on the writing of a small study report, and then the client asks you to help out on a few other reports to ensure consistency across documents, and before you know it, you have four reports to write and are being included in the team for writing the regulatory submission dossier. This is where the flexibility mentioned above comes in!



A. M.: Single-handedly running multiple departments is a daily challenge, for example, IT support, accounts, sales and marketing, administration, and office cleaning. Although I'm a principal-scientific-account-consultant-director-leader-strategic-strategy-strategist, I get judged largely on my ability to write. Turning a blank page into a manuscript that will be read by thousands of people around the world is always a challenge. It never gets easy.

A. B.: Poorly written source texts or texts written for what is called 'a mixed audience', coordination of different translations for different clients preferably with close deadlines.

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

G. P.: I love the flexibility and freedom of working for myself without the hassle of commuting to an office. I least like being too busy and worrying about how I'm going to get everything done in time.

D. J.: I actually like the challenges mentioned in my answers above and enjoy the 'buzz' of a challenging project that gets completed on time and that everyone is happy with. I also like working from home, since although my kids are now older and don't really need me to be at home,

The last of a series of interviews

it's nice being around when they come home from school. The down-side is that sometimes you can feel a bit isolated working by yourself at home and not in a busy office with other people to talk to and get advice from. However, most projects involve interaction with clients and I have a good network of colleagues and friends that I can call if I need to, so this isn't really a problem. I think I am very lucky to I have a job and a lifestyle that I love—long may it continue!

A. M.: I like writing, and I get to do it all day every day, so there's not much about my job I dislike. A favourable aspect of being freelance is being able to tell unreasonable people to "bog-off"; having said that, my ability to suffer fools is significantly greater as a freelancer than it ever was as an agency employee. On the odd occasion when I'm asked to do something ridiculous, although I always try to nudge the client in the right direction, I usually just do as I'm told. I suppose, part of the job I like least is sending off a piece of work which fulfils the brief, but isn't necessarily what the client needs; I just have to cringe and bear it. Oh go on then, I'll give you an example. I was once asked to copy and paste over five-hundred abstracts from PubMed into a Word document to "give the brand manager a comprehensive overview of the competition's literature." *sigh* Needless to say, on this occasion, I didn't just do it; I told them to bog-off.

A. B.: Most: The broad spectrum of topics to be dealt with in two languages and the know-how gained, to learn something new every day, to work for international companies and to learn about intercultural communication. Least: Poorly written source texts.

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

G. P.: 1) Gain experience within different companies or organisations before considering freelance work; 2) Don't think you can only be a regulatory medical writer if you have worked in a medical writing department; 3) Join EMWA and come to the conferences.

D. J.: Young medical writers need to make sure they get considerable experience in the industry before they even consider going freelance. They should work for several different companies or CROs to see how different companies do things and give more depth to their experience. They also need to network extensively so they are well-known and have gained a reputation for being a good writer before deciding to go it alone, since I find most of my work comes through recommendations or repeat work from existing clients.

A. M.: Once you get a trainee position, it can be tough. Training involves a process of writing, having your work covered in red pen, and then writing it again. But eventually the red pen subsides. The best advice I can give to novice writers is this: a brief is something your manager gives you at the start of a job, not half way through, and not at the end.

A. B.: I can only give advice on the medical translation career. Be prepared to compete with translation agencies and translation tools and to do further professional training forever, get expert advice on marketing and business matters, join professional organisations and find a niche.

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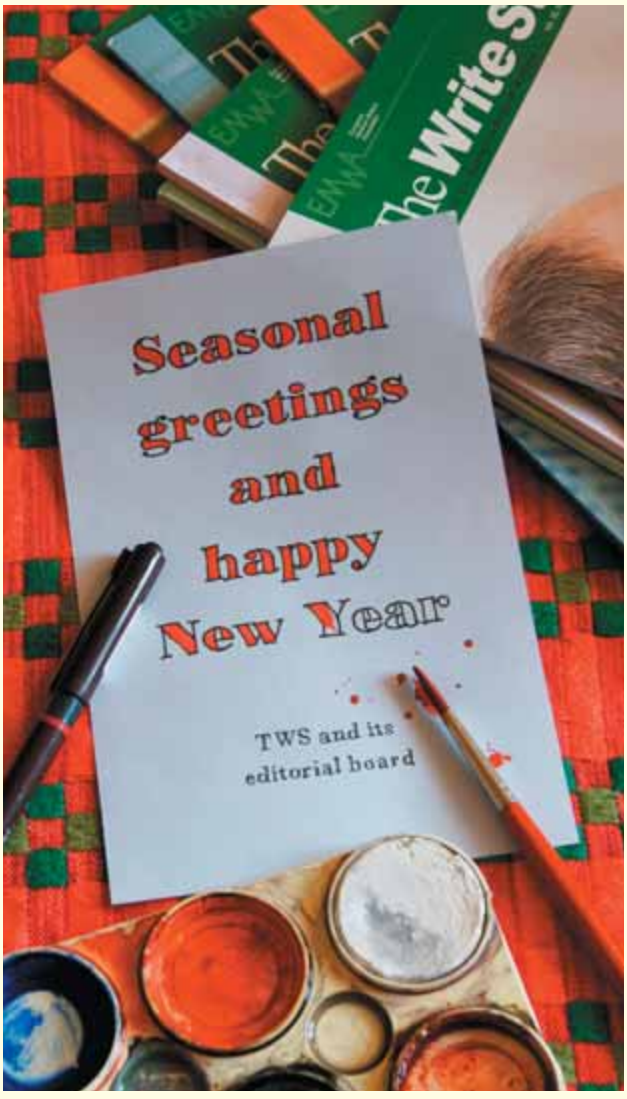

Answer to Medical Writing Jumble #1:

CERVIX, DOCTOR, HERPES, DOSAGE and "CROSS"-OVER

Words, Grammar & Co

Can you start a sentence with *it*—or *because*, *and* or *but*?

Frequently asked questions sections of websites can be a good source of grammar advice. Carol Klein's company, The Writing Center, Inc, provides training in effective business and technical writing and two questions on the company's website at http://www.writingcenter.com/ten-questions.htm deal with the use of *it* and *because* at the beginning of sentences. Here are her sensible answers to these questions quoted directly from the website.

