

# Medical writing around the world

Phillip Leventhal

Editor-in-Chief



As many of you are already familiar, *Medical Writing* began as *The Write Stuff*, a publication written by and for EMWA members. One of the goals in making the transition to *Medical Writing* was that it would

become an international journal with readers outside of Europe and EMWA. We are already on our way, with contributors frequently coming from outside of EMWA and Europe.

But for me this is not enough. I am convinced that *Medical Writing* should reflect the increased globalisation of medical writing. More and more, medical writing is being done locally and not only in the traditional areas of Western Europe and North America. Medical writing is also now often being outsourced to countries like India, and many regions of the world, especially Africa, the Middle East, and Asia, have a substantial need for medical writing but are currently underserved. This creates vast new opportunities and challenges for medical writers.

I therefore thought it important to organise an issue on medical writing around the world. When I sent out requests for contributions, I had no idea that I would get such a fantastic response. In this issue, we have 11 articles on medical writing in 10 countries or regions on 5 continents.

As a side-benefit of putting together this issue, EMWA has developed new collaborations with the Spanish Association of Medical Writers and the Australasian Medical Writers Association, both of which have provided short articles on their associations.

We will continue to seek out contributions from medical writers from around the world for future issues. This should make *Medical Writing* richer and more attractive to the global medical writing community.

## EMA's clinical trial data and transparency initiative

In the last few years, there has been much discussion about open access to clinical trial data. This

## Editorial

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has recently come to the forefront since the publication of *Bad Pharma* by Ben Goldacre (see the March 2013 In the Bookstores and Regulatory Writing columns). Because of increasing complaints, the EMA has decided to start making clinical trial data more widely accessible. In November 2012, they organised a workshop to bring together key stakeholders to discuss this initiative. Because of the importance of this topic to medical writers, this issue of *Medical Writing* includes articles by Susan Bhatti summarising the workshop discussions and by Faiz Kermani and Walter Fürst discussing the potential implications of wider data transparency.

## Other highlights of this issue

In addition to these articles Sanja Pavlica discusses the need for registration of preclinical studies, an important but often overlooked issue related to the subject of increased transparency of trial data.

Also, Josalita Salita explains how a mentorship programme can enrich EMWA members' experience. As budgets tighten and companies are less willing to pay for conference attendance, this may become an important value-added feature of EMWA.

## A friendlier *Medical Writing*

In talking to EMWA members at recent conferences, it has become clear that although the more professional look and feel of *Medical Writing* is appreciated, most prefer a less technical publication. Starting with this issue, we will be including logos for all regular sections and photos for the President's Message and the Editorial. We have also moved the Editorial to the first page of the issue to make the journal more welcoming.

I hope that you get as much enjoyment out of reading this issue as I did putting it together. I also hope that you like the changes that we are making to *Medical Writing*, and I appreciate any comments or suggestions for further improvements.

# Medical Writing

Medical Writing Around the World

## Contents

Volume 22  
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### Editorial

**Medical writing around the world** 79

**Message from the President** 82

### Feature Articles

**The yin and yang of medical writing in China**  
Karen L Woolley and Ping Sun 83

**The changing face of medical writing in India**  
Natasha Das and Saurendra Das 90

**Medical writing in India at a crossroads**  
Salil Bose 94

**Medical writing in the Middle East**  
Farhad Handjani and Farrokh Habibzadeh 96

**Medical writing in Finland**  
Sanna Lönnfors 99

**On the western edge of Europe – medical writing in Portugal**  
Eva Leiria and Marta Abrantes 101

**Announcing AERTeM, the Spanish Association of Medical Writers**  
Maria Fernandez-Piera 104

**From editors abroad into businesswomen back in Brazil**  
Marcia Triunfol Elblink 106

**Science writing workshops for AIDS vaccine researchers in Africa**  
Donna Rubens 108

**Medical postcard from Australia, the world's largest island**  
Justin Coleman 112

**Teaching English for Medical Academic Purposes at the Faculty of  
Medicine in Belgrade, Serbia**  
Danka Sinadinović and Sofija Mičić 115

**Regulatory medical writing in Switzerland**  
Raquel Billiones 119

<b>Medical writing in the Russian Federation: Promises and pitfalls</b> Anna Davydova	<b>121</b>
<b>Report on the EMA Workshop on clinical trial data and transparency</b> Susan Bhatti	<b>124</b>
<b>Potential implications of wider data transparency in medical communications</b> Faiz Kermani and Walter Fürst	<b>128</b>
<b>The need for registration of preclinical studies</b> Sanja Pavlica	<b>131</b>
<b>Mentorship in EMWA: A perspective</b> Joselita T Salita	<b>134</b>
<b>Regular Features</b>	
In the Bookstores	<b>137</b>
The Webscout	<b>142</b>
Regulatory Writing	<b>143</b>
English Grammar and Style	<b>147</b>
Medical Journalism	<b>150</b>
Medical Communication	<b>152</b>
<b>Out On Our Own</b>	<b>156</b>
The Light Stuff	<b>165</b>

### **Themes of upcoming issues of *Medical Writing***

September 2013: The theme will be '**Health Economics and Market Access**' to coincide with the recent conference in Manchester. The deadline for feature articles is June 19, 2013.

December 2013: The theme will be '**Good Pharma**'. This issue will be on efforts to improve transparency and ethics in the pharmaceutical and device industries and is being assembled in collaboration with the International Society of Medical Publication Professionals (ISMPP). The deadline for feature articles is August 20, 2013.

We are currently considering themes for 2013. Suggestions are welcome.

For correspondence related to these issues or further themes, please contact [editor@emwa.org](mailto:editor@emwa.org).

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# Message from the President

Susan Bhatti, Andrea Rossi

EMWA President

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## Dear Medical Writers



A year has passed so quickly and it is time for me to step down and hand over to Andrea Rossi, the new EMWA President and the first Italian to take on this important position. On reading through the various messages I sent you during the past year, I am pleased to say that the Executive Committee (EC) was able to implement several of the plans we envisaged when I assumed the role of leading the organisation.

Our journal has got a brand new look, a talented new Editor-in-Chief as well as a new title. New brochures have been printed in four different languages to help spread the word about EMWA and attract new members. We established the Geoff Hall student scholarship to help budding medical writers attend our conferences, and we are continuing to develop our cooperation with the International Society for Medical Publication Professionals. We have set up an online voting system for members who are unable to attend the Annual Meeting at the spring conferences, and we also performed several online surveys, including one to assess potential interest in online learning for our members. As I say 'goodbye' my warmest thanks go to all the members of the EC as well as our staff at head office and who have worked so hard to make all this happen. I am confident that the new EC will ensure continuation of these initiatives in order to better serve our members and the organisation. And on this note I will say, 'Over to you Andrea!'

June 2013

Susan Bhatti  
Retiring EMWA President



Thank you Susan. It is a pleasure to introduce myself to the membership. I'm an Italian biologist from Florence. I have been working in the Medical Department of Eli Lilly for 23 years, the last 9 being spent in performing and managing medical writing activities.

As EMWA President, my objective is to continue to build on the foundations laid down by previous presidents. The new EC and I will do our best to ensure that EMWA continues to be successful and to grow in both reputation and membership numbers. The challenges behind the scenes to keep the association running smoothly remain substantial. The EC will need an increased contribution from additional volunteers to maintain the EMWA Professional Development Programme as a reference for professional development, to improve the quality and visibility of *Medical Writing*, to enhance our internet portal (possibly including online learning), and to vitalize all media activities, as well as ensuring our conferences remain attractive to anyone who is interested in the various facets of medical writing.

Looking forward to the forthcoming conference in Barcelona, I am very pleased that we have been able to renew our collaboration with the Spanish Medical Writers Association. We are also very excited to have two guest speakers at the conference from the European Medicines Agency (EMA). We hope this is the beginning of a long and fruitful cooperation!

I hope I'll be able to transmit all my Mediterranean enthusiasm and my vision of EMWA's future in this exciting and challenging year. I look forward to catching up with you again in the near future.

June 2013

Ciao,  
Andrea Rossi  
EMWA President

# The yin and yang of medical writing in China

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## Abstract

China is becoming a superpower in many areas, including the global medical literature. In this article, we describe medical writing in China, with a focus on efforts to enhance the yin (quality) and yang (quantity) of publications. Quality encompasses integrity, so we also highlight how China, like many other countries around the world, is striving to enhance publication integrity. Finally, we explain how professional medical writers (whether working on publications from non-industry or industry research) can enhance the yin and yang of publications from China. Writers who have appropriate experience and cultural sensitivity will find such work challenging but rewarding.

**Keywords:** Medical writing, Medical writer, China, Journal, Ethics, Integrity

'...China needs to learn more about the world, and the world also needs to learn more about China.'

Xi Jinping, China's Communist Party General Secretary

15 November 2012<sup>1</sup>

Consistent with the theme expressed by China's leader, medical writers in China need to learn more about medical writing around the world and medical writers around the world need to learn more about medical writing in China. This special edition of *Medical Writing* should serve this theme well.

In Chinese philosophy, yin and yang represent the opposite sides of everything – their positions keep changing, but balancing yin and yang is essential for maintaining vitality and vigour. The yin and yang forces can be applied to the world of medical writing (Figure 1).

## The yang: quantity of publications from China

*Only when all contribute their firewood can they build up a strong fire.*

–Chinese proverb

In Chinese philosophy, the yang force can be associated with speed, focus, and aggression. The yang force may symbolise the remarkably strong and rapid increase in the quantity of publications from China. The dragon's fire is burning brightly! Based on the number of MEDLINE-listed publications, China has already passed England (Figure 2) and is expected to overtake the US in a few years.

The globalisation of medical research, coupled with strong incentives to publish internationally, have helped position China as a superpower in the international medical literature. Publications from China will be increasingly relevant to healthcare professionals and patients who live well beyond China's borders. Because of the regrettable increase in the prevalence of Western lifestyle diseases in China, an increasing number of publications from China will contribute to global understanding and management of many chronic diseases.

Understandably, the world's interest in China's research is intensifying. This interest and the desire of Chinese researchers to collaborate with researchers around the world have led to a marked increase in the number of internationally co-authored publications (Figure 3). These international collaborations bring many benefits, including the development of personal relationships (*guanxi*), a fundamental element of Chinese culture. For Chinese authors, internationally co-authored publications can enhance *guanxi*.

A focus on the quantity of publications is understandable, but also of concern. As in other countries, the 'publish or perish' mantra has put intense



Figure 1: The symbol for the yin (dark side with white dot) and yang (white side with dark dot). The yin force may be seen as symbolic of publication quality and the yang force symbolic of publication quantity. The yin and yang forces should be in balance. China is striving to ensure that the quality of its publications is as impressive as the quantity.

pressure on Chinese researchers.<sup>2</sup> The pressure in China, however, may be more intense than in other regions of the world because a large part of a Chinese researcher’s salary is insecure, with the fixed base rate of pay often lower than the variable performance-related rate of pay.<sup>3</sup> Chinese researchers must produce many papers year after year to avoid drastic reductions in their income.<sup>3</sup> Furthermore, promotions in China are typically linked to publication output and the number of publications in which the researcher is the first or

corresponding author.<sup>3,4</sup> Compared with authors from Europe, significantly more authors from Asia, including China, believe that their performance assessment is strongly influenced by the number of publications, as well as the number of authors on these publications.<sup>4</sup> The need to reform the performance appraisal system in China has been recognised,<sup>5</sup> but the yang force remains strong and continues to drive publication quantity.

### The yin: quality of publications from China

*It is simple to open a shop; another thing to keep it open.*

–Chinese proverb

In Chinese philosophy, the yin force balances the yang; whereas the yang may be seen as fast, focused, and aggressive, the yin may be seen as slower, more diffuse, and passive. The yin force can symbolise the journey being taken to enhance the quality of publications from China. This journey is taking time, requires effort from many sectors, and optimal progress will rely on co-operation, not force. Although the rapid increase in publication quantity has put China on the world stage, the quality of its publications may determine how long China stays there. Enhancing the quantity of China’s publications may have been the first and relatively simple step forward, but enhancing the

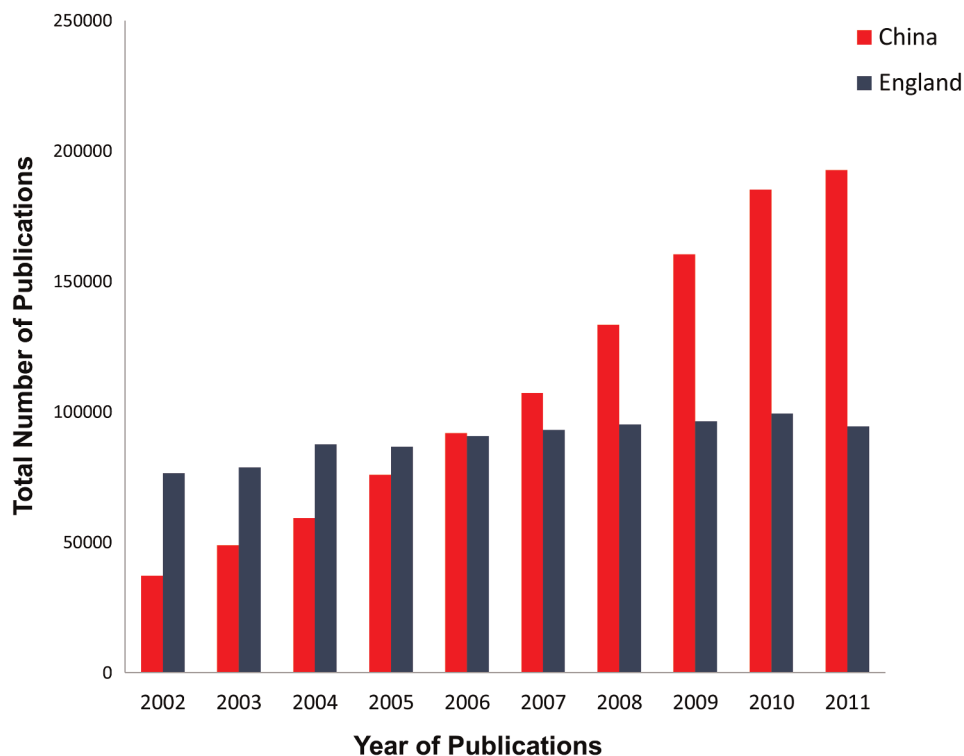


Figure 2: Number of publications from China and England, based on the number of publications listed in MEDLINE.

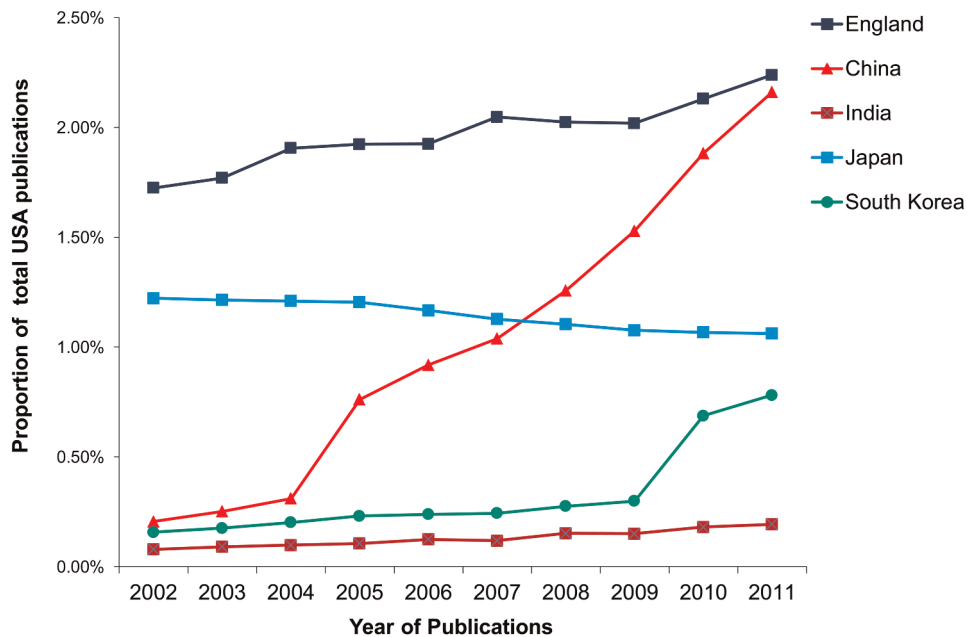


Figure 3: Proportion of publications listed in MEDLINE that were co-authored with an author from the US. During the last decade, co-authorship with authors from China has increased rapidly. In contrast, co-authorship with authors from India continues to remain very low (figure courtesy of ProScribe Medical Communications).

quality of its publications is the next important – and challenging – step.