Why shouldn't sentences begin with 'It is' or 'It is important to note that'? Meaningless openers weaken the power of a sentence. Readers look to the beginning of sentences—the subject position—for key ideas and to the verb position for key actions. Therefore, eliminate weak openings such as *It is* and *There are* and meaningless introductory phrases such as *It is important to note that*.

May a business writer begin a sentence with 'because'? Many writers remember learning the rule, "A group of words that begins with *because* is not a complete sentence." That is, "Because of increased account activity" is not a sentence. However, that rule does not mean "Do not begin a sentence with *because*." For example, the following is a correct sentence: "Because of increased account activity, we have hired an additional customer service specialist." Writers may begin a sentence with *because*. In fact, doing so allows them to use the very persuasive "Sell and then tell" sentence pattern in which reasons and benefits are presented at the beginning of the sentence.

Should a sentence ever start with 'and'? *The New York Times* has some useful tips for proofreaders which might also be of interest for those proofing scientific text http://topics.blogs.nytimes.com/2011/10/04/the-readers-lament/. Frequently asked questions http://topics.blogs.nytimes.com/2010/04/13/faqs-on-style/ include questions about whether you should start a sentence with *but* or *and*. The advice given is that over use of these coordinating conjunctions to begin a sentence should be avoided but they can be useful. *But* is often preferable to what they call the 'stilted' *however*, and *and* is simpler than *in addition*.

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A pity about enormity

The first column in the print edition of the weekly *British Medical Journal* (*BMJ*) is *Editor's Choice*. In one of her January columns, about the need to review raw data rather than published results [1], Fiona Godlee wrote "recognising the enormity of the task, [the Cochrane team] are recording how much work is involved".

The first meaning of *enormity* is a large-scale, grave crime or sin, but over time it has become also a synonym for hugeness, with no moral overtones. The 10th edition of the *Concise Oxford Dictionary* has occasional highlighted notes on usage, and there is a note for enormity: its increasing meaning as something very big is "now broadly accepted". Looking back at the *BMJ*, that is certain. Of enormity's ten most recent uses, six merely meant very big. In one editorial it was applied to hazard ratios ("The most impressive finding of these trials is the enormity of the hazard ratios"), which seems over-dramatic. One referred—undoubtedly correctly—to the Holocaust; another referred—arguably correctly—to the mid-Staffordshire health scandal. Another referred to the Boxing Day tsunami, but that was a natural disaster. One use that might have been correct was not. Written of the chemical accident at Bhopal, "The sheer enormity of loss was heartbreaking" sounds right, but the incident itself was the enormity; the *scale* of the loss was heartbreaking. (*Sheer* is unnecessary: it is what Keith Waterhouse called a "limpet adjective" [2], like *drastic* steps, *utmost* urgency and *true* facts.)

My response to this is that *enormity* is now a lost word, which careful writers should not use (just, as I have mentioned before, *disinterest* is better avoided). Meaning may be obvious from context, but better not to rely on context. If something is big, *size* is often enough: the *size* of the impending plans, the *size* of the task, the *size* of the hazard ratios. If that is not enough, try the *magnitude* of the disaster, or the *scale* of the loss.

But what of Auschwitz when *enormity* might just mean big? It is not as easy to find a single-word replacement. *Wickedness* seems somehow weak, *outrage* too small scale. Perhaps the best answer is to rephrase to use an adjective instead of the noun: I suggest *heinous* or *monstrous*.

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Solving the European Commission's English woes

Writing in the *Economist*'s language blog, Johnson, blogger S.D. from London ponders what can be done to improve the use of English in the European Commission [1]. The Commission's latest attempt to deal with the notorious impenetrability of much of its written communication, the Clear Writing campaign [2], was launched last year and is being promoted with the help of a ludicrous gospel tune, "Good news! Clarity's a-coming!" [3], essentially just a cheap jingle.

The main problem, as S.D. sees it, is that while the vast majority of the Commission's employees write in English, fewer than one in seven are native English speakers [2]. Moreover, slightly over half of them rarely or never get a

native English speaker to check their work. The upshot: a boatload of mistakes, several examples of which S.D. provides for our amusement.

To help its staff improve their writing standards, the Commission has, as part of its campaign, published a guide containing 10 top tips for increasing clarity [4]. Happily, this guide includes advice on avoiding/explaining jargon, so those of us not *au fait* with Commissionspeak should have more hope of comprehending future Commission documents.

It should be noted that the Clear Writing campaign covers 23 EU languages. However, S.D. dismisses this as political window dressing on the basis that the Commission's *lingua franca* is "bad English".

After exploring some of the dangers of poor writing, S.D. goes on to discuss the Commission's proposed solutions. These, we are told, include making editing compulsory and rewarding clear writing. The Commission is also planning a call for the development of "Clear writing software" [5]. Time will tell what becomes of these mooted ideas.

One of S.D.'s own suggestions is to get Commission employees to write in their native language and then have their work professionally translated. That ought to work, but it would be expensive.

According to Emma Wagner, an editor at the Commission, EU expansion saw the arrival of a lot of new personnel who "adopted the prevailing in-house style, rather than trying to reform it" [2]. What might now be needed, S.D. argues, are people who are willing and able to fight the tide, outsiders not "anaesthecised [sic] to the painful language" organisations such as the European Commission use.

Any volunteers?

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For regulatory writers

Review cycles for regulatory documents

Once again, I find myself drawing on EMWA's LinkedIn discussions for topics to discuss here. One thread that caught my eye was based on a post by Gregory Cuppan about review processes for regulatory documents. A 'high-quality' regulatory document must meet regulatory expectations while being 'on message' (and not in the sense that a company is spinning the results, but rather aiming to provide consistent and unified information about a product or group of products). In general (and this is a simplification), the scientists and clinicians involved in a project (the team) will be responsible for providing the message, while the medical writer will be in a good position to judge whether it meets regulatory requirements. For multidisciplinary projects in particular, review rounds will generally be needed to ensure that this information is properly integrated and unified. I think it is also important to note here that a review round might not necessarily improve the document as such (indeed, according to Gregory Cuppan, data gathered by his consultancy company seem to suggest that reviews often don't demonstrably improve 'quality'). Nevertheless, review is still an essential part of the process. By analogy with manuscripts, where appropriate author reviews are necessary to ensure that the final document truly reflects the authors' opinions and not those of the sponsor through the proxy of the medical writer, an appropriate review and sign-off process for regulatory documents ensures that the company position (and that of the team) is transmitted, and not that of the writer.

So reviews are essential, but they can be very inefficient. Gregory Cuppan suggests that reviewers all too often get engrossed in low-level edits while missing the opportunity to make high-level comments about information flow, key messages, etc. Adam Jacobs points out that people often seem to need to be seen to doing something, hence the fussy edits. Often it is annoying when people make minor (and inappropriate) style corrections, for example without being particularly familiar with house style. Another take, however, is that minor mistakes can be distracting and therefore, even with early drafts, it helps if the document is as free from errors as possible so people can focus on the content and overall message. It is a matter of judgment whether time spent cleaning things up at this stage will outweigh potential time savings later in the review cycles. The bottom line, I suppose, is try to avoid appearing sloppy.

Gregory Cuppan concludes by recognising that collaboration to produce complex documents "involves difficult cognitive and social practices", but is at a loss as to why weaknesses in the review system, which are associated with huge waste of resources and therefore money, are not addressed more vigorously by management. If it were easy, then more action would be taken. I don't know whether formal training for those who review documents would be of help, or cost effective. I will say though that I think that medical writers themselves can go some way towards ensuring smooth and efficient review cycles. In addition to sending out a tidy document with as few distractions as possible, medical writers can accompany the document with an explicit cover letter making it clear what they are expecting from this particular review and what parts they want each particular reviewer to focus on.

How much work is a clinical study report?

In another EWMA LinkedIn thread that caught my eye recently, Raquel Billiones, posted an article [1] which attempted to objectively measure the time taken on a first draft of a 'standard' phase II/III clinical study report (CSR). Clearly, it is often important to have an idea of how long the first draft of a CSR might take. If you are a freelancer, you need some clue to enable you to give a reasonable quote (even if it is ultimately adjusted according to the number of hours actually worked) and if you are a manager, you need to be able to track and optimise your resources.

The article came up with a time of 47 hours for a 100 pages of text, excluding figures but not tables. (A report of 70 pages of text would, according to the equation relating number of pages to time needed, take 23 hours. A 40-page report would take 0 hours, so clearly the derived equation doesn't handle extremes too well). To many of those who commented, these times given seemed too little, and certainly, it would be a best case scenario where the writer is familiar with the CSR template, company approach, the therapeutic area, type of study, and a number of etceteras. Personally, I also think this is low, but not outrageously so. And of course, there is plenty of variation in these figures (the number of pages per hour ranged from 1.99 to 3.64 for the sample of 10 CSRs from medical writers used as the dataset for the article).

The times were calculated by looking at the document properties in Word and seeing how many hours the document had been open, with confirmation from the writers that they did not leave the document open while doing other things. This would lead to an overestimation of the time spent. On the other hand, as was pointed out in the LinkedIn thread, you don't need to have a document open to be working on a report (you can be going through the outputs, or familiarising yourself with the protocol without having the document open). If this were the case, an underestimate would result. Given these methodological limitations, we should perhaps not place too much weight on the numbers given, but at least they represent an attempt to tease out an answer to a difficult question.

Most companies will require their employees to keep some sort of timesheet, and work billed by freelancers will often be based on an estimate of the number of hours worked, so presumably managers will have access to information about declared time spent on a CSR. This information would be interesting, though unfortunately it is unlikely it will be systematically analysed in a publication for all to see. Despite the uncertainties when giving a figure for the time spent producing a first draft, in a way it represents one of the better defined parts of the estimate of the time required for a full CSR through to sign-off. The comments

from subsequent review rounds will vary greatly in the speed with which they can be addressee—the CSR might sail serenely through to sign-off without much further work on the core draft or require extensive rewriting. The review process, as hinted at above, is not an exact science.

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Retractions are increasing

The number of research articles that are retracted by scientific journals after publication is increasing dramatically. An average of 30 papers a year were retracted in the early 2000s and it is predicted that the Web of Science will index over 400 retractions this year. Compare this with the 44% increase in the number of papers published over the same period. Probably the rise in retractions reflects an increased awareness of research misconduct and the emergence of software that can detect plagiarism and image manipulation rather than an increase in misconduct. Many editors fear legal action for defamation or do not have the time or staff to conduct a tedious investigation and insist institutions shoulder all the responsibility for integrity in publications. Interestingly though according to Nicholas Steneck, a research ethicist at the University of Michigan, journal editors are starting to embrace the role of gatekeeper themselves. Nevertheless retraction practice varies considerably from journal to journal particularly in the amount of detail they give about the reasons for retraction. Some retraction notices are obscure, e.g. stating little more than that the authors have requested the withdrawal because some information is incorrect. Ivan Oransky, co-founder of Retraction Watch (http://retractionwatch.wordpress.com/), believes notices should be explicit as otherwise misconduct is automatically assumed, which puts off honest authors who want to rectify the scientific record.

Source: http://www.nature.com/news/2011/111005/full/478026a.html

Conflicts of interest (COI)

An editorial titled 'Turning the tide on conflicts of interest' written by Fiona Godlee, editor of the *BMJ*, caused a flurry of letters to the journal in answer to a question posed at the end of the article. In her editorial the editor referred to the proposal by the US Food and Drug Administration to relax its conflict of interest policies because it could not find enough independent experts under its rule of no more than 13% of advisers with industry ties. Godlee considers this a bad idea because financial ties between academics and industry are declining. Quoting a survey of over 3000 academics in 2009 by Jeanne Lenzer, which found that half had no industry ties, Godlee states that now is not the time for cold feet because back tracking on conflict policies would send the wrong message. *The New England Journal of Medicine* (*NEJM*) abandoned its policy of no editorials and reviews from authors with ties industry in 2002[1] because it was unable to find enough authors. But Goodlee points out that things have changed since 2002 and ends her editorial with the question: should the *BMJ* repeat the *NEJM*'s experiment and ban editorials and clinical reviews from authors with ties with industry?

Source and letters in reply: http://www.bmj.com/content/343/bmj.d5147.full

Conflicts of interest in oncology

On the premise that disclosure of conflicts of interest in biomedical research is receiving increasing attention, Aaron Kesselheim and colleagues conducted a survey of oncology journals' COI policies. They found that there was no common standard on disclosing or publishing COIs among these journals. 85% had disclosure policies but their definitions of a COI varied, time periods prior to publication when a conflict was relevant were vague and few required a declaration of COIs that the authors' family members or institutions might have.