Research on the quality of China's publications provides reasons for both hope and concern. For example, compared with a number of European countries, more publications from China appear in leading oncology journals (Figure 4).<sup>6</sup> Medical writing workshops in China have stressed the importance of meeting international best-practice reporting standards.<sup>7,8</sup> Nevertheless, recent studies on the quality of reporting in manuscripts<sup>9,10</sup> and abstracts,<sup>11–13</sup> relative to CONSORT and CONSORT for Abstracts, respectively, demonstrate many deficiencies. Even high-impact journals in China, which specifically endorse CONSORT, publish studies that don't meet CONSORT standards.<sup>14</sup> Notably, a CONSORT for traditional Chinese medicine has been in development since 2007.<sup>15</sup> Given the poor state of reporting traditional Chinese medicine research,<sup>16</sup> finalisation of this CONSORT Extension Statement is clearly needed.

In response to concerns about the quality of Chinese publications and journals, the Chinese government has developed an innovative programme to reward high-quality journals. A new 90 million RMB yuan ( $\approx$ 11 million Euro) program, 'Enhancing the International Influence of Science & Technology Journals Program', was launched on 29 November 2012. The programme, co-sponsored by the China Association for Science and Technology and the Chinese Ministry of

Finance, will give financial rewards to journals that enhance their quality, influence, and international competitiveness. In the programme's first round, 35 English-language journals from China will each receive between 500 000 and 2 million RMB yuan ( $\approx$ 61 000–240 000 Euro) per year for 3 years.

Beyond concerns about publication quality in China, publication ethics are also a concern. Of course, these issues are not unique to China. Medical writing workshops in China,<sup>6,7</sup> as well as free and culturally appropriate social media tools (e.g. <http://www.youtube.com/watch?v=AQdzWDxKajg>) have stressed the importance of ethical practices, but more needs to be done.

One of the strongest proponents of ethical publication practices is the Chinese government, which supports various initiatives. In 2006, after a number of international scandals, the Chinese Ministry of Science and Technology (MOST) issued a decree describing how to handle misconduct in government-funded research.<sup>5</sup> In 2007, MOST established the Office of Research Integrity and established an inter-agency Joint Committee for promoting research integrity.<sup>5</sup> The Joint Committee issued a seminal policy paper on publication ethics (*Opinions on Strengthening Research Integrity of our Country*), and there have been numerous ethics workshops led by organisations such as MOST, the Ministry of Education, the Chinese Academy of Sciences, and the China Association for Science and Technology.<sup>5</sup> China has also participated in

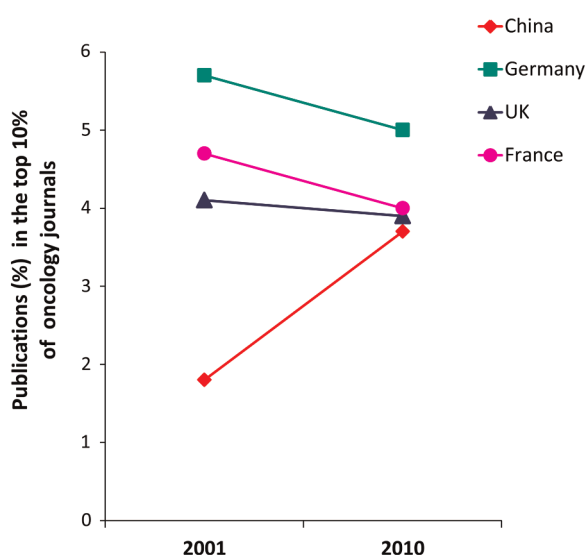


Figure 4: Percentage of publications from each country published in the top 10% of international oncology journals. During the last decade, publications from China in these leading journals have increased. In contrast, publications from the UK, Germany, and France appear to have decreased or stabilised.<sup>6</sup>

international efforts to establish ethical standards, with representatives from China involved in the recently released policy from a global network of scientific academies (IAC/IAP) and in the forthcoming 3rd World Conference on Research Integrity. The yin force is intensifying in China and must be sustained; enhancing publication practices and quality will enhance China's international reputation and contributions to the medical literature.

### Balancing yin and yang: how professional medical writers can help China

*To talk much and arrive nowhere is the same as climbing a tree to catch a fish.*

–Chinese proverb

Professional medical writers are well positioned to help China balance the yin and yang of publications. Although discussion forums, policy statements, academic reform, and educational initiatives can help China, it is unrealistic to expect these actions to cause immediate changes to current practices. In contrast, when Chinese authors work with professional medical writers, it is realistic to expect rapid and noticeable changes ... with the very next publication. Professional medical writers follow ethical publication practices and disclose their involvement and funding sources; these behaviours distinguish them from ghostwriters.<sup>17,18</sup> Chinese authors who are tempted to use ghostwriting services increase their risk of publication misconduct

and may bring dishonour to themselves, their superiors, their institution, and their country, causing great shame and loss of face (reputation).<sup>19</sup> Notably, professional writers who train Chinese authors must not only ensure that ethical and best-reporting practices are followed,<sup>20</sup> but these writers must also be trained in cultural sensitivity.<sup>19</sup> Ideally, especially given China's desire to contribute at an international level and the pressures to publish in English-language journals, trainers should be professional medical writers with many years of international medical writing experience, be native speakers of English, and have a track record of working successfully with Chinese authors.

#### Enhancing publication quantity (yang)

With respect to enhancing the quantity of publications, professional medical writers can help ensure that research that should be reported is reported. Although China is producing many publications, non-publication can still be an issue, as it is around the world.<sup>21</sup> Failing to publish important research results retards scientific progress and is unethical. Also, patients in China may be less likely to participate in research if they think the results will not be published as quickly or as completely as they should. The results from all industry-sponsored clinical trials in China should be submitted for publication in compliance with the Joint Position Statement from the International Federation of Pharmaceutical and Manufacturers Associations, of which China's R&D Pharmaceutical Association Committee is a member.

Professional medical writers can also help China's authors and sponsors prepare robust, international-standard publication plans, which can minimise the risk of non-publication or delayed publication. Research indicates that manuscripts prepared with professional medical writing support are accepted more quickly for publication than manuscripts without support.<sup>22</sup> Publication speed can be particularly important in China given the frequency of performance reviews and annual publication targets.<sup>3</sup>

#### Enhancing publication quality (yin)

With respect to enhancing the quality of publications, a professional medical writer can help ensure that publications are prepared in accordance with international best practice ethical and reporting standards. Manuscripts prepared with professional medical writing support are more likely to comply with best practice reporting guidelines (e.g. CONSORT) compared with those without support.<sup>23</sup> In China, authors and sponsor staff may



not be familiar with the myriad international reporting guidelines affecting publications. In our experience, authors are often grateful when we alert them to these guidelines and explain how and why they should be used. Authors and sponsor staff are also grateful when we help them navigate their way through the obvious and less obvious elements of Good Publication Practice 2 (GPP2).<sup>24</sup> Successful navigation requires detailed knowledge of GPP2, experience with applying GPP2 in China, and cultural sensitivity.

Although not unique to China, issues related to authorship, author payments, financial disclosure, audit trails, secondary publications, encoring, journal choices, and sponsor involvement can lead to disastrous outcomes in China (and beyond) if not handled in an expert and culturally sensitive manner. With the increasing scrutiny and reach of foreign agencies investigating bribery and corruption (e.g. via the US Foreign Corrupt Practices Act or the UK Bribery Act), it would be naive to think that questionable publication practices in China (e.g. paying public officials, including authorship payments to doctors employed at government-funded hospitals) would be exempt from investigation.

Manuscripts prepared with professional medical writing support are also less likely to be retracted for misconduct, including plagiarism.<sup>25,26</sup> Plagiarism has been a source of concern in China for many years.<sup>5</sup> Even if unintentional, plagiarism can result in retraction. The risk of plagiarism is higher when first authors come from lower-income countries or from countries with English as a second language.<sup>26</sup> The loss of face (*mianzi*) resulting from having an article retracted is devastating for Chinese authors. Anti-plagiarism software may detect plagiarised text, but a professional medical writer can help prevent plagiarism. Writers who can protect authors from losing *mianzi* are highly valued.

By working with professional medical writers, researchers in China will also gain access to informal, but highly relevant, education about publication practices. Practical advice from proven medical writers complements the knowledge that Chinese researchers gain from international exchanges or from working with their counterparts in other countries. China is also striving to attract talented researchers from overseas to help its researchers understand and meet international research and publication expectations. Professional medical writing companies, writing associations, editors, and international publishing groups are providing face-to-face and online education

sessions. A major challenge is for these entities to find creative and cost-effective ways to collaborate with China's leading and emerging researchers to achieve win-win outcomes.

In addition to helping China's researchers, professional medical writers can help editors of Chinese journals. Such assistance is particularly valuable given China's 'Enhancing the International Influence of Science & Technology Journals Program'. Professional medical writers can help encourage authors in China and around the world to consider submitting their manuscripts to China's top-tier English-language journals. They can also ensure that these journals receive high-quality manuscripts, alert editors to cutting-edge international research groups that routinely use their writing services, introduce editors to potential peer-reviewers from their networks, serve on editorial boards (e.g. to review compliance with best-practice reporting guidelines, ethical publication practices, and English-language standards), and, importantly, provide training workshops for editors on how professional medical writers can help editors enhance the quality of their journals while reducing their costs (e.g. how writers can enable editors to spend less time and money spent on copyediting, requesting disclosure information, checking compliance with submission requirements, and peer-review comments).

#### *Choosing a professional medical writer*

Enhancing the quantity and quality of publications in China would serve China and the world well. Professional medical writers have a great opportunity and a critical responsibility to contribute to the yin and yang of publications in China. Given the exponential increase in the extent of outsourcing international – and Asian – medical writing projects to writers in Asia,<sup>27</sup> authors and sponsors (including procurement staff) must validate the experience, credentials, and cultural sensitivity of the medical writers they choose. As it is currently possible for anyone to offer 'medical writing services' (even those who are unaware of basic guidelines such as CONSORT or GPP2), the onus is on buyers to ensure that writers have the requisite competencies, a proven track record of working ethically with authors from China, and a history of publication success in international journals. Writers should also have strong evidence-based insights as to where the greatest risks are for publication misconduct in China<sup>25,26</sup> and ensure that their processes take these risks into account. A well



Figure 5: Professional medical writers can help assist Chinese authors in a positive feedback cycle that enhances the authors' *mianzi* and *guanxi*. If authors and sponsors choose the wrong writer (e.g. inexperienced, unethical, or culturally insensitive), the cycle may be broken and authors could lose *mianzi* (e.g. publication retracted for misconduct) and *guanxi* (damaged relations with international researchers) (concept and figure courtesy of ProScribe Medical Communications).

chosen professional medical writer will ensure that authors and sponsors receive the services required and can enhance their *mianzi* and *guanxi* (Figure 5); conversely, a poorly chosen writer can damage reputations, increase costs, delay projects, and cause loss of *mianzi* and *guanxi*.

## Conclusion

*Great acts are made up of small deeds.*

–Lao Tzu (Chinese philosopher 600–531 BC)

Every high-quality publication from China may be seen as a small good deed. Collectively, these small good deeds can culminate in a great act – China becoming one of the leaders in medical research. The focus on publications from China has illuminated intense and increasing needs for medical writing support. Given the challenges regarding non-publication, complying with best-practice reporting guidelines, and following ethical publication practices, Chinese researchers could benefit from professional medical writing assistance. Further, given China's goal of enhancing the quantity and quality of its publications and the initiatives being introduced to achieve this goal, professional medical writers could benefit from assisting China's researchers. Indeed, for appropriately qualified and experienced professional medical writers, China offers many challenging, but rewarding, opportunities.

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# The changing face of medical writing in India

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## Abstract

Economic liberalisation has led to an influx of clinical research and a boom in the medical writing industry in India. Medical writers in India at present contribute mostly to medical communications, health journalism, and academic medical writing. Regulatory writing is fast climbing up the ladder too. Continued medical education (CME) writing is almost non-existent since CME is not mandatory for physicians. Lack of adequate experience as professional medical writers translates into quality issues. Unless we match up to global quality standards, we may soon be facing competition from other Asian countries. However, experienced medical writers who have learnt the hard way are hopeful that, with rigorous training and accumulating experience, those who offer quality are here to stay.

**Keywords:** Medical writing in India, Medical writing in Asia, Outsourcing to India, Cost benefit, Quality issues in medical writing

Medical writing is probably as old as medicine itself. Who comes to mind when you think of the earliest examples of medical writers? Probably Galen, the Roman physician of Greek ethnicity who wrote an encyclopaedia of medicine in the second century AD, or Hippocrates, the father of western medicine, who wrote the *Hippocratic Corpus* as early as the third century BC!

Interestingly, Indians wrote about medicine much earlier. *Sushrutasamhitam*, which contains 184 chapters on surgery, was written around the sixth century BC. *Charakasamhitam*, believed to be the oldest medical scripture in India, contains 120 chapters on ancient Indian medicine. It was written around 3000 years ago.

Indian writers have been writing about health and medicine for a long time in many different languages and for other systems of medicine as

well, including homeopathy, Ayurveda, siddha, and unani (see Box 1). They have written books, web content, and journal articles about all these systems of medicine. However, only recently have they started writing for the global healthcare community, making them one of the new players in the global platform.

## Box 1

Ayurveda, the oldest form of traditional Indian medicine, is widely practised even today. Ayurvedic *vaidyas* (physicians) prevent and treat diseases by ensuring a balance between the mind, body, and consciousness. Siddha, which originated in the southern Indian state of Tamil Nadu, is similar to Ayurveda. In this system, diseases are attributed to disturbance in the balance of seven elements: *saram* (plasma), *cheneer* (blood), *ooun* (muscle), *kolzuppu* (fatty tissue), *elumbu* (bone), *moolai* (brain), and *sukila* (semen). According to unani, which has a Greek origin, the human body is made of four humours: blood, phlegm, yellow bile, and black bile. In each of these three systems of medicine, disease can be treated through modifications of diet and lifestyle, massage, and use of drugs from herbs and mineral sources.

## The medical writing boom in India

In the late 20th century, a boom in the information technology sector and economic liberalisation in the country brought India closer to the world. It offered a platform for drug research and development, as well as outsourcing. This increased the growth of the clinical research and medical writing industry in the country. In the late nineties, most people in India were unaware of terms such as 'clinical research' and 'medical writing'. However, going by the sheer number of mail queries we now receive each week, it seems that many youngsters in the

country are currently looking at one of these fields as a viable career option.

In the mid-1990s, physicians like us, who chose clinical research or medical writing over clinical practice, were believed to be anything but sane. People who trod these unfathomed paths often drew flak, even from family. Dr Bimal John, who founded a professional medical writing and health IT consulting firm in Bengaluru in 2006 after having worked as a freelance medical writer for three years, believes that ‘professionals who got into this stream early have managed to sustain themselves through very difficult times. They have played a strong role in changing the perceptions about medical writing and the contributions medical writers could make to the industry. Over the last decade, the industry has evolved and medical writers are now recognised as a vital part of the healthcare industry. Today, there are countless opportunities as well as established career paths for medical writers’.

There is now an increased need for better medical writing. ‘Medical writers have had to pull up their socks and do a better job than before’, says Dr Sanjay Pai, who sits on the editorial boards of the *National Medical Journal of India* and the *Indian Journal of Medical Ethics*. He is glad to notice that while the number of peer-reviewed journals published in India has increased, there has also been a simultaneous improvement in the standard of Indian journals, something he believes was deficient only a decade ago.

There has been an upward move for regulatory writing as well. Dr Roopa Basrur, Director, Medical Writing Services India at PAREXEL International, believes that the outsourcing of pharmaceutical industry-driven medical writing has resulted in the creation of a new profession in India and the need for new talent. ‘The Indian medical writer has evolved to become a key player and member of the clinical study team in the drug development world’, she says, adding that ‘confidence and reliance on the work that we can do in India is on the rise as well’.

Continued medical education (CME) writing does not seem to have caught up, though. This is because CME is not mandatory across India. Some industry-driven CME is offered at conferences. Without it, we might have had none. The Medical Council of India (MCI) recommends 30 hours of CME every 5 years but does not make it a mandatory requirement. Since 1985, when the MCI planned its first CME, we have not come a long way where CME writing is concerned. The State Medical Councils in Maharashtra, Punjab, Kerala, Tamil Nadu, and

Gujarat now have mandatory CME systems which require doctors to get re-registered with the councils after they obtain a certain number of CME credits within a certain number of years. However, the CME systems have only been in place for the last couple of years and it will be another few years before the first doctor re-registers. Moreover, their accreditation systems are not uniform across State Medical Councils. Hopefully, in the coming years, as the need for CME is better recognised, the scope for CME writing will also increase.

## Medical writing as a career in India

With a lot happening in the medical writing industry across the country, several institutes have started offering courses to create a pool of talented medical writers. Many students who take these courses go on to work as medical writers in various contract research organisations (CROs), medical communications agencies, and pharmaceutical companies. A few years ago, many writers would join the profession but then move on to the ‘next big thing’ after just a couple of years of writing. Medical writing as a full-time, long-term profession did not seem an attractive option for most.

Has the situation improved? Is medical writing a viable career option in India today? Dr Arun Bhatt, President of the CRO Clininvent and an honorary editor for *Perspectives in Clinical Research*, thinks it is too early to say. He feels medical writing in India, by and large, contributes to the non-regulatory variety and unless it moves up the ladder to include a lot of regulatory medical writing as well, the value of this field will not increase. Dr Pai, however, is more positive. He believes many Indian medical writers have been quite successful and are creating a space for themselves in the global arena.

According to the Confederation of Indian Industry, the Indian pharma industry showed a compound annual growth rate of over 15% during the period from 2005 to 2011.<sup>1</sup> It is likely to be among the top 10 global markets by value by the year 2020, if this trend continues. This staggering growth will bring with it a higher demand for quality knowledge-based solutions and information dissemination. There is also likely to be a burst in the bubble, with businesses seeking quality over cost advantages. This will eliminate providers who do not provide quality services. Both Dr Bhatt and Dr John believe that the growth of the medical writing industry over the next few years will depend largely on big pharma’s assessment of the quality of medical writing that comes from India.

Dr Basrur states that ‘as the pressure to reduce costs increases and the quality and experience of medical writing in India increases too, there is bound to be more activity in this region. Apart from outsourcing of global pharmaceutical work, there is also a need for medical writing for our own Indian pharmaceutical research and drug development – a wonderful and positive step forward’. The media too is changing and Dr Pai believes there are some good consumer healthcare magazines and daily newspapers out there, some of which would be interested in good medical reportage. Whether it is regulatory writing or medical journalism or medical communications, there seem to be bright prospects for the growth of medical writing in India.

India also has its own medical writers association, the All India Medical Writers Association (AIMWA), which currently has over 250 members. This shows the growing interest in the field. AIMWA provides a networking platform for medical writers and works towards catalysing, supporting, and strengthening the medical writing service in India, and helping it to meet global standards. It also promotes and facilitates training through medical writing workshops.

## Challenges for medical writing in India

Companies such as Indegene, Bioquest, and Novartis hire several Indian medical writers each year and rigorously train and prepare them to meet the standards expected globally. Dr Anand Kiran, who manages scientific operations at Indegene, says that ‘identifying the best-fit talent in India, taking them through well constructed and executed training programs, and providing them the opportunities to learn and grow – through cost-effective, process-driven, scalable systems – are essential to being the preferred destination for off-shored medical writing’.

Probably the biggest challenge here is the lack of sufficient experience related to professional medical writing. The industry faces challenges similar to other outsourcing businesses. Medical writing involves various complexities, and as Dr Kiran puts it, many have learned the hard way that having the necessary talent pool alone does not always translate into high-quality, ‘first-time right’ documents. Dr Basrur adds that ‘while we have many appropriately qualified, English-speaking professionals in India, finding the right mix of skills remains a challenge’. She is hopeful that as the profession grows, these teething problems will diminish and capabilities in training will increase.

India is currently a low-cost destination. However, experienced medical writers in India are starting to ask for a fair price. Dr Basrur sees the rising cost of living in some of our larger cities as one of the future challenges. We have to wait and see how sustainable this will be in the long run.

If we ask for a price similar to our global counterparts, we will have to provide an equally good quality. Dr John feels customers are no longer going to offer contracts solely on the basis of price, but will also demand higher quality in the services and products. Vendors and professionals who cannot offer quality will be eliminated. Medical writers in India will have to take great care in this regard, or else professionals from the Philippines, China, and other Asian countries will take away any advantage that we have.

## Does the cost–benefit translate into quality issues?

Companies outsource medical writing to India not solely because of the low cost but also, we believe, because of the quality they get at that cost. There are over 250 medical colleges in India offering MBBS degrees, which are fully recognised by the MCI.<sup>2</sup> In addition, there is no dearth of science graduates in the country. According to our survey in 2008, over two-thirds of the medical writers in India were physicians and more than 90% had a life science background.<sup>3</sup>

What is perhaps lacking is proficiency in English. While English is not our native language, it is an official language in India and the medium of instruction during school and university education for many. Compared to writers from countries that use English as a native language, Indian medical writers need to develop proficiency in the language. Drs Bhatt, Pai, Kiran, Basrur, and John, all of them agree on this. ‘But one also needs to bear in mind that the demand for medical writing in other languages is also increasing’, remarks Dr John. An average educated Indian can read and write in three to four different languages, English being one of them. India has 22 official languages and many regional dialects and one can choose to write in one or more of these languages. However, ‘irrespective of the language, the essence of success in this profession is a commitment to quality’, says Dr John. As the medical writing industry here matures, writers will gain experience in how to write better.

It is very difficult to make a one-on-one comparison between an Indian medical writer and one from a different part of the world, reflects Dr Basrur, who

in addition to being the President of AIMWA is also a member of EMWA. Most of the writers she knows in the West are highly experienced. She does not see too many people with that kind of decades-long experience in India. When comparing new medical writers, she does not find much difference. 'Our education system has traditionally not focused on research and working independently and this is where we have a steeper learning curve', she feels.

### The future of medical writing in India

If we medical writers in India can deliver medical writing of global standards, we should not fear losing business to other low-cost destinations. Also, there is no reason why we should remain a low-cost destination for outsourced medical writing. By asking for low pay for quality medical writing, we may be gaining an unfair advantage and becoming a cause of concern for the worldwide medical writing fraternity. Several medical writers in the West have voiced concerns about losing their business to low-cost destinations such as India. We should ask to be paid well since we have the experience and skills to deliver good quality. After all, you get what you pay for. It is time for Indian medical writers to gain all the experience they can and hone their talents in order to be considered among the best in the world.

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Vice President, Global Operations, Indegene Lifesystems Pvt Ltd; Dr Roopa Basrur, Director, Medical Writing Services India, PAREXEL International and President of the All India Medical Writers Association; and Dr Bimal John, Founder and Editorial Head, iLogy Healthcare Solutions.

### Conflicts of interest and disclaimers

Dr Natasha Das is a freelance medical writer providing medical writing, editing, and training. She is the Founder Secretary of the All India Medical Writers Association. This is an unpaid position. She runs occasional (paid) courses and workshops on medical writing. She has also co-authored a book on becoming a medical writer in India. It is therefore possible that by publishing this article she may benefit financially by acquiring new customers, running extra courses, or selling more copies of her book.

Dr Saurendra Das has no conflicts of interest to declare.

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# Medical writing in India at a crossroads

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## Abstract

Pharmaceutical regulatory medical writing for document submissions to Western health regulatory agencies has been undertaken in India for almost 10 years. From humble beginnings in a couple of non-Indian pharmaceutical multinational giants – Novartis and Sanofi-Aventis (as it was) – this activity has now expanded into multiple companies and almost a dozen information technology firms and contract research organisations. The biggest advantage is the cost, although this often comes at a ‘price’, in terms of document quality. However, medical writing in India may be turning a corner for the good as a result of the rapidly increasing body of experience in the field.

**Keywords:** Medical writing, India, Outsourcing, Quality, Cost arbitrage

Few people understand what medical writing is all about, even within the scientific community. Often, it is an excruciating experience for a medical writer to explain what they do in the pharmaceutical development world. Also, the broad range of medical writing activities adds to the problems. This range extends from regulatory writing for submissions to the health regulatory authorities worldwide to writing intended for publication in scientific journals and for presentation at conferences. So it can be quite challenging to articulate to the ‘native’ English speakers of the world the full scope of this professional activity within India (with its ‘non-native’ English-speaking population).

India, according to some estimates,<sup>1</sup> has the second largest English-speaking scientific force in the world after the USA. With hundreds of thousands of graduates with master’s and PhD degrees (achieved in English) adding to that pool every year, India presents a formidable cohort of young life science graduates entering the job market. All

they need to become fully ‘employable’ is appropriate in-house training by the many global big pharma innovator companies that have an Indian presence.

According to an Ernst and Young report published in 2009,<sup>2</sup> India offers significant cost arbitrage to service providers and sponsors when compared with developed and emerging economies. The cost of services, such as medical writing, in India is typically 40–60% lower than in developed economies and around 10–20% lower than in other emerging economies.<sup>2</sup> Medical writing services would typically include writing documents such as clinical study protocols, investigator brochures, clinical study reports, patient narratives, and various safety reports. Since almost all pharmaceutical companies are under increased cost-cutting pressure and look to outsource their development functions, such as clinical data management, statistical programming, medical writing, and pharmacovigilance, India is the natural choice for most of them. Of the functions listed above, medical writing requires a unique skill-set: the abilities to apply scientific knowledge and to create sense and order out of the gargantuan sets of data generated in clinical studies.

In a special report published in 2009,<sup>3</sup> the authors discuss the history, current state, and projected future growth of biological research in India. They consider the establishments that churn out hundreds of thousands of young life scientists, many of whom will turn to the pharmaceutical industry for employment because of the lack of well-developed and well-paid research jobs in academia. Some established chains of institutes, such as the Indian Institutes of Science Education and Research, offer 5-year combined bachelor’s and master’s degree programmes, some of which include scientific writing in their curricula. The report’s authors opine that in order to realise its aspirations, India needs to educate, recruit, and develop its next generation of scientists. Similar challenges exist in the



developed world, but they are particularly acute in developing countries that are racing against time to achieve globally accepted standards.

Traditionally, Indians may not have formal English writing courses in schools and colleges, although the medium of instruction may very well be English. And although India has a large number of people who may know how to speak in English, albeit incorrectly some of the time, writing is a whole different ballgame. As Reeves noted,<sup>4</sup> professionals in the fields of science and medicine are expected to write well in English, but most often they do not. A significant mass of 'educated' and urban Indians learn English at school with little emphasis on grammatical correctness. If a major effort is made at school to lay strong foundations in written English, instead of just spoken English, most students will eventually become better writers, regardless of their chosen career. Apart from the grammatical perspective, most Indians tend to construct tortuous sentences, which fail to convey their intended meaning. Learning to write short, crisp sentences would likely help them to clarify their messages.

The current scenario offers better prospects than did the 'teething' years for the quality of medical writing in India. Now that it is approaching a decade since regulatory medical writing began in India, a good number of writers have gained valuable experience as a result of working in different companies that undertake medical writing. Such companies include Western pharmaceutical companies, Indian information technology (IT) companies, Indian subsidiaries of Western IT companies, Indian

contract research organisations (CROs), or Indian subsidiaries of Western CROs.

Indian medical writers and their employers have one more challenge to overcome, that of the relatively high attrition rates. Writers switch jobs in search of quick pay rises and people management roles. In the process, they neglect to hone their writing skills and become a true expert in the field, which usually takes a few years spent just writing. At the same time, employers need to give their writers adequate recognition and timely rewards so that they continue to develop their key skill – writing.

### Conflicts of interest and disclaimers

The author declares no conflict of interest. The views expressed by the author in this article are personal and do not necessarily represent the views of any organisation with whom the author may be associated.

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# Medical writing in the Middle East

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## Abstract

Medical researchers in Middle Eastern countries have been forced to confront the fact that scientific publication has become the cornerstone of knowledge dissemination and academic promotion. Regional initiatives, such as the foundation of the Eastern Mediterranean Association of Medical Editors and the AuthorAID project in the Eastern Mediterranean, have helped, but challenges remain. The Middle East has taken great steps forward in medical research and writing, but improved training and educational programmes are needed, and the concept, importance, and principles of scientific writing need to be incorporated earlier in existing educational programmes.

**Keywords:** Medical writing, Scientific writing, English, Plagiarism, Education

Over the past three decades, Middle Eastern countries have made substantial progress in both conducting and publishing scientific research.<sup>1-4</sup> For example, the growth rate of science production in Iran is 11 times faster and in Turkey 5.5 times faster than the global average.<sup>1-4</sup> As the number of research studies has increased in the region, there has also been a sharp rise in the number of scientific journals being published in the region. For example, the number of medical journals published in Iran has increased from less than 10 in the 1970s to more than 450 currently.<sup>5,6</sup> Medical journalism has also flourished in the Middle East over the last several decades.

## Initiatives in the Middle East to promote medical writing

*WHO Regional Office for the Eastern Mediterranean and Eastern Mediterranean Association of Medical Editors*  
Medical researchers in Middle Eastern countries have been forced to confront the fact that scientific

publication has become the cornerstone of knowledge dissemination and academic promotion. Initiatives aimed at building infrastructures and educational programmes have crucial roles in improving and promoting the medical writing in the region. In 2003, the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) organised the First Regional Conference on Medical Journals in the Eastern Mediterranean. Journal editors, researchers, and academics gathered at the meeting to discuss issues related to scientific publication, including authorship, editorship, peer-review, plagiarism, and copyediting. At this meeting, it became clear that a regional association of editors was needed to tackle issues related to scientific writing and publication. Thus, a provisional Executive Council for the Eastern Mediterranean Association of Medical Editors (EMAME) was formed (<http://www.emro.who.int/entity/emame>).

EMAME, with the help of WHO/EMRO, created a listserv to attract medical researchers and academics in the region as members. Other than the first meeting in Cairo, EMAME has had four other meetings to date: Riyadh, Saudi Arabia in 2004; Shiraz, Iran in 2006; Manama, Bahrain in 2008; and Karachi, Pakistan in 2010. Prominent regional and international speakers were invited to these meetings to lead panel sessions and workshops dedicated to scientific writing, authorship, editorship, peer review, publication ethics, and copyediting. Gradually, the notion of a medical writer, as it is known in the West, has emerged and has been discussed in various forums.

*AuthorAID project in the Eastern Mediterranean*

The idea of an AuthorAID project in the Eastern Mediterranean (AAEM) emerged from the EMAME meetings and was initiated in 2009 by Karen

Shashok and Farhad Handjani with the support of Shiraz University of Medical Sciences in Shiraz, Iran.<sup>7</sup> AAEM matches AuthorAID volunteers with academics and researchers who have prepared manuscripts but need help to improve the English and the manuscript quality. The AAEM project also includes consultations and editorial guidance to regional journals to upgrade their quality and to help them get listed on major indexing systems, and it includes talks and workshops on various aspects of scientific writing and publication. The AAEM project continues to be active and continues to seek volunteers and host institutions.

#### *Institutional scientific writing workshops*

Because scientific publication is essential for academic promotion and to compare scientific output between countries, ministries of health and higher education in the region have promoted national and university initiatives to create scientific writing workshops. The number of workshops has increased several fold, and they are now held on a regular basis. Also, in some institutions, special centres have been created to help researchers and academics not only write their manuscripts but also to design study protocols and statistical analysis.

#### *Professional medical writer training*

Many freelance medical writers, small medical writing agencies, and associations have arisen to try to respond to the sharp increase in need for manuscript publishing. However, many of the people working professionally as medical writers have not been formally trained. Universities are just beginning to fill the need for training in this area. The first to do so has been Shiraz University of Medical Sciences in Iran, which established a Master's degree in Medical Journalism in 2009.

## **Challenges faced in the Middle East region**

#### *The challenge of publishing in English*

Writing itself poses a challenge for many researchers.<sup>8</sup> Even eminent scientists like Charles Darwin, the creator of the scientific masterpiece, *On the Origin of Species*, once asserted that 'a naturalist's life would be a happy one if he had only to observe and never to write'.<sup>9</sup> In Middle Eastern societies, due to cultural issues, most people, including scholars, are talented at oral communication but have trouble with writing.<sup>10</sup>

The situation is further complicated by the need for medical researchers in the Middle East to publish in English. Interestingly, although

English is currently recognised as the *lingua franca* of science, it has not always been in this position.<sup>10</sup> In fact, for centuries, the Middle East was the centre of science and culture,<sup>2</sup> and many manuscripts were written in Arabic and Persian, which were the main language of science at the time.<sup>11</sup> This shift from East to West is captured in the aphorism *ex oriente lux*. Nonetheless, to increase the chance of being read and accepted by the medical community and of being included in prestigious indexing systems like MEDLINE, many of the journals in the Middle East are published in English.