Source: Keeelheim AS, Lee JL, Avorn J, Servi A, Shrank WH, Choudry NK. Conflict of Interest in Oncology Publications. *Cancer* 2011. http://onlinelibrary.wiley.com/doi/10.1002/cncr.26237/abstract;

Cochrane calls for public access to trial data

The Cochrane Collaboration contends that the results of clinical trials are often selectively reported in a way that exaggerates the beneficial effects of healthcare interventions and underestimates their harms. To reduce the consequent risk to patients they have issued a statement calling for among other things:

- all randomised clinical trials to be registered at their inception, before recruitment of the first participant,
- governments to consider introducing legislation requiring data from all trials to be made public within 12 months from the end of the randomised phase of the trial,
- governments to also consider the following measures: punitive measures for non-compliance; a requirement to continue to hold and make available core data indefinitely, or to pass such data to a central and accessible repository; and recognition that ownership of trial data should be shared among sponsors, investigators and trial participants.

Source: http://www.cochrane.org/features/clinical-trials-statement-press-release

1 The policy was changed to only prohibit researchers who have a significant financial interest in manufacturers of the products. 'Significant' = having stock, patent positions, having received more than $10 000 in the last 2 years (ownership in mutual funds, honorariums for lectures are excluded)

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Health management: The role of preventive medicine

by Diana Raffelsbauer

About 10 to 20 years ago, preventive medicine was limited to the administration of vaccines, some blood tests and occasionally electrocardiograms at the family practice. At that time, if someone had said that blueberries help prevent Parkinson's disease, that person would not have been taken seriously by the lay community and far less by the scientific world. Since then, things have changed considerably with our increasing knowledge of the impact of nutrition and other lifestyle factors on health and disease states.

The efficacy of blueberries against Parkinson's disease was presented in April 2011 at the 63rd Annual Meeting of the American Academy of Neurology in Honolulu, USA [1], and this is not the only scientific report providing evidence on the crucial role of diet in health maintenance. Green tea (or more precisely its polyphenol epigallocatechin gallate) helps prevent protein misfolding disorders like Alzheimer's disease. This is not a buzz from the general press but was published in a journal of the prestigious *Nature* publishing group [2]. Another study just published in *Stroke* shows that a high intake (> 171 g/day) of white fruits and vegetables is inversely associated (hazard ratio: 0.48) with the incidence of stroke [3].

Studies like these are arising from different fields of biomedical research, including cancer and neurodegenerative disorders. This article describes a few recent findings in preventive medicine that may illustrate the potential of a well-balanced diet, a reasonable use of nutritional supplements and lifestyle changes to improve our health, with a focus on prevention of brain aging and neurodegeneration.

What is preventive medicine?

Preventive medicine refers to measures taken to prevent diseases or injuries rather than curing them or treating their symptoms [4], which are the objectives of curative and palliative medicine, respectively. The rationale for preventive medicine is to identify risk factors in each individual and reduce or eliminate these risks in an attempt to prevent disease.

There are three different levels of prevention:

1. Primary prevention intends to avoid the development of a disease;
2. Secondary prevention attempts to diagnose and treat an existing disease in its early stages;
3. Tertiary prevention aims to reduce the negative impact of an established disease by restoring function and reducing disease-related complications.

This article focuses on primary prevention only, encompassing three supporting pillars: nutrition, physical activity and the mind. Primary prevention includes, besides vaccination, all measures aiming to reduce modifiable behavioural risk factors for developing future diseases, such as obesity, inactive lifestyle and stress. While targeting healthy individuals, it aims to promote a healthy and active lifestyle with a well-balanced diet, physical exercise and stress management.

The underestimated power of prevention

A recent article in the *Lancet Neurology* alerted to the fact that up to half of the Alzheimer's disease cases worldwide are attributable to seven potentially modifiable risk factors: diabetes, midlife hypertension, midlife obesity, smoking, depression, cognitive inactivity or low educational attainment, and physical inactivity [5]. A 10-25% reduction in all seven risk factors could potentially prevent up to 3 million cases worldwide. The economic impact of this prevention is easily envisioned based on the predicted increase in Alzheimer's disease prevalence from the current 34 million to up to 100 million cases by 2050.

Of the ten leading causes of preventable deaths in the global adult population in 2001, eight were directly or indirectly caused by bad nutrition practices, lack of physical activity, smoking and/or alcoholism: hypertension, smoking, high cholesterol, malnutrition, poor diet, overweight and obesity, physical inactivity and alcohol abuse [6, 7]. Not included in the statistics are deaths by diseases that cannot be prevented, e.g. infectious diseases other than sexually transmitted diseases, which ranked number five. It is striking that only two factors (diet and lifestyle, including physical exercise, smoking and alcohol consumption) were responsible for the death of 30 million (out of 35) people. How come?

One could argue that with the improved sanitation and the wide availability of vaccines and antibiotics, infectious diseases, the leading cause of death in the past century, are now under control. Life expectancy has increased, and longevity has brought lifestyle diseases into our lives. In fact, aging is the main risk factor in a long list of lifestyle diseases, including Alzheimer's disease, atherosclerosis, cancer, chronic liver diseases, pulmonary diseases

like asthma and COPD[1], type 2 diabetes, heart disease, metabolic syndrome, chronic renal diseases, osteoporosis, stroke, depression and obesity. However, a more detailed analysis can differentiate between age-related and civilisation-related diseases, the latter being associated with lifestyle (e.g. Western way of life) rather than age. Nevertheless, lifestyle diseases are insidious, and as a result, they do not lend themselves to a quick fix by allopathic medicine.

Obesity: A civilisation disease

In the last 100 years machines have replaced heavy physical labour and reduced work time, both in business and private environments. Net leisure time has increased, but also our leisure activities have changed and become more sedentary. All together, this has reduced our caloric expenditure. At the same time, our diet has changed drastically. Industrialised, highly processed, pre-prepared food (often with a high content of artificial food additives) has become the basis of our diet sheet. This tendency is fostered by one- or two-person households. Fewer and fewer people have (or want to spend) time to prepare and cook fresh meals. Fast food has come to stay. It is a paradox though that while societies in developed countries are facing severe health problems as a consequence of overweight and obesity, millions of people are starving in East Africa.