#### *The challenge of plagiarism*

The obligation not only to write but to write in a language other than one's mother tongue is probably the main reason that some scientists in the Middle East resort to plagiarism.<sup>12-15</sup> Plagiarism can be categorised into two main types: plagiarism of ideas and plagiarism of text.<sup>14</sup> Globally, scientists agree that plagiarism of ideas should be considered a blatant and unjustifiable misconduct tantamount to theft. Recycling of words is also unacceptable where the innovation and the originality of the work are the eloquence and uniqueness of wording used, especially in the humanities and literature. However, there are controversies surrounding the plagiarism of text in reporting science.<sup>15</sup>

Based on our experience, the main reason for authors from the Middle East to plagiarise text is because they are disinclined to sacrifice accuracy and quality due to a lack of linguistic expertise; many non-English speakers admit that they find it difficult to resist the urge to 'borrow' a text when it describes what they mean more fluently and clearly than what they can write.<sup>16</sup> Another important reason for plagiarising text is that in some cultures, it is not considered misconduct.<sup>10</sup> In fact, in many developing countries, recycling of words is not an uncommon practice among academics, mostly because they lack a clear declaration that it is considered unethical.

Some researchers question the regulations on plagiarism of text (and self-plagiarism).<sup>14,15</sup> They argue that in reporting the results of scientific research, the role of the language is to convey the message, no matter how eloquent the text is; the essence of a scientific work is in the content. Unlike literature, where uniqueness of wording is paramount, in scientific writing, we ask the authors to use simple language. Therefore, many feel that reuse of scientific text could be overlooked, particularly for non-English speakers with limited access to professional editorial assistance.

## Conclusion

In the last few decades, the Middle East has taken great steps forward in medical research and publishing, but challenges remain. Increased training and educational programmes are needed. Medical researchers need to be better informed about the concept, importance, and principles of scientific writing, topics that need to be incorporated earlier in existing educational programmes. In addition, the profession of medical writing needs to be developed further. Medical writing organisations and groups like EMAME and AAEM should help further advance medical writing in the Middle East.

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**Farrokh Habibzadeh** is the President of World Association of Medical Editors (WAME), Honorary Editor of The Lancet Middle East edition, Editorial Consultant for The Lancet, Editor and founder of The International Journal of Occupational and Environmental Medicine (IJOEM), and Director of Shiraz NIOC Health Organization Medical Education and Research Centre.

## Oh, the misery of medical writing

Medical writers work and play with words, but even though we are confronted by kinds of names, rarely do we joke about an author. It is not really prudent. Having said this, I can't help share this reference with you, found one wintry Wednesday while looking for references.... With respect for the author concerned, allow yourself a little snigger, or a wee giggle...

Misery L. Depression and psoriasis. *Ann Dermatol Venereol* 2012;139(Suppl 2):S53-7. doi: 10.1016/S0151-9638(12)70111-4. French.

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# Medical writing in Finland

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## Abstract

Finland has a flourishing pharmaceutical and life science industry and research scene. Medical writing, however, is an unfamiliar term to many Finns and there is no Finnish equivalent for the title 'medical writer'. Those people who do medical writing in Finland, but are by job description something else, may be members of other associations or unions and may not even be aware that what they do is actually called medical writing. Finnish medical writers do not have an association of their own, so EMWA could serve as a forum for bringing medical writers in Finland together with each other and with medical writers in other countries.

**Keywords:** Medical writing, Finland, Association

Although I am originally from Finland, I have studied and worked mostly outside my native country. I have often found myself having to explain what I do for a living in other countries and in other languages, but this has been a special challenge when talking to my fellow Finns. I recently asked 'What does a medical writer do?' on an online discussion board of a Finnish patient association whose members are lay people and do not work in medicine but who, because of their illnesses, are frequently in touch with various medical professionals.

The result: nobody knew. Different things were suggested. The most popular guesses were a medical secretary, medical transcriptionist, pharmaceutical sales representative, or health journalist – the type of journalist that writes those 'Ten easy tips for losing weight' articles you find in women's magazines. Fair enough, there can be overlaps, where someone mentioned above does medical writing or vice versa; however, medical writing by definition is none of those things.

What probably makes it trickier for an average Finn to figure out what a medical writer does is that the title 'medical writer' has no real Finnish

equivalent. The direct translation into Finnish, *lääketieteellinen kirjoittaja*, can be used in some contexts, but it is not an established job description. It is also a rather long description for everyday use, and besides it does not really describe the job. Furthermore, many Finnish medical writers work for international companies, where English job titles simply make more sense. The lack of an established Finnish term reflects the fact that the medical writing field is small and rather unknown in Finland.

This does not, of course, mean that no medical writers are needed in Finland. Although a small country of five million people, Finland has a flourishing pharmaceutical and life science industry and research scene. Research is being done in companies of various sizes as well as in academia, and many international companies are represented in Finland. Moreover, hundreds of clinical trials are carried out in Finland each year, although the number of new trials has diminished in recent years, as has been the trend in Europe in general.<sup>1,2</sup> Nevertheless, documents will need to be written for all the trials that are conducted. The person who does medical writing in a given company, however, may have a completely different job description.

Finnish medical writers do not have an association of their own, but many are members of EMWA or AMWA. Those people who do medical writing in Finland but are by job description something else may be members of other associations or unions, and may not even be aware that what they do is actually called medical writing. They would, of course, benefit from being able to network with fellow medical writers instead of colleagues that do similar but still different jobs, such as technical writers. Reaching these medical writers is a challenging task that will require a wider public awareness of what medical writing is. As there is no national Finnish medical writing association, EMWA may succeed in bringing medical writers together, not only in a European context, but also on a national level.

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## Author information

**Sanna Lönnfors** After finishing physiotherapy studies in Finland and working for some years as a medical writer specialising in manuscript writing at a clinical research centre in Berlin, Sanna Lönnfors is now living in Tel Aviv and working as a freelance medical writer, translator, and journalist. Sanna has a Bachelor's degree in

Physiotherapy from Satakunta University of Applied Sciences in Finland and a Master of Science in Public Health from Charité Universitätsmedizin Berlin in Germany. She is currently studying for an MA in creative non-fiction writing at Bar Ilan University in Israel.

## Plagiarism watch

Another month, another European politician enveloped in a plagiarism scandal. This time it is the turn of Annette Schavan, who, this time last year, was the German Minister of Education and Research and the holder of a doctorate. Now she is neither.

After a blogger claimed to have found evidence of plagiarism in Schavan's PhD thesis,<sup>1</sup> the institution that awarded it, the University of Düsseldorf, officially investigated the case and concluded that there were sufficient grounds to revoke the PhD. This decision left Schavan without an academic degree – pretty embarrassing for the minister in charge of education. Her inevitable resignation soon followed, although she refutes and is challenging the university's decision.

A week after it announced its decision, the University of Düsseldorf issued a press release explaining it.<sup>2</sup> The university claims that Schavan's case was handled just as anyone else's would have

been, and denied that the investigation was politically motivated. It further claims that what constitutes plagiarism is no different now than it was in the 1980s, when Schavan received her PhD.

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# On the western edge of Europe – medical writing in Portugal

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## Abstract

Within Portugal, medical writing is a new and rare profession. We describe our personal career routes to medical writing and discuss the barriers and the emerging opportunities for medical writers in Portugal. The profession of medical writing is not widely known about within the research community or the medical profession, and is not recognised as a potential career. The lack of pharmaceutical companies in Portugal also hampers the development of medical writing. The rapid increase in scientific research within Portugal over the last 30 years, however, has resulted in a substantial pool of highly trained researchers, a potential source of medical writing recruits. This development of research has increased the pressure to publish, and practising physicians are subject to similar pressure. Such pressures are likely to lead to an increasing demand for medical writers in Portugal.

**Keywords:** Portugal, Medical writing, Career development, Opportunities

## Different paths to medical writing – two personal accounts

*Eva Leiria*

My career path differed from what might be expected for a medical writer. After finishing my degree in psychology and while still working on my masters in the same field, I started working part time at Keypoint, Lda (a national contract research organisation) with responsibility for collecting data for several epidemiological studies. When the company needed to train and hire more monitors, my collaboration evolved into a job as a Clinical Research Associate (monitoring clinical studies). Soon, my enthusiasm for writing and for developing scientific skills was clear and I was given the opportunity to improve them by collaborating in the development of several study documents. Thus, I

was introduced to a completely new career – medical writing – of which I had previously been completely unaware. Since then (2008), I have been working full time at Keypoint in the development of different kinds of study documents (e.g. study protocols, informed consents, clinical study reports, manuscripts, abstracts) as a medical writer. In my continuous efforts to learn and grow in this field, and recognising the paucity of training for medical writing in Portugal, I found EMWA and began my EMWA Professional Development Programme (EPDP), thus acquiring a Foundation certificate.

*Marta Abrantes*

I started my career with a degree in pharmaceutical sciences. However, soon after becoming a licensed pharmacist I became interested in pursuing a research career in chemistry. After completing a PhD and post-doctoral studies, I took up a post as a research associate in the area of chemistry in a university and found myself spending most of my working time preparing (with much enthusiasm), in English, original manuscripts, reviews, and grant proposals for my research work.

Additionally, I have also started to prepare, in Portuguese, documents for science education and dissemination for the general public and funding benefactors. While looking for writing resources I became familiar with the concept of medical writing and started to consider it as a potential career path. EMWA and its conferences seemed the right place to begin. I started the EPDP, which has given me the opportunity to access high-quality training in medical writing, specifically in areas in which I had no background or no formal background (e.g. I have been proofreading papers for a while but had never been formally trained to do so). The fact that I will be awarded a certificate at the end of the programme was a decisive factor in my choice of EMWA as a training organisation. I believe that the EMWA certificate will enhance my curriculum vitae and improve

my future employment opportunities. EPDP training has already improved my skills as a scientific writer. It was also through EMWA that I made contact with my Portuguese colleague Eva. EMWA conferences are a great place to network even for new members.

## Medical writing in Portugal: barriers, opportunities, and needs

### *Lack of awareness of the medical writing profession*

Despite the major developments in the field of research and development in Portugal, research careers remain largely within the universities and funded by the state. In this scenario, scientific and medical publications and other documents are usually developed by the researchers themselves. Most of these researchers are not aware of the existence of scientific or medical writers who can help them to write research documents. In addition, there is an enormous gap in Portugal in training in the medical writing field. Only a few college degrees include references to or training in medical writing in their curricula. Thus, students in scientific areas are not usually conscious, unless they are very proactive, that medical writing is a possible career for them. It is usually only after a period working in the field and/or by being involved in research and development that they discover this possibility. Even then they have to be very lucky or very proactive to begin a career as a medical writer and to get adequate training. Additionally, although training courses in medical writing outside university exist, they are still scarce.

### *Lack of Portuguese or Portugal-based pharmaceutical companies*

One of the most important difficulties for potential medical writers in Portugal is related to the lack of Portuguese or Portugal-based pharmaceutical companies. Internationally, the pharmaceutical companies generate the majority of medical writing work. In Portugal, however, this work is usually confined to the writing of manuscripts, abstracts, and posters, since regulatory documents are generally developed by the central offices of international pharmaceutical companies. Usually, when part of an international clinical study is conducted in Portugal, all the documentation has already been produced abroad and the role of the Portuguese medical writer is to translate and adapt the documentation to comply with Portuguese law and requirements.

### *Highly trained researchers available*

In the last 30 years Portugal has undergone a revolution in the field of research and development. The number of researchers has increased exponentially

from 0.9 (per 1000 of total employed) in 1982 to 8.3 (per 1000 of total employed) in 2010,<sup>1</sup> bringing Portugal in line with EU levels (number of researchers in EU27 = 6.5 per 1000 of total employed).<sup>2</sup> The number of publications from Portuguese institutions in international peer-reviewed journals has consequently risen from 3.9 to 121.3 publications per 100 000 inhabitants annually.<sup>3</sup> The contribution of health and medical sciences to the overall number of publications decreased slightly from 1982 to 2010 (31.3% and 26.6%, respectively) but still represents one quarter of all the publications of Portuguese institutions.<sup>4</sup> About half of the publications produced by Portuguese institutions (in all areas of knowledge) are written in collaboration with international partners, indicating the extent of international collaboration in scientific research. Publications reveal collaborations mainly with the following partner countries (in order of importance): Spain, the USA, the UK, France, Germany, Italy, Brazil, and the Netherlands.<sup>5</sup> In Portugal the distribution of researchers in activity sectors is not typical when compared with the rest of the EU27 (Figure 1).<sup>6</sup> Almost two-thirds of researchers (62.8%) work in higher education institutions and only 22.6% in private companies. It seems likely, however, that this distribution will change in future years. With limited recruiting by state stakeholders, highly trained researchers, especially those with international experience, are likely to be of interest to international companies as potential recruits.

### *Growing market for medical writers*

While, in Portugal, the role of the scientific and medical writer often remains unknown, the development of the Portuguese scientific system has increased the pressure to publish in all scientific areas. The motto 'publish or perish' and its consequence for careers has motivated many

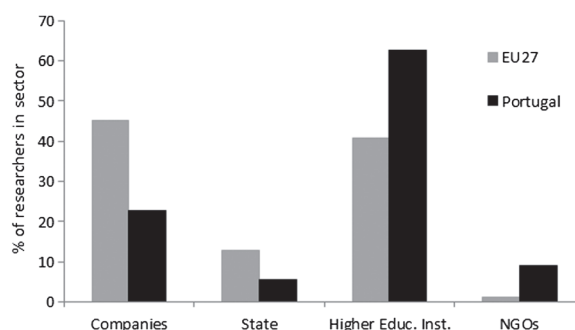


Figure 1: Distribution of researchers in different activity sectors (or types of organisations) in Portugal compared with the whole of the European Union (EU27). Types of sectors or organisations: companies, state, higher education institutions (higher educ. inst.) and non-governmental organisations (NGOs).



professionals (including medical doctors) to dedicate themselves more to research and to getting it published. Thus, we believe that Portugal is likely to see an increase in the market for the medical writing profession in the near future.

At the time of writing, we understand that there are currently only two EMWA members based in Portugal. Used to being a minority in many international associations and institutions because of our relatively small population (inhabitants of Portugal represented 2.1% of the total EU27 population in 2010)<sup>7</sup> this small number came as no surprise. A search in the professional network, *LinkedIn*, reveals a dozen or so people claiming to be medical writers in Portugal.<sup>8</sup> However, we understand that these numbers must underestimate the number of people working in the field. It is, however, our conviction that within Portugal more professionals do medical writing but do not label themselves as such. Identifying the other people based in Portugal who act as medical writers is an important first step towards national networking, education, and promotion of this professional activity in Portugal.

## Conclusion

We come from very different professional backgrounds and discovered medical writing in the course of our careers, through a combination of our interest in science and writing, luck, and proactivity in seeking out career development and growth. At present, few Portuguese students and researchers are aware of medical writing or have the opportunity to start a medical writing career as we have done. Nevertheless, we believe things are changing. With the help of EMWA, the two of us found each other, and we hope to spread the word about medical writing in Portugal and to help others to find their paths into this exciting career.

## Acknowledgement

The authors are grateful to Diarmuid De Faoite for putting us in touch and encouraging us to write this article.

## Author information

**Eva Leiria** started her research career as a Clinical Research Associate at a Portuguese CRO. She developed her scientific skills and began to work as a medical writer by supporting the development of protocols, informed consents, and other study documents. She was subsequently trained in scientific study design and publications.

## Disclaimer

The opinions expressed by the authors are theirs alone, and do not necessarily represent official opinions of their employers.

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# Announcing AERTeM, the Spanish Association of Medical Writers

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## Abstract

The Spanish Association of Medical Writers – in Spanish, the *Asociación Española de Redactores de Textos Médicos* (AERTeM) – is a young association focused on the specific needs of Spanish writers. Local organisations such as AERTeM can augment the role of international organisations such as EMWA by providing a local forum to improve and professionalise medical writing and by serving as an expert resource of country-specific knowledge.

**Keywords:** Spain, Medical writing, Association

The Spanish Association of Medical Writers – in Spanish, the *Asociación Española de Redactores de Textos Médicos* (AERTeM) – was created in February 2005 by Santiago Rosales, a paediatrician from Barcelona who had been doing medical writing work for several years. Having experienced the positive ‘international feel’ of EMWA meetings, he felt that the Spanish medical writing community would benefit from a similar local association. As there was no current Spanish language association he contacted other Spanish medical writers and decided to create AERTeM.

According to its charter, AERTeM’s goals are:

- To promote and facilitate professional training for its members;
- To promote the linguistic quality and accuracy of biomedical documents used in the pharmaceutical industry, for marketing and for the communication of science;
- To facilitate information sharing among its members, as well as between members and sponsors of biomedical publications (i.e. publishers and the pharmaceutical industry).

To reach these goals, members of AERTeM are working on a number of initiatives, such as

establishing a training program, implementing training exchanges with similar associations, developing a web page (<http://www.redactoresmedicos.com>), organising scientific meetings, and publishing general topics of interest for its members. To date, AERTeM has conducted three general meetings. These have focused on topics related to medical writing and have featured discussions on the association itself and our future plans. Since its creation, the association continues to grow and currently (December 2012) has 45 members.