An estimated 1.5 billion people worldwide are overweight, and the predicted prevalence rate will continue to grow, with dramatic impacts on future generations' health and economics. Obesity during childhood and adolescence is an increasing and particularly serious problem, not only because children and adolescents are easy to manipulate in terms of nutritional habits and are hence a profitable market for manufacturers of high-sugar and high-fat foods, but also because childhood overweight is associated with adult obesity, increased morbidity (in particular a higher incidence of cardiovascular diseases, colon cancer and diabetes) and higher mortality rates.

The global obesity epidemic is no longer the health problem of each overweight individual alone, but a social, economical and not in the least a political problem that affects whole nations. In a paper published in the *Lancet* in August 2011, Gortmaker et al. called for a sustained worldwide effort to monitor, prevent and control obesity [8]. They argued that many parties (including governments, international organisations, the private sector and civil society) need to contribute complementary actions in a coordinated approach. Priority actions include policies to improve the food and built environments (e.g. high tax rates for unhealthy foods), cross-cutting actions (such as leadership, healthy public policies and monitoring) and much greater funding for prevention programmes.

We are what we eat

It has been only recently that school medicine has drawn attention to the impact of nutrition on health. As "time is relative" (Albert Einstein), the term 'recently' might deserve an explanation. It is recent in comparison with the more than 2,000-year old traditional Chinese medicine (TCM), which incorporates the principles of dietary therapy and herbal medicine into a holistic concept that views the body as a complex system interacting with the environment, ideally in balance. While health is perceived as a harmonious interaction of internal functional entities and the outside world, disease is interpreted as an imbalance or a disharmony in this interaction. Even though many TCM concepts have not been proven by modern evidence-based medicine, I think that the lower prevalence of lifestyle diseases in East Asia before globalisation speaks for itself.

Coming back to Western lifestyle and school medicine, there are now countless articles in PubMed reporting the effect of specific diets and basic food components (e.g. Mediterranean, fruits & vegetables, low-fat, low-carb, etc), dietary supplements and nutritional products on a variety of diseases. It is impossible to summarise them in this article. For instance, at the time of writing, a search using the terms 'diet' and 'cancer' yields almost 30,000 hits. This will be the topic of my article in the March 2012 issue of *TWS*, which will be dedicated to the theme 'medical writing in oncology'. In the present issue, I will provide a few examples of recent findings regarding the influence of diet on brain aging and the onset of neurodegenerative disorders.

Brain food

Neurones are particularly vulnerable to oxidative stress and inflammation, two processes that play crucial roles in aging and neurodegeneration [9-12]. Oxidative stress can induce neuronal damage and modulate intracellular signalling that ultimately leads to cell death. Excess production of reactive oxygen species (ROS) in the brain has been implicated as a common underlying factor for the aetiology of a number of neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease and stroke [13, 14]. But even without a concomitant neurodegenerative disease, the increase in inflammatory and oxidative processes is associated with cognitive deterioration and motor function decline in the elderly. This is the basis of the 'free radical theory of aging' [15]. It is also worth noting that caloric restriction has been shown to protect against neuronal loss in various cellular and animal models of Alzheimer's and Parkinson's disease, and epidemiological studies have reported an inverse relationship between caloric intake and the risk of both diseases [16-18].

Numerous epidemiological studies have indicated that the risk for age-related cognitive deterioration and for developing neurodegenerative diseases is reduced in individuals who consume diets containing large amounts of fruits and >

1 chronic obstructive pulmonary disease

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> vegetables [17, 19-22]. Fruits, vegetables, nuts, spices and teas are rich in antioxidant and anti-inflammatory agents, and these activities are largely attributed to polyphenols. Examples of polyphenolic compounds are: anthocyanins in eggplants and berries (e.g. açaí berry, blackberry, blueberry, cranberry, elderberry, raspberry, strawberry, cherry and red grapes), resveratrol in red grapes (also in red wine!) and peanuts, curcumin in turmeric (a component of the curry spice), catechins and theaflavins in tea, the dihydrochalcones aspalathin and nothofagin in rooibos, and the xanthone mangiferin in honeybush. They are thought to reduce the age-related sensitivity of neurones to oxidative stress or inflammation and to counteract neurodegenerative processes [17, 23, 24].

Blueberry or Concord grape juice supplementation in the elderly has been shown to increase memory performance, suggesting that the intake of high-antioxidant foods may prolong the neuronal 'health span' in aging. In a small randomised, placebo-controlled, double-blind trial with Concord grape juice supplementation, significant improvements in verbal learning and non-significant enhancements of verbal and spatial recall were observed at week 12 [25]. Daily consumption of wild blueberry juice in a sample of nine older adults with early memory changes improved paired associate learning ($p = 0.009$) and word list recall ($p = 0.04$) at 12 weeks [26]. In addition, there were trends towards reduced depressive symptoms ($p = 0.08$) and lower glucose levels ($p = 0.10$).

Anthocyanins can pass the blood-brain barrier. They are particularly high in brain regions specifically involved in learning and memory, and their concentrations have been found to correlate with cognitive performance in rats [27]. There is evidence from animal studies suggesting that polyphenolic compounds found in blueberries exert their beneficial effects by a) altering the signalling involved in neuronal communication and promoting synaptic plasticity, b) improving calcium buffering ability, c) enhancing neuroprotective stress shock proteins and suppressing stress signals, or d) activating expression of transcription factors (CREB[2]) and neurotrophic factors (BDNF[3]) [28-33]. A recent *in vitro* study showed that anthocyanins inhibit monoamine oxidases (MAO) A and B, two enzymes implicated in the aetiology of depression, anxiety, Alzheimer's disease and Parkinson's disease [34].

Another prominent antioxidant is vitamin E, which has been shown to stop ROS production during fat oxidation and to protect cell membranes by reacting with lipid radicals [35]. A potential role of vitamin E in Alzheimer's disease prevention has been postulated based on evidence that the toxicity of the amyloid beta protein is mediated by peroxides and by peroxidation of membrane lipids [36]. However, dietary supplementation with vitamin E is a polemic topic [37, 38], notably due to negative results in various reports from the Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) study [39]. Among other controversies, it has been observed that foods containing small amounts of vitamin E provide greater benefits than larger doses of vitamin E alone [35]. The current consensus in the medical community is that there is no good evidence to support health benefits from vitamin E supplementation in the short term, nor is there good evidence to support adverse effects on health.

In addition to plant polyphenols, polyunsaturated fatty acids (PUFAs) represent another class of compounds which may reduce brain aging and neurodegeneration [17]. They are found in nuts (particularly walnuts) and fish oils. The most prominent examples are omega-6 fatty acid linoleic acid and omega-3 fatty acid alpha-linolenic acid. PUFAs are critical components of neuronal cell membranes. They maintain membrane fluidity that is essential for synaptic vesicle fusion and neurotransmitter communication within neuronal networks. Animal studies have shown that the amount of PUFAs in the cortex and hippocampus decreases during aging [40]. Epidemiological studies have associated increased fish consumption with reduced cognitive decline and lower Alzheimer's disease incidence [17].

In the search for the Holy Grail of health and longevity, there is a huge industry of dietary supplements and an increasing consumer market behind it. Whereas 5-10 years ago synthetic vitamins were dominating, the current trend is towards compounds purified from natural products. Dried whole fruit, vegetable and berry extracts in the form of capsules are en vogue. The rationale behind this is complex. For instance, scientific evidence on supplementation with isolated compounds has often been inconclusive or conflicting, and our current knowledge on dosing, efficacy and long-term safety is limited. At the same time, evidence for additive and synergetic effects with other natural compounds found in fruits, vegetables and teas is accumulating. Not only the complex balance of phytochemicals in natural mixtures is important for this synergism, but also the matrix factor plays a key role in controlling bioactivity. All together, this means that a well-balanced diet rich in fruits and vegetables is far better than any nutritional supplements either alone or in combination.

A healthy mind in a healthy body

Mens sana in corpore sano is a 2,000 year-old quote of the Roman poet and satirist Decimus Juvenalis. This empirical observation from ancient times has been confirmed by modern science. Physical activity is a major protective factor against neurodegeneration of varied aetiologies. Exercise training reduces oxidative stress and improves

2 cAMP response element-binding protein
3 brain-derived neurotrophic factor

neuroendocrine autoregulation, which counteracts damage from stress- and age-related neurodegeneration, brain ischemia and traumatic brain injury [41]. Human and animal studies demonstrate that exercise targets many aspects of brain function and has broad effects on overall brain health. Its benefits have been best elucidated for learning and memory, protection from neurodegeneration and alleviation of depression, particularly in elderly populations [42].

A growing body of scientific evidence suggests that exercise has a neuroprotective effect on cognition and in particular, aerobic exercise may attenuate cognitive impairment and reduce dementia risk. In a review study with the promising title '*physical exercise as a preventive or disease-modifying treatment of dementia and brain aging*', Ahlskog et al. found significantly reduced risks of mild cognitive impairment (MCI) and dementia associated with midlife exercise [43]. Randomised controlled trials (RCTs) in dementia and MCI patients recorded better cognitive scores after 6 to 12 months of exercise compared with sedentary controls. One year of aerobic exercise in a large RCT of seniors was associated with significantly larger hippocampal volumes and better spatial memory. Other RCTs in seniors documented attenuation of age-related grey matter atrophy with aerobic exercise. Aerobic exercise is also associated with significantly improved cognitive scores in healthy adults. Human and animal studies have suggested that exercise promotes neurogenesis, interneuronal connectivity, synaptic plasticity and the release of brain neurotrophic factors with improved learning outcomes [44], besides reducing cerebrovascular risks, which may lead to stroke and vascular dementia.

Besides improving cognition and preventing dementia, exercise is as effective as antidepressants, as shown by the recent Treatment with Exercise Augmentation for Depression (TREAD) study [45]. The study was designed to test the efficacy of aerobic exercise as an augmentation treatment for major depressive disorder patients who had not remitted with selective serotonin reuptake inhibitors. Participants were divided into two groups of different exercise intensity: either 16 or 4 kcal per kg per week. After 12 weeks, almost 30% of patients in the higher physical activity group and 15% in the lower activity group were symptom-free. The higher-dose exercise regimen was most effective in men, regardless of a family history of mental illness, and women without a family history (men: 85%; women: 39%). Taken together, these studies suggest that physical activity is helpful not only in the prevention but also in the treatment of different psychiatric disorders.

Reading into the future

In his book '*The sixth Kondratieff. Productivity and Full Employment in the Information Age*' the German economics expert Leo Nefiodow uses the Kondratieff cycles theory[4] to predict future economic and societal development in the 21st century [46]. Five Kondratieff cycles have come and gone since the late 18th century. The fifth Kondratieff cycle between 1950 and 2000 was driven by the development and exploitation of information technology (IT). Since the turn of the millennium, we have been experiencing a transition into the sixth Kondratieff cycle, the era of 'Integral Health'.

According to Nefiodow, the health sector will be the bearer of the next long-term cycle. He forecasts that human health in a holistic sense (physical, mental, psychic, social, ecological, spiritual) will be the driving force of the world market in the period 2000-2050. While advances in biotechnology will revolutionise treatment of organic diseases, the field of psychosocial health will improve our understanding of humans' internal information processes, the wide field of mental and social potentials. Biotechnology and psychosocial competence are the main pillars of this new basic innovation, which he calls 'information medicine'. The rationale for this prognosis, however, is not that pharmaceutical, nutritional and wellness industries will drive the economy. Rather, it has deep socioeconomic roots. Nefiodow argues that what will set companies and economies apart in the competition of the future are the productivity improvements enabled by the health of their employees and the quality of their public health system, seen as a whole: bodily, mental, psychological, social, ecological and spiritual [47].

To improve productivity, healthcare systems need to be restructured to focus on health rather than on illness. This requires new concepts and approaches that are designed to maintain health and well-being instead of to follow the established complaint-response system aimed at treating diseases. This view resembles the salutogenesis concept developed by Aaron Antonovsky[5]. The term is a fusion of the Latin *salus* (= health) and the Greek *genesis* (= origin), and its health-oriented approach has been widely adopted in preventive medicine.

Holistic health writing

With the growing proportion of the aged population in developed countries and the increasing expenditure with disease costs, including nursing, governments will further withdraw their regulatory activities and subsidies from healthcare systems. Consequently, each individual will become more responsible for his own health and will financially have to carry the can for his diseases. It will however require intensive information campaigns, both from public

4 Theory developed by the Russian economist Nikolai Kondratiev. Each cycle is 40-60 years long and consists of three economic phases: expansion, stagnation and recession.

5 Aaron Antonovsky was an American sociologist whose work focused on the relationship between stress, health and well-being.

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> and private initiatives, to raise awareness that how we live today will decisively determine whether and how we will live tomorrow.