## Key findings from our member survey

To understand the needs of its members, AERTeM conducted a survey in the spring of 2012. Major findings were that most (72%) of the respondents were female, all but one were Spanish (we have one member from Panama!), and most were between 36 and 45 years of age (48%). The most common university degree was in a biological science, and 60% had a doctoral degree. The average number of years of medical writing experience was 9.5, with over 50% having 5–10 years of medical writing experience. Forty percent of the members were freelancers, 28% worked for a pharmaceutical company, and 28% worked in a clinical research organisation. All performed their work in Spanish and English, and 4% also in Catalan. The most common types of documents written dealt with ‘scientific communication’ such as peer-reviewed manuscripts, posters, scientific summaries, review papers, and meta-analyses, and the best known and most frequently used guidelines included ICH, CONSORT, and ICMJE. The majority of the responders found AERTeM membership useful, quoting networking as the biggest factor influencing their continued membership. Access to additional training was also a key factor for the responders.

## Augmenting the role of international organisations like EMWA

AERTeM can augment the role of international organisations such as EMWA by providing a local forum to improve and professionalise medical writing and by

serving as an expert resource of country-specific knowledge. We encourage writers across Europe to investigate forming similar associations, or if one already exists, to join it and reap the benefits of interacting with like-minded writers who probably have many of the same questions and needs.

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**Maria Fernández-Piera** is a Principal Medical Writer at PRA International and a member of EMWA since 2005 and of AERTeM since 2007. More information about AERTeM is available at <http://www.redactoresmedicos.com>.

## Plagiarism watch (part 2)

In some countries there are laws preventing felons from profiting financially from their crimes, but there seem to be no such rules for plagiarists.

Journalist Jonah Lehrer was forced to resign from *The New Yorker* after it was revealed that he had fabricated Bob Dylan quotes and engaged in plagiarism and self-plagiarism. His disgrace did not, however, preclude him from speaking at an event held by the Knight Foundation, a charitable US organisation dedicated to furthering education, journalism, and the arts.<sup>1</sup>

The subsequent revelation that Lehrer was paid \$20,000 for his participation triggered a wave of controversy, which prompted the Knight Foundation to rush out a feeble and contradictory statement expressing regret at their decision, but at the same time appearing to defend it.<sup>2</sup>

The Foundation invited Lehrer to talk about decision making in the knowledge that he would discuss some of the 'mistakes' he made. Can the fee be justified if his talk prevents others from

engaging in the kind of malpractice he committed? The condemnatory comments the Foundation's statement provoked<sup>2</sup> suggest that many think not.

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# From editors abroad into businesswomen back in Brazil

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## Abstract

After living for 12 years in the United States, and a career shift from bench scientist in molecular biology to science writer and editor, the author goes back home to Rio de Janeiro, Brazil, to found Publicase, a science communication company specialised in health sciences, biology, and biomedicine. This article discusses what the author learned on the way about the challenges, opportunities, and rewards of creating and growing Publicase.

**Keywords:** Scientific writing, Science communication, Brazil

When I chose to major in biological sciences back in 1988, I had no idea that the knowledge I would gain while pursuing masters and PhD degrees, followed by a 2-year post-doc training at the National Institutes of Health, would be crucial in making me who I am today: the CEO of a small company specialising in scientific communication in Brazil. Publicase (<http://www.publicase.com.br>) was founded in 2008 upon my return to Brazil after living in the United States for 12 years.

The journey I took, which began with endless hours among a myriad of tiny PCR tubes in labs in Brazil and continued in the United States, culminating in my finally creating a niche away from the laboratory bench, is described in an article published in *Science Careers* entitled 'Beach, Bench, and Beyond'.<sup>1</sup> What I have to share here is some of what was waiting for me *beyond* life at the bench.

At Publicase, we edit and review papers, do translations, write press releases, and teach hands-on workshops on how to elaborate a research paper. At first, it was just two of us. We were former lab researchers who also had significant editorial experience. While I held a position in the editorial department of *Science Magazine* at the American Association for the Advancement of Science, my partner Andrea Kauffmann-Zeh was a Senior Editor at *Nature* for six years. Now we are a group

of 10 people including editors and workshop instructors.

Since 2008, we have faced many challenges at Publicase. Our first obstacle was to convince an initially reluctant scientific community that non-native English speakers like ourselves could teach how to elaborate and write research papers in English. We had to challenge the belief that only a native English speaker is capable of doing a good edit of a paper written in English, a belief that is both unjustified and unethical. It is unjustified because being a native speaker offers no guarantee of good writing. It is unethical because it assumes the existence of a level of 'excellence' in English that cannot be acquired by a non-native English-speaking editor and which only those who are born in English-speaking countries are granted the privilege to claim.

How then to transform biologists-turned-editors into businesswomen? Neither of us had any formal training in business. Everything we know today we have learned along the way. First, we needed a mission for Publicase. What did we want our company to accomplish? We defined our mission as *helping increase the visibility of Brazilian science in the international scenario*. Next, we defined the type of service we would offer. To provide a service that is useful and helpful, an editor working with authors for whom English is not their first language needs to combine many skills. This frequently requires the editor to be involved in a way that goes far beyond simply editing the paper. It is not uncommon at Publicase to find ourselves teaching authors how to build each section of the research paper, indicating flaws in how controls are presented, or pointing out all the spots in the text where a reference should be added to indicate the source of scientific evidence.

Indeed, a recent book published in Brazil<sup>2</sup> shows that it is not the English language but a lack of a clear understanding of the scientific discourse and how research projects should be carried out that

are the main obstacles for researchers in Brazil in attaining a better publication record. Thus, at Publicase we are *multifunctional editors* – we are teachers, sometimes writers, and very frequently translators. All these skills are necessary to achieve our main goal: to help authors to get published.

To assume the role of a *multifunctional editor*, some level of knowledge in the field of study of the research paper is necessary. Being ourselves trained as biologists, we have limited our scope to papers in health sciences, biology, and biomedicine.

Explaining to a prospective client that we are not a translation company or a company that ‘reviews the English’ has been an additional challenge. When prospective clients ask us why we cannot work on their physics or chemistry research papers, we offer the following explanation: for the same reason McDonald’s does not sell hot-dogs. In other words, limiting our scope to the health sciences, biology, and biomedicine was a business decision we made in order to ensure a unified, specialised, well-recognised product.

Besides deciding to work only within our areas of expertise, another important decision in our business model was to focus on the scientific community of Portuguese-speaking countries. We believe that good editing of a scientific paper written by a non-native English speaker requires the editor to be able to recognise the author’s original voice in order to grasp all the subtlety originally intended by the author. Thus, our website is available only in Portuguese for a reason.

In Brazil, most of our clients are government-owned universities and research institutes. Having the Brazilian government as our main client has been both our most exciting challenge and our biggest nightmare because of its size and the endless bureaucracy associated with hiring a small company like us. Working with the Brazilian

government offers many challenges, mainly because the person who hires us, usually a university professor, is not the person responsible for paying us and in many cases the communication between the two is very poor and prone to misunderstandings. Additionally, we are frequently asked to issue our invoice in advance in order to trigger a long payment process (it can take up to 90 days) for services we have not yet provided. In Brazil, once the invoice is issued, 16% tax is due in the next billing cycle, which is never longer than 30 days. Thus, on many occasions, we pay taxes for a service we have not yet provided or been paid for.

With more than 50 workshops already scheduled for 2013, we certainly need help to keep organised and on track. To this end, we have relied on a number of free tools available on the Internet, mainly those provided by Google. Tools such as Google Forms and Google Docs have delivered more than we could have asked for and have allowed us to do our business from our home offices, each one located in a different city in the world.

In hindsight, my going back to Brazil in 2007 was definitely the right move. In the United States I would most likely have become one more freelancer desperately searching for jobs and opportunities. In Brazil, I feel that I make a difference – I know that the services that my company offers have helped researchers to get published, thus increasing the visibility of Brazilian science.

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## Author information

**Marcia Triunfol Elblink** is the founder and current CEO of Publicase, a company specialising in scientific communication in Brazil (<http://www.publicase.com.br>). She has an MSc in Genetics, a PhD in Molecular Biology, and extensive experience as a science writer, editor, and translator. She lives in Rio de Janeiro with her family and two German shorthaired pointers, Moby and Bebel.

# Science writing workshops for AIDS vaccine researchers in Africa

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## Abstract

The International AIDS Vaccine Initiative (IAVI) is a global scientific and advocacy organisation dedicated to ensuring an AIDS vaccine for use worldwide. In Africa, IAVI partners with seven research centres who conduct vaccine trials and studies. This research requires extensive medical and scientific writing support, for regulatory submissions and for the publication of data. IAVI and its African partners publish widely in international peer-reviewed publications; however, African authors are underrepresented as first authors. To address this disparity, IAVI created and honed a series of science writing workshops that so far has reached 85 investigators.

**Keywords:** Medical writing in Africa, Science writing workshops, Manuscript writing

Since AIDS was identified 32 years ago, more than 30 million people have died from the disease. Today, some 34 million people are living with HIV, the virus that causes AIDS, and the number newly infected continues to far outpace global efforts to treat the disease. The International AIDS Vaccine Initiative (IAVI) is dedicated to ending the AIDS epidemic by hastening the development of a preventive vaccine against HIV. Its work is largely supported by development funds from government donors, most notably the United States Agency for International Development (USAID), which is IAVI's single largest donor. European donors include the governments of Denmark, Ireland, Netherlands, Norway, Spain, and the UK. IAVI also receives support from foundations, corporations, and individuals around the world.

Established in 1996, IAVI has long been committed to building the scientific capacity of developing countries, where HIV has exacted its greatest toll and where much of the organisation's vaccine development efforts are focused. These efforts, which have enjoyed the full support of USAID and other public sector donors, have contributed to the first clinical assessment of an AIDS vaccine candidate

tailored to the epidemic in East Africa and the conduct of the first AIDS vaccine trials in Kenya, Zambia, and Rwanda. IAVI has helped to build capacity for HIV vaccine research and development in these and other developing countries and supported the efforts of their researchers to join the global scientific discourse. Improving the quality and volume of the medical and scientific literature produced by partnering institutions in Africa has been an important part of these efforts.

## IAVI-sponsored clinical research in Africa

IAVI's global research & development effort spans the continuum from applied research concentrated in the US, UK, and India, to early clinical evaluation of candidate vaccines and HIV epidemiology concentrated in Africa, the US, and UK.

These activities require extensive medical and scientific writing support, not only for the publication of data but for regulatory submissions that are essential to the legal and ethical conduct of clinical research. IAVI's clinical partners in Africa contribute to the production of documents for local regulatory review, clinical study reports and responses to laboratory and quality systems audits. Scientific writing for publication, the major focus of this paper, is taken up in detail below.

## Building capacity for scientific publishing by our partners in Africa

To conduct HIV vaccine trials and studies in Africa, IAVI partners with national and international research institutions in Kenya, Uganda, Rwanda, Zambia, and South Africa to establish a network of HIV vaccine trial and study centres (Table 1).

### *Addressing disparities in publication output*

Circumstances are favourable to boost the publishing output of IAVI's collaborating African researchers. Although Africa's contribution to the worldwide research literature is comparatively small,<sup>1</sup> publications

Table 1: IAVI's Primary Clinical Partners in Africa

Country	Collaborating centre	Type of affiliation	
Kenya	KAVI	Kenya AIDS Vaccine Initiative, Nairobi and Kangemi	Academic: University of Nairobi
Kenya	CGMRC-KEMRI	Centre for Geographic Medicine – Coast, Kilifi	Government: Kenya Medical Research Institute
Uganda	UVRI-IAVI	Uganda Virus Research Institute-IAVI HIV Vaccine Program, Entebbe	Government
Uganda	UVRI-MRC	Uganda Virus Research Institute-Medical Research Council on HIV/AIDS, Masaka Field Station	Government
Rwanda	PSF	Projet San Francisco, Kigali	Academic: Emory University (USA)
Zambia	ZEHRP	Zambia Emory HIV Research Program, Lusaka	Academic: Emory University (USA)
South Africa	AI-Rustenburg	Aurum Institute, Rustenburg	Independent non-profit (corporate spin-off)

tend to be concentrated in medicine, immunology, and microbiology.<sup>2</sup> International partnerships are central to this output (see Table 1). Kenya contributes more to the scientific literature than many other countries in sub-Saharan Africa – the University of Nairobi and KEMRI (Table 1) are major nodes – and South Africa's productivity is ranked high and growing rapidly.

But how much of this output is led by African researchers? An analysis of the peer-reviewed scientific papers co-authored with IAVI-affiliated researchers since 2005 reveals that African nationals are underrepresented as first authors. Among 129 such papers published since 2005, 27 (21%) have an African national as the first author, and 33 of the papers (26%) have an African national as the second or third author. However, the percentage is more than twice as high for conference abstracts. Among 244 conference abstracts, half had African nationals as first authors.

## IAVI's scientific writing workshops

IAVI has since 2009 sponsored four scientific writing workshops to improve the scientific writing skills of

partnering researchers (see Table 2). Although IAVI leads the publication of results from clinical trials and major studies, IAVI-supported studies generate a treasure trove of data that can be mined by co-investigators for additional publication.

### *Abstract writing (2009)*

IAVI convened its first scientific writing workshop in 2009, in response to an expressed need by IAVI's East Africa Regional Office and collaborating researchers (Table 2). The presenter was Monique Oliff, who holds a PhD in international public health from the London School of Hygiene & Tropical Medicine. This and subsequent workshops were not part of an institutional programme of scientific writing but a modest attempt to fill a perceived skills gap for researchers who wished to build a publication record. In a one-day workshop on 14 August, researchers at Uganda Virus Research Institute (UVRI) learned the principles of abstract writing, how to identify publishing opportunities, and how to create a culture of peer review so they would continue to have access to editorial support.

Table 2: IAVI-sponsored science writing workshops for African researchers, 2009–2011

Workshops	Presenter (sponsor)	Structure/content	Participants
Abstract Writing 2009 Uganda	Monique Oliff, PhD Wellsense International Public Health Consultancy (IAVI)	<ul style="list-style-type: none"> <li>• 1-day workshop, August 2009</li> <li>• Content: Principles of abstract writing, awareness of publishing opportunities, peer/staff review</li> </ul>	14 research staff from 2 collaborating clinical research centres (CRCs) in Uganda
Abstract & Manuscript Writing 2010 Kenya	Joseph Oloo Mugah, PhD, Managing Director, SCIDCOM International and Daisy Ouya, MS, IAVI (IAVI)	<ul style="list-style-type: none"> <li>• 6-day Intensive, May 2010</li> <li>• Content: Abstract preparation, drafting scientific paper, illustrations, editing, publishing process, web tools</li> </ul>	<ul style="list-style-type: none"> <li>• 10 early career researchers</li> <li>• 6 CRCs in Uganda, Kenya, Rwanda, South Africa, Zambia</li> </ul>
Manuscript Writing 2010/2011 Kenya, Uganda, Rwanda	Randall Kaja, MS, Pfizer Global Health Fellow (IAVI)	<ul style="list-style-type: none"> <li>• Four 2-part, workshops Aug-Feb 2010/2011 Combining daylong classroom instruction writing exercises, one-on-one</li> <li>• Content: Data mining, manuscript essentials, choosing a journal, research ethics, overcoming writer's block, grammar and word usage</li> </ul>	<ul style="list-style-type: none"> <li>• 40 researchers/lab personnel</li> <li>• 4 CRCs in Kenya, Uganda, Rwanda</li> <li>• Includes 20 one-on-one mentees</li> </ul>
Grant Writing 2011 Rwanda	Tendesayi Kufa-Chakezha, MPH, Aurum Institute (IAVI/First Lady of Rwanda's Imbuto Foundation)	<ul style="list-style-type: none"> <li>• 2-day workshop, Nov 2011</li> <li>• Content: Finding grants, elements of grant proposal, importance of following guidance, overview of study design, how to write concept note</li> </ul>	<ul style="list-style-type: none"> <li>• 20 junior-to-mid-level professionals</li> <li>• 4 CRCs in Kenya, Uganda, Rwanda, Zambia</li> <li>• National University of Rwanda/ other</li> </ul>

### *Abstract and manuscript writing (2010)*

The following year IAVI sponsored a workshop on abstract and manuscript writing for early career researchers working on IAVI sponsored trial and study protocols. Ten researchers from collaborating clinical research centres in Uganda, Kenya, Rwanda, South Africa, and Zambia attended this intensive, 6-day classroom-based training. The instruction helped build skills in drafting, editing, and submitting scientific papers, including the preparation of tables and illustrations and the application of web tools to improve manuscripts.