In the same way as IT experts were highly in demand in the last cycle, healthcare professionals are now absolutely required to shape the new economic cycle. They include not only physicians but also alternative practitioners, dieticians, sports trainers, physiotherapists, psychologists, career and life coaches. Holistic strategies that perceive people as a whole and as part of a physical and sociopsychological system with whom they interact continuously will be in the ascendancy. In the intersection between the information and the health cycles, medical writers and journalists are best equipped with communication skills and scientific know-how to exploit market potentials that are now arising.

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How do I select a target journal for a manuscript?

by Phil Leventhal

Selecting an appropriate target journal is an important part of submitting and publishing a manuscript. Targeting the wrong journal can greatly slow publication in a journal because each rejection means several months lost in rewriting, reformatting resubmission and peer review. Rejection can also invite criticism of a medical writer's ability to write effectively and publish.

Step 1: Consider journals publishing similar articles

The first step in selecting a target journal is to identify those publishing similar articles to the manuscript to be submitted. Consider where the key references for the introduction and discussion were published.

JANE (Journal/Author Name Estimator; http://www.biosemantics.org/jane/) [1] greatly simplifies the search for candidate journals. Key words, the title, the abstract or any other text can be used as search terms to find related journals. The journals are listed according to the 'confidence' of similarity (Figure 1). In addition, for each journal the site gives the 'Article Influence', which is a measure of how often articles in the journal are cited within the first 5 years after its publication. The relevant articles in each journal (and links to PubMed) can then be viewed in a separate pop-up box.

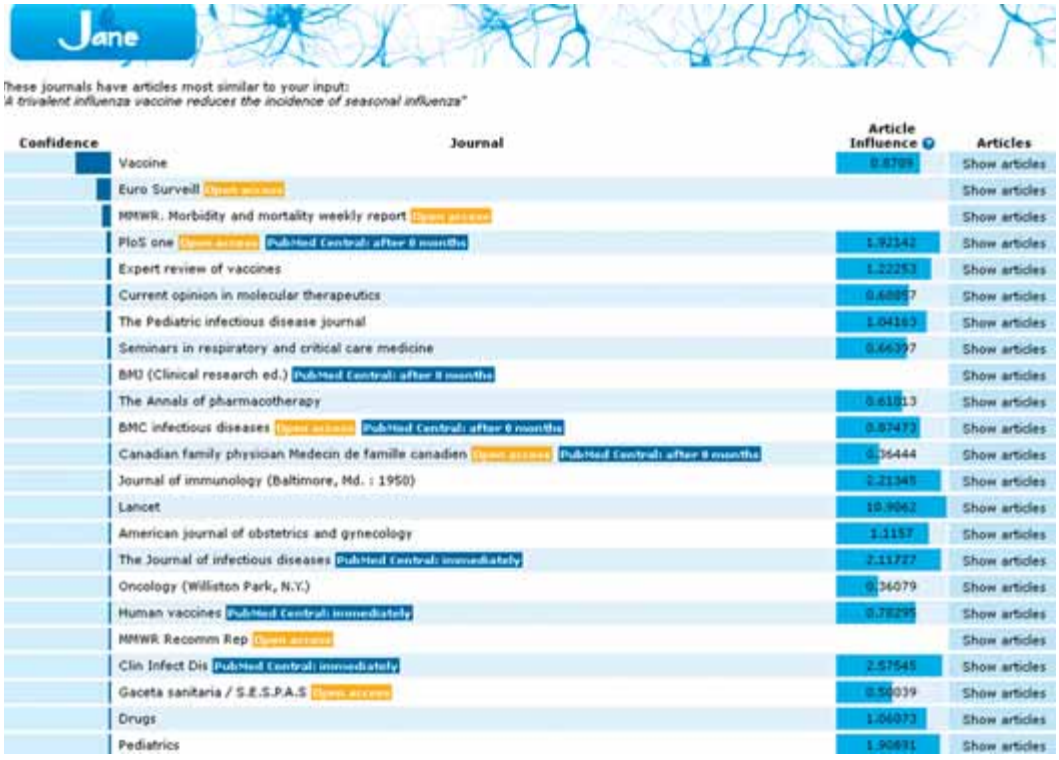
Once you have a list of potential journals, the list can be narrowed down by looking closely at whether the format and type of data presented in the related articles match those in the manuscript. Look at recently published articles that you have from the candidate journals. Some journals offer a free sample issue online that can be used to examine the typical format and content.

Finally, previous publication of similar articles may also be used as justification when explaining to a journal (in a cover letter or enquiry) why they should publish your article.

Step 2: Identify the aims and target audience of the manuscript and match them to the journal's scope and audience

Content irrelevant to the journal is a principal reason that editors reject manuscripts [2]. Therefore, in addition to considering whether a journal published similar articles, check the journal's scope (subject covered) and audience (who reads it) to make sure that it is appropriate for your article. Scope and audience information should be available >

Figure 1. Screen capture from JANE using the search term 'A trivalent influenza vaccine reduces the incidence of seasonal influenza'.



Manuscript writers' corner

> on the journal's website and is often listed in the instructions for authors, although sometimes it's difficult to find. If not available on their website, you can obtain scope and audience information by writing or phoning the journal's editorial office. Some examples are shown in Table 1.

Step 3: Consider the impact, prestige, and reputation of the journal

Some idea of the relative influence and impact of a journal within a specific area of medicine can be obtained from the journal impact factor (JIF). The JIF, published annually by the Institute for Scientific Information since 1961, represents the average citations per article the journal received during the previous 2 years [3]. In other words, the JIF is a "measure of peer attention or interest" [4].

The 'Article Influence' value that JANE provides covers the previous 5 years. Other ways of measuring journal impact are available or have been proposed, although the JIF remains the most commonly used [5,6].

Many authors use the JIF as the deciding factor for which journal they should target. However, impact factors are indirect measures of journal quality, they do not guarantee the quality of the journal's content, and they do not guarantee increased citation of an author or their publication [7,8]. Even Thompson-Reuters, who now publishes the JIF, states:

"Thomson Reuters does not depend on the impact factor alone in assessing the usefulness of a journal, and neither should anyone else." [9]

Therefore, when considering a journal, consider its actual merits not just its impact factor [10].