### *Manuscript writing (2010/2011)*

Positive feedback on these early workshops prompted IAVI to consider more sustained skills-building opportunities in medical and scientific writing for researchers at collaborating research centres in Africa. IAVI tapped the support of Pfizer's Global Health Fellows programme, the company's international corporate volunteer programme, which places its highly skilled colleagues in short-term fellowships with leading international health organisations. It designed to strengthen access, quality, and efficiency of health services in under-resourced communities around the world.

From September 2010 to February 2011, Pfizer Global Health Fellow Randall (Randy) Kaja, MS, drew on his extensive background in medical writing and clinical operations to train researchers at clinical research centres in scientific writing. The 6-month fellowship allowed for fluid, intensive instruction in science writing for investigators at Kenya AIDS Vaccine Initiative (KAVI), UVRI, and PSF, delivered through classroom-based training, assigned writing exercises, and individual editorial assistance and mentoring. Daisy Ouya, MS, board-certified science editor (BELS) and IAVI's communications manager at that time, helped develop the curriculum and prepare course materials. In the first part of the workshop, Mr Kaja brought students together for formal instruction, sent them off with specific exercises designed to improve their papers, and then brought them back together weeks later for a follow-up workshop. He also offered help individually to researchers before, during, and after the workshops, as needed.

Over the course of his fellowship, Mr Kaja also assessed the participants' skills, including their ability to access study-specific data, to conduct a literature review, and to organise material within a paper. He evaluated their technical writing skills, incentives to publish, and provided support in data analysis, and adjusted the workshops to suit their particular needs. Mr Kaja also delivered a

condensed version of the training, without writing exercises, for lab techs and research nurses at KAVI. Two participants even travelled to IAVI's East Africa Regional Office in Nairobi on more than one occasion to obtain support from Mr Kaja and a contract statistician.

In all, 40 people participated in the programme, including a few graduate students preparing final reports for Masters in Public Health or similar programme requirements. Twenty of the participants met individually with Mr Kaja, sometimes weekly. Ms. Ouya reviewed materials and provided feedback along the way. She also participated in the workshops for KAVI senior researchers, led discussions on several topics, and helped showcase IAVI's scientific writing workshops on the USAID Impact Blog, in a post co-authored with USAID's Margaret McCluskey, Senior Technical Advisor, HIV Vaccines.

### *Grant-writing (2011)*

In November 2011, IAVI co-hosted a grant writing workshop with the Imbuto Foundation, which is headed by the First Lady of Rwanda. Led by consultant Tendesayi Kufa-Chakezha, MPH, an epidemiologist at the Aurum Institute in South Africa, the 2-day workshop introduced 20 junior and mid-level professionals to the basics of finding grants and the elements of a grant proposal. The participants included many physicians from the National University of Rwanda's Kigali Teaching Hospital, along with four staff from IAVI-supported research centres in Kenya, Uganda, Rwanda, and Zambia.

### *OCTAVE, an online learning platform*

IAVI contributes to the NIH OCTAVE project (Online Collaborative Training for AIDS Vaccine Evaluation) that includes manuscript writing. The 2013 programme using the Kenya AIDS Indicator Survey (KAIS II) data set culminates in the submission of manuscripts by participants to a peer-reviewed journal for publication around World AIDS Day (1 December).

## **What IAVI has learned from the workshops**

The workshops were very well received by participants, based on written evaluations from the 2010/2011 manuscript writing workshop and grants writing workshop in 2011, as well as interviews with workshop presenters Randy Kaja and Daisy Ouya and IAVI's Regional Director, Africa. With one exception, the various formats offered benefits; however, the 6-day workshop proved too intensive



for most participants with too little time to practice. The residency format that allowed for extensive individual support seemed most conducive to manuscript preparation. Two participants from the UVRI-IAVI HIV Vaccine Trials Unit who attended the 2009 Abstract Writing workshop had abstracts accepted for poster sessions at the 2010 International AIDS Conference (*AIDS 2010*) in Vienna. Each also subsequently had an abstract accepted for *AIDS 2012*, in Boston, as did two other IAVI affiliated researchers. A KAVI researcher who worked with Mr Kaja over several months had a manuscript accepted for publication in PLoS One. She also had abstracts accepted for poster presentations at the *AIDS Vaccine 2011* conference in Bangkok and at the *6th Conference on Global Health and Vaccination Research* in Oslo, Norway (2011).

When Mr Kaja started his workshops, he found that many researchers were eager to publish but faced what he described as a ‘chasm between the data and the blank page’. Others were better prepared to handle the challenges of analysing data in a manner fit for publication, but were simply stalled in the drafting process. They were eager to learn about the mechanics of technical writing – how to link the introduction and discussion sections, for example, or to present results using tables and illustrations. In response to a written survey, many of the participants simply wanted ‘more’: longer sessions, more hands-on training, more details about writing up different types of research.

‘KISS’ principles (Keep It Short and Simple) were noted as a favourite topic, but few respondents wanted to dwell on grammar and punctuation, even though Mr Kaja viewed this as a critical skills gap and recommended that a demonstration of proficiency in these areas be a prerequisite for attendance in future scientific writing workshops.

Other barriers also became clear during the workshops, such as limited access to statistical analysis and uncertainty about research ‘ownership’ and the publication plan. Unlike academia, the clinical research settings tend not to be ‘publish or perish’ research environments. With fewer incentives,

investigators must find time to write on the margins of their workday, without expectation of promotions or merit increases.

## Conclusion

IAVI’s science writing workshops reached nearly 85 young, early career, and senior researchers at IAVI’s collaborating clinical research centres in Uganda, Kenya, Zambia, Rwanda, and South Africa and at other health-related institutions. The workshops gave early and mid-stage investigators a place to start in their efforts to build a base of publications, and roadmaps for the development of required skills. We believe that the general findings are applicable to other organisations wishing to introduce scientific writing workshops. The residency model of group training combined with one-on-one editorial assistance and mentoring may offer the most potential for successful outcomes. However, any format must be combined with institutional incentives for publishing. Capacity building remains a core commitment for IAVI and its partners, who are increasingly helping to build the technical capabilities of research institutions in the region. IAVI will continue to foster scientific writing skills at partner institutions as part of that larger effort.

## Acknowledgements

I would like to thank Bonnie Bender, IAVI Regional Director, Africa and Daisy Ouya for their insights and helpful suggestions in preparing this document. IAVI acknowledges the United States Agency for International Development (USAID) for its generous support of IAVI’s capacity-building work in Africa.

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## Author information

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# Medical postcard from Australia, the world's largest island

Justin Coleman

President, Australasian Medical Writers Association, Brisbane, Australia

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## Abstract

The Australasian Medical Writers Association (AMWA) comprises about 300 journalists, writers, editors, and health professionals based in Australia and nearby island nations, particularly New Zealand and Fiji. AMWA has held a popular conference annually since its formation in 1982. Members whose writing is essentially product promotion are restricted to affiliate membership, and AMWA does not accept sponsorship from the pharmaceutical industry.

**Keywords:** Australia, New Zealand, Fiji, Australasia, Association, Medical writing

Dear Northern Hemispherean,

If I asked where *Australasia* is, would you throw a net over about half of the world's population, wondering why this correspondent is based in Australia rather than Hong Kong or Singapore? Not, perhaps, if you were a writer with an interest in etymology.

In 1756, Charles de Brosses – I suspect he was a European chap – coined the term to describe the region south (Latin: *australis*) of Asia. Australasia therefore includes Australia, New Zealand, Papua New Guinea (PNG), Fiji, and nearby island nations, but excludes Asia. Had Charles stopped to chat as he sailed by, he may have been disappointed not to have understood a word of the 300 local languages in Australia or 840 in PNG. These days, we do all our medical writing in English ... although that would possibly be an even greater disappointment for Monsieur de Brosses.

The Australasian Medical Writers Association (AMWA) – not to be confused with our American counterpart, which antecedently borrowed our acronym – was formed thirty years ago. In 1982, the Australian Journalists Association merged with Actors Equity to form the Media, Entertainment & Arts Alliance, but no association supported the subspecialty of medical writing. Additionally, health professionals who were writers but not journalists

had nowhere to nurture their craft. For this reason, a group of interested writers in Sydney formed an association under the driving force of medical editor Ron Lord, who was elected the first AMWA President.

Original member Cal Miller PhD recalls the event: 'Our first ever meeting in '82 was at the old Journalists' Club in Surry Hills over a lot of beer and peanuts, and I suppose that there were about 20 journalists there. AMWA's initial focus was just on news and journalistic reporting'.

The 'A' stood for Australia, and most members lived in Sydney. Membership quickly expanded to include every Australian state, and a number of New Zealanders joined throughout the 1990s, so in 1999 we added two extra letters to our name to become Australasian.

In recent years, we have encouraged members from Fiji, a country with relatively few writing resources, to join us in AMWA. We support the important work of Fiji's medical journals to encourage local health professionals to write and publish more 'home-grown' content.

## Two paths to the same page

The career paths of AMWA members usually emanate from one of two distinct backgrounds: medicine and professional writing. Typifying this distinction would be two of our past presidents.

Dr Amanda Caswell trained as a medical doctor but soon discovered a passion for writing, eventually leaving medicine to edit Australia's largest general practitioner newspaper. AMWA is secretly delighted when a health professional realises that the keyboard is mightier than the stethoscope. Our ranks are full of nurses, dieticians, doctors, and researchers who have seen the light. Most straddle the two worlds, still working part-time clinically – we just borrow them.

Then there's Rada Rouse, a self-confessed school science dropout, who had been a journalist at news wire service Australian Associated Press (AAP) for 14 years when the opportunity arose to apply for

the job as AAP's National Medical Correspondent. Seventeen years on, she has written and edited thousands of medical articles, including award-winners, for both consumer and physician readerships.

'You certainly build up a fair body of medical knowledge over the years', says Rouse. 'You don't realise how much until, suddenly, your writer friends are asking you medical questions at barbecues!'

Whether from a health or a writing background, AMWA's 300 members form the backbone of our region's mainstream press, electronic media, health promotion organisations and publications for patients and health professionals. Sophie Scott is the chief medical reporter for ABC TV, Australia's national broadcaster. Melissa Sweet has reinvented the way Australia's public health news is read and analysed, with her innovative online news site Croakey and its associated twitter feed @croakeyblog.

### Arm's length from industry

AMWA differs significantly from EMWA and our US cousins across the Pacific in one respect. From the outset, AMWA has grappled with whether to grant membership to writers who work solely in public relations or for commercial organisations promoting products and services – particularly pharmaceuticals. AMWA decided to grant these writers affiliate membership, which allows access to AMWA services but precludes voting rights.

This two-tiered membership has caused some controversy over the years. As Cal Miller recalls, 'The big debate in the first couple of years was the precise role of PR professionals in AMWA. They were given an affiliate status for the simple reason that they were not journalists, although they disputed that!' One can imagine some interesting discussions over the beer and peanuts!

While AMWA accepts technical or regulatory writers from the pharmaceutical and medical devices industries as members, we do not accept any direct or indirect sponsorship from these industries. This has various consequences, not the least of which is that our budget remains relatively small and we have no paid positions within our organisation. Because of our members' sway, politicians, famous writers, world-beating medical researchers, and eminent academics line up to address our conferences but are reimbursed only in cab fares and coffees – and perhaps a biscuit in a good year.

Thus, the product-promotional focus of EMWA's upcoming seminar 'Writing for Health Economics and Market Access', would be a foreign concept at AMWA. Our conferences, workshops, and webinars

tend to be based around evidence-based medicine, ethical perils such as ghost writing, improving professional writing skills, and cutting through the hype in the news. Last year's 2-day conference, *Social Justice in Health* included issues around Aboriginal and Torres Strait Islander and refugee health, as well as the usual writing, editing, and social media workshops and plenaries. And it was a whole lot of fun.

### Meeting each other

Australia has about the population density of the Mediterranean Sea on a good yachting day. With just 300 members scattered across a land which could put Eastern Europe in its pocket, we need to excel at networking.

AMWA conferences are held in a different capital city each year and we hold regular state-based functions to provide education opportunities. We produce a bi-monthly newsletter, and our Professional Development Program earns attendees an AMWA PDP certificate after participating in eight workshops or webinars.

We live on the web at <http://www.medicalwriters.org/> where we maintain a directory of freelance writers, offering opportunities for employers and editors to commission work, and for our members to advertise their skills.

We are on Twitter at @AusMedWriters and have just started a writing blog at [medicalwritersblog.com](http://medicalwritersblog.com) entitled, as is appropriate for our group of large islands, The Beach.

AMWA would be delighted to welcome any Europeans onto our soil for a conference 'down under', and will even supply beer and peanuts if requested. You will feel quite at home – the other half of you are here already! Sydney is virtually run by Brits, and Melbourne contains more Greeks than any city outside Athens – and has a healthier economy.

At AMWA, we believe medical writing should be accurate, concise, balanced, and interesting, and the execution of it should be enjoyable... most days, anyway.

If this really were a postcard (we make postcards big, down here, and can write very small), the picture would feature a long, undisturbed beach on a sunny day. On the golden sand, a couple of empty chairs face the horizon, with a laptop or blank notepad on each armrest, ready to capture one's contemplations. Beaches breed expansiveness, and we Australasians have plenty of both.

Just out of camera shot, I walk towards one of the chairs.

Wish you were here.

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## Author information

Dr Justin Coleman is a general practitioner with a Master's in Public Health and works in Aboriginal health in Brisbane and the remote outback. He lectures in medicine, public health, and medical writing at Griffith University, the University of Queensland, and

for the Royal Australian College of General Practitioners. He has been a medical writer and editor for 17 years and AMWA President for three. He can be found on the Internet at <http://drjustincoleman.com/> and on Twitter as the 'Naked Doctor' at @drjustincoleman

## The Not-so-wise Owl: A lesson in cultural awareness for medical communicators

Cross-cultural communication is often difficult. Therefore, materials developed by medical communications agencies at a regional level are usually adapted by local medical writers to meet local needs. However, most societies are a patchwork of cultures and the interests of minorities can be easily overlooked in favour of the majority.

For example, Maori, the indigenous Polynesian people of New Zealand, have long been known to suffer from poorer health outcomes compared with the Pakeha (Caucasian) majority. Most health sciences graduates in New Zealand are educated in issues of Maori health, including the need for understanding cultural differences.

The need for understanding cultural differences is highlighted by a medical communications case study in which the European symbol of wisdom, an owl, was used as the centrepiece graphic in a poster aiming to promote childhood vaccination as

a wise choice for Maori parents. The programme was a resounding failure because native New Zealand owls, known as a ruru (Maori) or morepork (English), are a symbol of death in Maori culture. Accordingly, the very clear inference for Maori parents was that childhood vaccinations were associated with death! Once this association was understood, the Maori community was consulted to identify more appropriate symbols. The vaccination programme was reinvigorated when the owl graphic was replaced with images of woven baskets and rainbows, symbols of wisdom for Maori. This is a classic example of the need for medical writers to understand their target audience.

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# Teaching English for Medical Academic Purposes at the Faculty of Medicine in Belgrade, Serbia

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## Abstract

The Faculty of Medicine in Belgrade, Serbia, has a long tradition of learning and teaching English for Medical Academic Purposes (EMAP). EMAP is considered extremely important for our medical students' academic and professional life. Our EMAP syllabus is based on an integrated approach to the four language skills (reading, listening, speaking, and writing), although writing is emphasised as the most demanding and valuable skill.

**Keywords:** English, Medical students, Syllabus, Language skills, Writing

In many countries, English has become the *lingua franca* for science and technology; almost all important discoveries and most research results are now published exclusively in English. English has become so powerful that some linguists are seriously worried about the destiny of other, so-called *small* languages for specific purposes.<sup>1</sup> English for Medical Academic Purposes (EMAP) is an important and rather specific sub-group of English for Specific and Academic Purposes. EMAP has developed considerably over the last decade and is attracting increasing attention from the linguistic and medical fields.

EMAP is well developed in English-speaking countries, especially Great Britain, where there are many workshops and campaigns on the importance of English for Academic and Professional Purposes. Moreover, knowing EMAP is thought to help physicians make more precise diagnoses, establish better physician-patient communication, and reduce the number of clinical errors.<sup>2</sup> Thus, EMAP is important for health-care practitioners even in non-English-speaking countries.

## EMAP at the Faculty of Medicine in Belgrade, Serbia

The Faculty of Medicine in Belgrade, Serbia, has a long tradition of studying and teaching EMAP. Belgrade University focuses on helping its students to successfully manage the many academic and professional tasks they will face during their studies and professional life. At Belgrade University, EMAP is required during the first and second year of integrated academic studies, whereas it is an elective for students during their third, fourth, and fifth year of studies.

Medical students are required to take 60 hours of EMAP during their first two years. These classes are based on the textbook *English for Medical Academic Purposes*,<sup>3</sup> which is intended for students with upper-intermediate and advanced knowledge of English. The textbook familiarises students with authentic medical texts. It also introduces students to the most important medical topics and gives the students the opportunity to practice skills that they will need in their future jobs. Furthermore, the book covers a variety of scientific areas, including biology, biophysics, biochemistry, social medicine, medical ethics, anatomy, physiology, systems of organs, and types of diseases. Each topic is followed by discussion points, a glossary, vocabulary, and grammar exercises. There are also many additional readings used in class.

Most students will attend international conferences and symposia and will need to communicate and exchange ideas with their colleagues from abroad. They may even work in another country. Accordingly, the EMAP syllabus for the first- and second-year students bases the classes and materials on an integrated approach to the four language skills: reading, listening, speaking, and writing.<sup>4</sup> Although each class usually involves all four skills, reading is the main activity during the first two

years because students need to be able to read and understand English texts in various fields of medicine, using different strategies, and according to context.<sup>5</sup> Although listening is essential for following lectures, conferences, and formal meetings, in our classes, listening is mostly taught through interactions rather than by passively listening to monologues. Finally, the students often engage in role playing, where they act out physician–patient or physician–physician communication. This helps the students learn to interact with both patients and colleagues, the most important skill they need to give and receive medical information.

### A focus on writing

In both General English and English for Specific Purposes, writing is often neglected, and it is the subject that most mystifies students. It is also often considered the most difficult language skill. To make matters worse, students are often poorly motivated to complete writing tasks, and both teachers and students are easily intimidated by writing in class.

In General English, a student's writing reveals how much progress they have made, and it allows teachers to provide feedback and to monitor students and diagnose potential problems.<sup>6</sup> General English could therefore be called 'writing-for-learning'.<sup>7</sup> On the other hand, in English for Specific Purposes, and especially in English for Academic and Professional Purposes, writing should be perceived as 'writing-for-writing' because the goal is to be able to write whole texts in English during the students' education and their later professional life.<sup>8</sup>

For medical students, it is especially important that they are competent in writing English because their career may depend on international exchanges and presenting and publishing internationally. In this sense, writing can be perceived both as a *product* and as a *process*,<sup>4,9</sup> depending on the level at which it is practiced. Furthermore, unlike general academic writing, where essays are the principal genre and are written according to general academic conventions, in EMAP, writing is discipline-specific and influenced by medicine itself, borrowing its principles, strategies, and practices.<sup>10</sup> Furthermore, medical students should be able to write in several genres, such as research articles, submission letters, conference abstracts, and PhD theses.<sup>11</sup>

Although Serbian is the official language at Belgrade University, universities worldwide are becoming more bilingual,<sup>12</sup> so we need to ensure

that our students learn the necessary academic English writing skills even though they are not studying in an English-speaking country.

### The EMAP syllabus: years 1 and 2

Our goal for the required EMAP classes, taught during the first and second year of medical school, is that students perceive English writing as an essential product and that they therefore practice it as a basic skill. This includes gap-filling (filling in gaps in text with grammatically correct words), note-taking, and paragraph (re)construction.<sup>13</sup> At this level, writing tasks are strictly guided and teacher controlled. The students are introduced to medical genres and are later trained to reformulate and reconstruct texts. Because classes tend to be large (between 70 and 100 students), students usually work in teams of two or more for both pre-writing (writing drafts) and editing tasks. In addition, students have set writing tasks as homework, which teachers later comment on in detail. Summarising survey results is an advanced creative idea<sup>14</sup> that we employ in these large groups. Another is 'writing to real people', where students are asked to answer an advertisement, such as a job listing for a physician or internship position in a foreign hospital. We also employ some medical websites and even some popular television shows (Grey's Anatomy and House, MD) to provide students with realistic context and vocabulary. Naturally, writing at this stage depends largely on the students' general knowledge of English and their ability to properly acquire other elements of EMAP that have a higher priority at this level. In other words, writing skills tend to progress faster in groups that contain the most talented, hard-working, and motivated students.

### The EMAP syllabus: years 3–5

Medical students in their third, fourth, and fifth years can choose to learn EMAP on a more advanced level. Students who do so will be equipped with a much better and a more applied knowledge of writing in English. In addition to improving English writing skills, one of the main aims of the EMAP classes is to improve knowledge in clinical medicine so that the students are more able to profit from the professional literature, to exchange their knowledge with others, and to write scientific and professional papers for international symposia and conferences. Introducing the students to the language of teaching is also emphasised because many will eventually become

teachers. Of course, the language of science is emphasised because students will write scientific papers with their teachers, including articles for their own journal, *Medical Youth*. Moreover, starting with the third year, students must read articles from contemporary British and American medical journals, follow the latest achievements in medicine (and form their own opinion on them), and use the Internet to find information on a variety of topics. Students are also expected to make both oral presentations and write projects, both individually and in teams, and they learn how to complete written projects, compose research articles and abstracts, write case reports, curricula vitae, formal letters, posters, and slide presentations. Thus, the EMAP syllabus for the third, fourth, and fifth years is adapted to the students' real needs.

The class sizes during the third through fifth years are much smaller than in the first and second years, so there is more space for creativity and feedback. In this way, writing can be approached as a process, not only as a product. There are 30 hours of EMAP per level during these last three years, and they are based on teaching using all four language skills. For example, the third-year students listen to recordings, watch videos, discuss, and later write about medical emergencies, transplantation, histopathological autopsy, and drug abuse. At this level, students are also expected to write abstracts, essays, a case report, and a large project on a patient, all of which are then discussed and critiqued by the student's teacher and peers. During the fourth year, students discuss topics such as chronic non-infectious diseases, immunisation, internal medicine, neurology, psychoses, and addictions. History taking, presenting graphs and charts, and writing research papers are emphasised, although students are also expected to make a poster presentation and to write a project on a patient. Finally, during the fifth year, students work on topics such as infertility and contraception, childhood diseases, surgery and emergencies, and endoscopy. They also practise taking patient histories in several medical disciplines and must make a poster presentation.

### General principles

At each of these levels, students are first given clear instructions about writing in a particular genre.

Pre-writing and brainstorming are always done in class to help the students organise their ideas and learn the rules. Working in pairs and teams has proven to be very successful for such writing projects, as students join forces and knowledge. The result has been some truly enjoyable pieces of writing.

### Conclusions

The EMAP syllabus at the Faculty of Medicine in Belgrade, Serbia, is based on an integrated approach to the four language skills (reading, listening, speaking, and writing). The first two years, which are required for all students focus on listening, while the three elective years focus on writing is emphasised, the most demanding and valuable skill both academically and professionally. Students themselves find such a syllabus useful and practical and are fully aware that the syllabus has been considerably and consciously adapted to fit their real academic and professional needs.

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## Medical Writing Jumble #7

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 another word that will answer the

- riddle in the cartoon. *Hint: The answer is probably a pun.*
3. Use British English.

## Medical Writing Jumble # 7

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 two new words that will answer the riddle in the cartoon. *Hint: The answer is probably a pun.*
3. Use British English.

by Anuradha Alahari

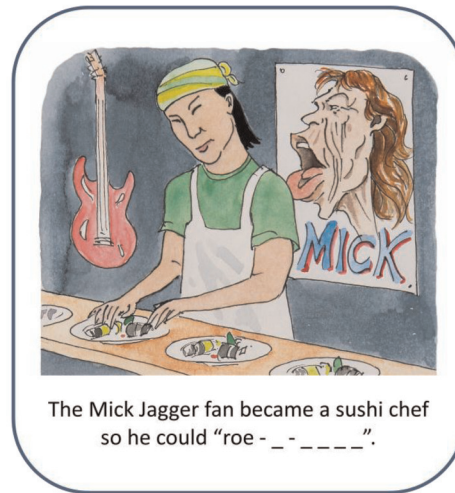
Illustration: Anders Holmqvist

BNERUM    ○ □ □ □ □ ○

BATTLE    □ □ □ ○ □ □

HOGUC    □ ○ □ □ □

PALMC    □ ○ □ □ □



The Mick Jagger fan became a sushi chef so he could "roe - \_ - \_ \_ \_".

Answer: roe - □ - □ □ □ □



# Regulatory medical writing in Switzerland

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## Abstract

Switzerland is practically unknown in the drug/medical device regulatory landscape despite being home to some of the world's biggest pharmaceutical firms. This article briefly describes the regulations governing clinical trials in Switzerland and cites examples of Swiss-specific regulatory documents.

**Keywords:** Switzerland, Swissmedic, Regulations, Medical writing

Switzerland is not a member of the European Union (EU) or the European Economic Area. This makes this small country a minor player in the global drug/medical device regulatory landscape. However, in this issue on Medical Writing Around the World, I would like to place Switzerland on the medical writing map. Switzerland is my place of residence for now and this is where I spent most of my medical writing years. Switzerland is home to some of the world's largest pharmaceutical companies. Switzerland also hosts the secretariats of the International Committee on Harmonization (ICH), the Council for International Organizations of Medical Sciences Working Group, the International Standard Organization, and the World Health Organization - institutions and organisations which play vital roles in clinical research and drug/device regulations.

## Swiss regulations and regulatory body

The Swiss drug regulatory body is called Swissmedic (<http://www.swissmedic.ch>). Because of the country's many languages, its website is in German, French, Italian - and English. There is a fourth official country language, Raeto-Romanisch, but this is seldom used in written form. This multilingual setting makes English practically the regulatory lingua franca and makes life easier for non-Swiss medical writers.

The legislations governing clinical research in Switzerland are embodied in the Swiss Federal

Law of Therapeutic Products (HMG) and the Ordinance on Clinical Trials (VKlin),<sup>1</sup> roughly equivalent to the EU directives and the EU guidelines, respectively. HMG and VKlin require that clinical trials follow ICH E6 Guidelines on Good Clinical Practice. However, other ICH guidelines are not specifically mentioned.

Unfortunately, VKlin contains a lot of ambiguities that make life difficult for clinical researchers. It does not, for example, make a distinction between interventional trials and non-interventional or observational studies, so that both types of studies are subject to the same regulations. In addition, it does not address some aspects on medical devices, data protection, and biological samples.

## The GSASA dossier and the succinct statement

Working in Switzerland for the last 7 years, I have had the pleasure of writing Swiss-specific regulatory documents. The GSASA (*Gesellschaft Schweizerischer Amts- and Spitalapotheker*) Questionnaire for the Information of Hospital Pharmacist about Proprietary Drugs is one of them. The GSASA dossier is structured like a very much abbreviated Common Technical Document (CTD) of about 100 pages. Because the source documents are mainly in English, the GSASA dossier is usually written in English and then translated to German and French. The appendices include a copy of the drug packaging, the Swissmedic-approved summary of product characteristics in German and French, and the package inserts in German, French, and Italian.

The succinct statement (*gekürzte Fachinformation* in German) is probably the shortest and most concise regulatory document I have ever written. Varying from a quarter to a full page, it still covers all the essentials of therapeutic product information, from the formulation and posology, to contraindications, interactions, and packaging, and thus really lives up to its name. The trick in writing succinct statements is NOT using full sentences and using

as many commonly known abbreviations without defining them.

## The PEB protocol

PEB stands for *Praxiserfahrungsbericht*, a special type of clinical research project that is as observational as it can get but cannot be called an observational study. Translated by Swissmedic as ‘monitoring of use report’, a PEB documents data on therapeutic efficacy or safety within the framework of clinical practice.<sup>2</sup> I have seen other translations as a ‘field report’ or ‘clinical survey’.

Because VKlin does not distinguish between interventional and non-interventional studies, all studies have to go through the process of Swissmedic and independent ethics committee notification, approval, and reporting – except the PEB. For the PEB, only ethics notification is required, and informed consent is usually optional. A study protocol is needed, but a very short and abbreviated one at that. There is a catch though, as sponsors are very careful about the terms used in a PEB protocol, lest their project be elevated to observational study status. For example, the terms ‘study’, ‘treatments’, ‘visits’, ‘schedule’, and ‘follow-up’ may be deemed inappropriate for a PEB as they may connote intervention. Ever written a protocol without using these words?

## The clinical study report Swiss style

The clinical study report (CSR) is the bread-and-butter of many regulatory medical writers. Yet, writing a CSR as we know it, for Swiss trials, is not must.

I remember back in 2007, one of my very first freelance projects was to write a publication on a clinical trial. I asked for the CSR, and the client’s response was ‘the publication will be the report.’ To understand this rather cryptic statement without belying my ignorance, I researched a little deeper into the Swiss regulations, and this was what I found:

*Independently of whether the trial is a commercial or non-commercial one, and whether it ends normally or is prematurely discontinued, a final report must*

*always be submitted to Swissmedic. The time limit laid down in VKlin is 6 months following the end of the study[...] Swissmedic does not, however, stipulate any binding format for the report. The final report must nevertheless be in line with ICH GCP requirements (although it is not mandatory for it to be in ICH E3 format) and in accordance with current medical and scientific standards.<sup>2</sup>*

I must say many Swiss sponsors still go for the ICH E3-compliant report, especially if a trial is planned to be used in a marketing authorisation application somewhere. But I also know many who opt for the shortcut of submitting a publication *in lieu* of a CSR.

## Changes in 2013

At the time of writing, this is where Switzerland stands in terms drug and medical device regulations. However, a new law is expected to take effect in 2013. The Law on Human Research<sup>3</sup> will supersede the VKlin and redefine the roles and duties of the local independent ethics committee and Swissmedic in regulating clinical trials. The distinctions between different studies and therapeutic products will be clearer and critical issues such as research on embryos and cadavers will be addressed. How this will affect regulatory medical writing is hard to say. I will keep you posted!

## Disclaimer

The views and opinions expressed herein are those of the author alone and do not necessarily represent those of Clinipace Worldwide.

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# Medical writing in the Russian Federation: Promises and pitfalls

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## Abstract

More and more clinical studies are taking place in Russia, making it an attractive market for medical writing. In 2011, the Ministry of Healthcare of the Russian Federation approved over 550 new clinical studies of all types, a 16% increase over the previous year. Currently, the Russian government is making huge investments in its infrastructure for drug development. Demand for medical writing is high in the rapidly growing sector of biotechnology in Russia. Because there are some differences in local requirements compared to the EU or USA, many specific regulatory aspects have to be considered by medical writers in Russia.

**Keywords:** Russia, Medical writing, Clinical trials, Regulatory requirements

More and more clinical studies are taking place in Russia, making it an attractive market for medical writing. In 2011, the Ministry of Healthcare of the Russian Federation (MoH) approved over 550 new clinical studies of all types, a 16% increase over the previous year, while in 2012 approvals of new studies for the year increased by 20%. Over 70% of all approved studies in Russia are either multinational studies or local studies sponsored by foreign companies.<sup>1</sup>

## Key Russian regulatory documents

Russian Federal Law #61 on 'On Circulation of Medicines', which came into force on 12 April 2010, controls all processes related to drug circulation, namely, drug manufacturing, nonclinical and clinical development, monitoring of drug safety, and state control and registration of a drug. Another important regulatory document providing guidance on conducting clinical studies in Russia is the National Standard of the Russian Federation, GOST - 52379-2005, which is an essentially translated version of International Conference on Harmonisation (ICH) Good Clinical Practice (GCP). It stipulates that all clinical studies in the

Russian Federation must be performed in accordance with GCP.<sup>2</sup>

When the clinical part of the drug development has been successfully completed in a study population omitting Russian patients, Federal Law #61 stipulates that a controlled, evidence-based confirmative study must be performed in Russia as part of the drug registration process. To justify this requirement, Russian lawmakers point to differences in the characteristics of the country's population and imperfections in the legislation for the acceptance of foreign studies. Therefore, a phase III study must be conducted in Russia, and this is not considered a violation of GCP. However, no specific national guidelines on the minimum acceptable number of patients or the choice of primary endpoints have been developed.

Therefore, medical writers must study all available ICH general guidelines on study design and specific guidelines issued by regulatory agencies (e.g. FDA, EMA, and Health Canada) and make a scientific judgement on which guideline is applicable to a particular study. After that, the medical writer must work closely with statisticians to create study designs that will meet the study objectives within the study's budget. Validated software for sample size calculation and publically available study results must be taken into consideration to determine the sample size. In our experience, and according to verbal communication with experts from regulatory authorities in Russia, it is generally accepted that objective clinical criteria are preferred over pharmacodynamic parameters as primary endpoints, although no official guidance has been issued on this matter.

Federal Law #61 also prohibits phase I clinical studies involving healthy volunteers with 'medicinal products manufactured outside the Russian Federation'.<sup>3</sup> Medical writers therefore have to think about alternate study designs involving patients instead of healthy volunteers as is the case for phase I studies with certain types of drugs, like antipsychotics, or anti-tumour agents.