The importance or impact of a journal should also not be the end of the story because they need to be matched with the importance and impact of the manuscript. Often co-authors will feel that the manuscript deserves a premier journal, or they will want to 'aim high' for the first attempt, but remind them that premier journals can have rejection rates over 90% [11-13], so aiming too high can substantially delay publication; additional time is needed for each round of submission, editorial review, reformatting, and rewriting. Co-authors should also be reminded that because of PubMed, the article will be seen and referenced if published in any reasonable quality English-language journal.

Step 4: Consider how fast the journal reviews and publishes articles

Depending on the co-authors' needs, you may need to consider how fast the journal reviews and publishes articles.

Typical medical journals take 2 to 3 months for peer review. Additional time will be needed for revisions, so the total time from submission to acceptance is typically 2.5 to 6.5 months [14]. Furthermore, between 1 and 6 months are typically needed for an accepted manuscript to be published [13,15]. Therefore, more than 1 year may pass between submission and publication in traditional print journals.

If the co-authors are in a hurry to publish, an online-only journal may be appropriate. For example, *PLoS Medicine* reviews articles within 6 weeks of submission, and their time from acceptance to publication is usually 6 to 8 weeks [16].

Information on the time for peer review and the time from acceptance to publication are often available on the journal's website, although it may be necessary to contact the editorial office to obtain this information.

Step 5: Consider the length of articles allowed by the journal

Article length may be an important factor in the selection of a target journal. The best time to think about this is before you start writing because it can change the nature of the article or may result in substantial rewriting late in the process if the journal allows only short articles.

Most journals have strict limits on the number of words and figures or tables, typically 3500 to 5000 words for the main text and 5 to 6 display items. Some journals allow online supplements, which can allow publication of details that cannot fit within the word and table/figure limits. Finally, some online-only journals, like *PLoS Medicine* have no word limit.

Table 1. Scope and audience for some typical medical journals

Journal	Scope	Audience	Where the information can be found
Lancet	"The Lancet is an international general medical journal that will consider any original contribution that advances or illuminates medical science or practice, or that educates or entertains the journal's readers."	"Whatever you have written, remember that it is the general reader whom you are trying to reach. One way to find out if you have succeeded is to show your draft to colleagues in other specialties. If they do not understand, neither, very probably, will The Lancet's staff or readers."	First paragraph of instructions for authors (http://www.thelancet.com/lancet-information-for-authors)
Journal of Infectious Disease	"The Journal of Infectious Diseases (JID) is the premier global journal for original research on infectious diseases. The editors welcome Major Articles and Brief Reports describing research results on microbiology, immunology, epidemiology, and related disciplines, on the pathogenesis, diagnosis, and treatment of infectious diseases; on the microbes that cause them; and on disorders of host immune responses."	Not explicitly stated, although they indicate that "JID is an official publication of the Infectious Diseases Society of America."	Journal home page (http://jid.oxfordjournals.org/)
New England Journal of Medicine	Detailed information of different article types available at be http://www.nejm.org/page/author-center/article-types	Not explicitly stated.	Author Center-Article types (http://www.nejm.org/page/author-center/article-types)

Dear Editor,

I am writing to you to make a presubmission enquiry regarding suitability of our manuscript "Compound X reduces the incidence of toenail fungus in adults 18 to 60 years of age" for publication in *The Journal of Clinical Toe Care*. **[Introductory sentence]**

Toenail fungus is a serious and growing problem in Western Europe. Currently, more than 50% of the adults in Western Europe suffer from toenail fungus, up from 42% in 2003, and existing treatments are ineffective at preventing its spread (Johnson et al. International Journal of Toenail Fungus. 2005; 3:27-90). **[Importance of the topic]**

Compound X was discovered in our laboratory from an extract of bacteria common to suburban swimming pools (Smith et al. Journal of Swimming Pool Chemistry 2003; 10:19-27). We previously showed that compound X prevents the growth of toenail fungus in vitro and in vivo animal models (Smith et al. Journal of Western European Toe Care, 2009; 1:1-10). Accordingly, in the current study we examined the ability of Compound X to treat toenail fungus in a clinical study. **[Summary of some relevant background and why the study was done]**

This manuscript describes the results of a multicentre, double-blind, randomised clinical study involving a total of 78 ½ adults 18 to 60 years of age. We show that a single treatment with Compound X reduces toenail fungus by 97% within 1 week. In addition, Compound X was well tolerated, with the only major adverse event being permanently staining the toenail a hot pink color. **[Short summary of the key findings.]**

We feel that *The Journal of Clinical Toe Care* would be an excellent forum for these revolutionary results because of their great interest to the toenail research community. **[Explanation of why this should be published in the journal]**

Attached please find a copy of the abstract for the manuscript. Thank you for considering our presubmission inquiry. **[Closing]**

Sincerely,
John Smith

Figure 2. Sample enquiry letter

Optional: Make a pre-submission enquiry

When in doubt about which journal to target and certainly to save a little time, a pre-submission enquiry is a good idea. Pre-submission enquiries simply ask the journal whether they *might* be interested in the article. In other words, if the journal says that they are interested, they are not guaranteeing that it will eventually be accepted. Making a pre-submission enquiry can save a great deal of time when considering premier journals because they have high rejection rates.

For most journals, pre-submission enquiries are optional but usually welcome. For PLoS journals, however, a pre-submission enquiry is required [17].

Enquiries can be made by e-mail, and many journals have online submission forms or instructions. Generally, they are answered within a few days, in which case the answer will be either "no, we are not interested" or "yes, we are interested, please send the manuscript".

Be diplomatic when writing the pre-submission enquiry. Avoid asking directly whether the journal will publish the article. Rather, ask in general whether the journal would consider publishing an article on the topic. Unless there are specific instructions, the enquiry letter should be similar to the format of a cover letter and should include the following (see Figure 2) [18]:

- The questions or findings that led to the study
- What was done
- Why the methodology or findings are important
- Why the article fits within the journal's scope and target audience or why it is of special interest to the journal's readers
- A copy of the manuscript's abstract or a one-page summary that can contain citations and additional details not normally included in an abstract.

Conclusion

Selecting a relevant target journal is an important part of manuscript writing. Targeting an inappropriate journal can slow the process of publication by several months. When choosing a journal, carefully consider not only journal impact factors and prestige but also the journal's rejection rate, scope and audience, speed of review and publication, and length of articles allowed. Finally, a pre-submission enquiry may help determine whether a journal is appropriate and reduce the chance for rejection.

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