## Bioequivalence studies

Since the Russian MoH approved the guidance on conducting bioequivalence studies in 2008, the number of these studies conducted in Russia has increased almost four fold, from 85 in 2011 to 300 in 2012.<sup>1</sup> According to Federal Law #61, bioequivalence studies are performed to assess the extent and rate of absorption of the active substance of investigational drug in comparison with that of a drug registered in the State Drug Registry.<sup>3</sup> For drugs possessing systemic effects after extravascular administration (e.g. oral, topical, or rectal), pharmacokinetic equivalence between a generic and registered drug is a guarantee of the drug's therapeutic equivalence and similar safety profile. The requirements for bioequivalence issued by the MoH differ from those issued by other regulatory agencies (e.g. EMA, FDA, and Health Canada) in the following aspects:

- Russian bioequivalence studies may only be performed in people aged 18–45 years, and the minimum number of volunteers should be at least 18.
- Medicines administered by the parenteral route, via inhalation, and by the enteral route as solutions need to undergo prior therapeutic equivalence studies.
- The washout period between treatment periods has to be at least six half-lives of the drug substance. The acceptable interval between blood samplings is at least four half-lives of the drug substance.<sup>4</sup> According to the WHO, the minimum required washout period has to be five half-lives of the drug substance or at least 7 days.<sup>5</sup> Health Canada requires this period to be 10 half-lives but not more than 4 weeks.<sup>6</sup>

When a foreign sponsor wants to conduct a bioequivalence study in Russia and provides a protocol written in accordance with the European or the American guidelines, local medical writers must adapt the protocol to the national legislation and requirements. In addition, attention should be given to the nonclinical comparative toxicity studies of the generic and original drug. These studies are generally demanded by the regulatory agency and should be described in the investigator's brochure and protocol. A renewal of the guidance on bioequivalence is expected, but the impact of the proposed changes cannot be assessed because the draft version has not been made publically available.

Another problematic area is writing protocols on biosimilar drugs. Currently, many companies are developing such drugs and are interested in developing them in Russia. Again, the first challenge is

study design and medical writing for such studies because there is no national guidance on pre-clinical or clinical development programs for biologicals. Moreover, current Russian legislation does not give a definition of a biosimilar drug.<sup>7</sup> Medical writing on biosimilars is complicated and requires multiparty knowledge. Because there are no specific national guidelines on biosimilars in Russia, medical writers have been referring to EMA's general and product-specific guidelines like 'Guideline on similar biological medicinal products containing monoclonal antibodies' for development of clinical and preclinical programs. The EMA's guidelines are quite precise and stringent, so compliance with these provides a better chance of approval of a drug in Russia. Currently, several clinical studies of biosimilars and biobetters from local and foreign pharmaceutical companies have been approved by the Russian MoH and are on-going.

While planning a clinical study to show comparability of pharmacodynamics and pharmacokinetics of a biosimilar and the original drug, the following aspects must be considered:

- Choice of the study population: healthy volunteers or patients?
- Choice of pharmacokinetic parameters of interest
- Availability of relevant pharmacodynamic markers of efficacy
- Determination of a required sample size
- Study cost, including the cost of the original drug

To design a pivotal study to show the similarity of a biosimilar and the original drug, the availability of relevant pharmacodynamic markers of efficacy need to be considered as stated in the EMA's guideline.

## Orphan drugs

Absence of orphan drug status is another problem that we face in Russia during the drug development process. The terms of orphan disease and orphan status were first defined in Russian legislation in 2011. However, no initiatives have yet been taken to promote such product discovery by Russian companies. Developing an orphan drug in Russia is challenging because the number of trial participants cannot be lowered. Statistically, there are no exceptions for an orphan drug study, and as many patients as a regular study must be enrolled.

## Expert advice from regulatory authorities in Russia

Another problem we face when developing clinical study programs is the lack of scientific advice from

regulatory authorities in Russia. To obtain the opinions of regulatory experts, sponsors and contract research organisations often have to resort to unofficial expert recommendations from the MoH. This expert opinion obtained in this manner may not be reliable and is not supported by any written documents. In addition, different experts may have different point of views on the same issues.

To obtain the official opinion of regulatory authorities in Russia one must apply for approval of a clinical study that takes 35 working days. In case of refusal of permission to conduct a clinical study, the authorities issue a letter with recommendations for modifications in the study proposal. But even after all the recommendations are accepted, the MoH is likely to issue a second list of requirements, with no guarantee of acceptance.

Unlike Russia, scientific advice is a routine practice in the USA and Europe and features such as the study design, primary endpoints, choice of control group can be disputed and a modified protocol draft can be submitted for review by the experts. When the expert joins the discussions, the sponsor can defend its point of view and provide evidence that the authorities had misunderstood or were wrong. In Russia, this situation is difficult to imagine outside an arbitration court.

### Ongoing improvements to Russian regulatory requirements and infrastructure

Russia's Federal Antimonopoly Service requires that amendments to the Law #61 be introduced to simplify the procedure for registering orphan drugs. Changes to be implemented in 2013 include introducing an expedited registration procedure for orphan drugs and first-to-market generics. For orphan drugs, data obtained from pre-clinical and clinical studies conducted abroad according to Good Laboratory Practice and ICH-GCP will be acceptable in Russia.

Currently, the Russian government is investing heavily in its infrastructure for drug development. The demand for medical writers is substantial because the biotechnology sector is growing rapidly. Because Russian universities do not offer courses in medical writing, medical writers usually are medical doctors or those who have advanced degrees in

medicine or natural sciences. Typically, successful medical writers have experience in nonclinical and clinical drug development and have trained abroad in medical writing. These professionals can only gain experience by working in pharmaceutical companies or contract research organisations and, thus, are considered an extremely valuable workforce.

### Conclusion

Although there are many formal barriers to conducting clinical studies in Russia, current governmental legislation has increased the demand for clinical studies conducted in Russia. Therefore, we are looking forward to improvements in the regulations and are working to elevate our medical writing to the highest international standards.

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# Report on the EMA Workshop on clinical trial data and transparency

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## Abstract

Access to patient data gathered in clinical trials is a highly controversial and complex issue that needs to balance three aspects: the public right to transparency regarding data used to approve new medicines, protection of the data privacy rights of patients involved in the studies, and commercial confidentiality concerns of the trial sponsors. In response to an increasing number of formal complaints about restrictive practices in publicising clinical data, the European Medicines Agency has started an initiative to enable access to patient-level study data. In November 2012, they organised a workshop to bring the stakeholders together to discuss and establish the way forward.

**Keywords:** Clinical trials, Data access, European Medicines Agency, Data protection

In November 2012, the European Medicines Agency (EMA) hosted a workshop to discuss how data collected during clinical trials should be made available to the public. The Agency clearly stated at the beginning of the workshop that it is committed to making patient-level clinical trial data publically available following the decision on marketing authorisation, irrespective of whether the decision is positive or negative, with the goal of increasing transparency and thus confidence in the system for approving new medicines in Europe. The aim of the EMA workshop was to create a dialogue among representatives from health agencies, data protection institutions, the pharmaceutical industry, academia, the press, physicians, patient groups, and other stakeholders on *how* public access to clinical trial data can be implemented.

## What led up to the workshop

Discussions on the right of access to clinical trial data were initially triggered by complaints to the

Office of the European Ombudsman about the EMA refusing to grant access to documents in the possession of the Agency. Four main reasons were given for the EMA's refusal:

- TRIPS agreement<sup>1</sup>
- Disproportionate effort required to prepare and release documents for publication and disclosure
- Data protection issues
- Commercial interest prevailing unless outweighed by public interest

The Agency was unable to convincingly show that the first three arguments were valid, and they also failed to establish the existence of a specific commercial interest that would be undermined by disclosure of the data concerned. Therefore, the EMA agreed to grant access to the documentation.

In his introduction Gerhard Grill (Director of the of the European Ombudsman office) pointed out that the Treaty of Lisbon has now extended the right of public access to information to all EU institutions, including the Medicines Agency. The treaty stipulates that the widest possible access should be granted, that exceptions should be interpreted strictly, and that justification must be provided. (As a side note, legal action against the EMA has recently been taken by some of the companies involved.)

## Differing perceptions of the evaluation of clinical trial data

During the meeting, it became clear that there is considerable discrepancy between how academic research institutions, the press, and the pharmaceutical industry perceive the evaluation of clinical trial data used in the marketing authorisation process. Although the meeting was set up as a workshop, in some aspects, it resembled a public hearing: panel members from academia (Peter Göttsche) and the press (Virginia Barbour and Ben Goldacre) presented the prosecution

case that industry is withholding and manipulating clinical data in order to coerce the regulators into approving new medicines, while industry representatives (Susan Forda and Neil Wier) filled the role of defendants and a patient representative (François Houyez) acted as expert witness.

Peter Gøtzsche, Director of the Nordic Cochrane Centre and cofounder of Cochrane Collaboration, kicked off the discussion. He stated that because the pharmaceutical industry is acting as judge of its own data collected in clinical trials this results in bias in the data analysis. He believes that access to both results and raw data should be available to everyone and anyone for re-analysis. Even when access is currently granted to documents in possession of the Agency, it is not available in electronic and searchable form. As the data are provided freely by patients, it belongs to all of us and industry must be obliged to provide access so that it can easily be re-evaluated by others. Gøtzsche propounded that the third biggest cause of death in USA is the harmful effects of drugs and that this is partly because we do not know what harm many drugs can cause because data analysis is inadequate. He demanded open access to clinical data for everybody and publishing of data on a public website.

Industry was represented on the panel by Susan Forda, Chair of the European Federation of Pharmaceutical Industries and Association (EFPIA) Scientific, Regulatory Manufacturing Policy Committee, and Neil Wier, who sits on the EFPIA's Research Directors Group and is also Senior Vice President of Discovery at UCB Pharma. Wier pointed out that the pharmaceutical industry is now looking to develop personalised medicines and so future clinical trials will include patients' genetic information, increasing data confidentiality issues. He also pointed out that new products must yield an appropriate commercial return on investment. Forda agreed that public access to clinical data is important, but this should be handled on a case-by-case basis with consideration of intellectual property rights and personal data. She was not in favour of making clinical data available for products where applications are withdrawn or product development is cancelled. In her view, an appropriate and balanced approach to data access is required to protect the legitimate interest of the trial sponsors.

Ben Goldacre gave a typically emotive speech on how public engagement in clinical research in his view can only be positive and that having many eyes perform assessment of safety and efficacy of medicines would be beneficial. He called for industry to meet all requests to release data on clinical trials, which should be publicly available to academia and

competitors alike, with a public record of all such requests. He cited a UK general practitioners research database that enables doctors to access the full health records of 3 million patients as a valuable tool for physicians. He does not see patient data protection issues as an insurmountable hurdle. He also called for full details of study protocols to be publically posted, as there is not enough detail in current trial registries. He pointed out that not all studies on medicines are posted on the clinical trial databases and said that all trials for all drugs should be made public.

Not surprisingly, Chief Editor of PLoS Medicine, Virginia Barbour, stated that clinical research data should be published to ensure it is reliable and reproducible. Suppression of research results should be combatted and technology used to enable transparency. Subject data that support a successful marketing authorisation application should be made publicly available at the time the authorisation is granted and in the longer term data from unsuccessful applications should also be made available. To enable reproducibility, the data and the analysis must be made available in such a way that others can reassess the data, so data must be stored in a readily accessible format, with datasets and links to specific protocols. Anonymisation standards are required to protect the personal data of trial participants. She also thinks that funding and incentives are required to enable data access, which could be in a separate repository or an independent web-portal.

Interestingly, François Houyez, representing patient organisations, described his experience of collaboration between patient groups and the EMA as being very open and positive. He thought that FDA hearings are a good model for enabling transparency in the decision-making process for drug approval and that something similar might be worth considering in Europe. With regard to data privacy, he perceived that while some patients may be willing to forgo data privacy rules if it can benefit future generations (e.g. for rare diseases in children), they are greatly concerned about access to individual data in areas like transmittable diseases or those with social stigma (e.g. HIV patients). He does not support data access for everyone, because, in his view, uncontrolled reanalysis of data can also lead to confusion and undue concern, citing the situation with research on genetically modified organisms, where contradictory evaluation of data has resulted in less rather than more transparency about the real risks. Houyez suggested that third parties wishing to have access to data must be required to state the purpose and need for access, to describe the analytical methods to be used, demonstrate the necessary expertise to

perform such analyses, and ensure that the data will be adequately protected. Results of such reanalysis should then be disclosed to the EMA before being made public. In his view, if clinical data are to be shared with any third parties, this needs to be clearly stated in the informed consent form provided to the patients.

With regard to adequate data protection of subjects involved in clinical trials, Giovanni Buttarelli, Assistant European Data Protection Supervisor, pointed out that data protection is not incompatible with full transparency, but the fundamental rights of patients must be respected. The intention is to allow access to full data sets for interested parties, but what is covered by the notion of ‘public interest’ in this context must be determined, and as a general rule, sensitive data on individual patients may not be published. If access is restricted to selected groups or individuals via a platform, it is critical to identify who has access and when, as well as who controls access and their level of competency, i.e. would the EMA be the only competent body to decide on data access or should someone else be involved?

### **Is there a risk of bad analysis of data?**

Interestingly, the only consensus within the panel was in response to the question asked by Chairman Mark Walport ‘*Is there a risk of bad analysis of data?*’ All agreed that there is, although Gøtzsche commented that ‘the argument about bad analysis is a bit amusing, as the situation cannot be worse than it is today where the only people who have seen all the data are the people working in the company that is going to earn a lot of money from these products’. Weir responded that clinical experts are almost always involved in the evaluation of the data; however, Gøtzsche denied this, stating, ‘Clinical investigators are never allowed to see all the data, if they ask for the raw data they are turned down every time’.

### **What is in the public interest as far as disclosure of clinical data is concerned?**

Responding to the question, ‘*What is in the public interest as far as disclosure of clinical data is concerned?*’ Houyez sympathised with groups who express an interest to see the patient data but pointed out there is an ethical problem if you do not know who has access to the data. In his view patients ‘would feel safer if those who do the secondary analysis or look at the data are clearly identified and have the skills and come with a method to analyse the data’. He suggested that an independent

body could review the request and decide on whether to grant access to the data. Barbour replied that flaws in the patient consent forms cause problems with access to data and this can be avoided using correct wording in the form. She did not agree that who can access the data should be pre-specified, stating, ‘it is much better to have many eyes on data than few eyes’.

In Goldacre’s view, the trust placed by patients in the trial sponsor is often misplaced since ‘the main analyses conducted by the trialists themselves are often flawed’. He remarked that ‘we know that people very commonly, for example, switch their primary outcome between protocol and analysis without even adequately declaring that’ and added ‘we know that the results of clinical trials are often not disclosed to doctors and patients’. On the issue that patients should prospectively consent before sharing the clinical data, he pointed out that this would prevent access to data from trials that have already been conducted and delay transparency for at least 5 years. In his view, ‘the problem of bad analysis is best solved by requiring fully published protocols and analytic strategies from everybody before they start’. With regard to peer review of secondary analyses, he did not think that journals are the best place to publish clinical trials. Secondary analysis should, however, only be regarded as evaluable if the analysis plan is published beforehand.

### **How are we going to minimise the potential harm to a population from data being published that is wrong or misinterpreted?**

The next question, posed by Mark Walport, was ‘*How are we going to minimise the potential harm to a population from data being published that is wrong or misinterpreted?*’

According to Gøtzsche, ‘primary publications are by and large pretty unreliable, and have cost the lives of hundreds of thousands of people... We need to be much more open about this – it’s very simple’. Forda suggested that a ‘Good Practice of Analysis’ should be implemented along with a public forum where the analysis plan can be published and reviewed by others before the analysis is conducted, as this would help to minimise harm. She recommended that third parties who want to do analyses approach the companies directly for data and publicly post this request. Ben Goldacre remarked, ‘we have an on-going reality, right now, of bad quality analyses by industry and academics of their own data’. He believes



that fixing this requires public posting of protocols and public sharing of data so that everybody can cross-check everybody else's work. 'We fix this by making sure that primary and secondary data analyses are both conducted as transparently and properly as possible'. In Barbour's view 'by sharing data and by sharing analyses, people do much smarter things than the original investigators ever thought of, and that is the democratisation of data that I think we want to see'.

Houyez commented that if his organisation wishes to reanalyse data then they approach the person conducting the study and confront them before going public with the data, and he thinks this is a model that could be applied. The EMA will soon have public hearings on safety and therapeutic benefits of product, which would provide a public arena for different results to be confronted. He noted the risks of confusion among the public and miscommunication as well as disclosure of information that can identify patients. For him, it is important to discuss on a case-by-case basis which data-sets can be made public. 'The problem is that when privacy is breached, it is done and then you cannot recall the information – it is released and any harm which is done is done'. Mark Walport agreed that any data released must maximise the privacy of the trial participants and Giovanni Buttarelli commented that a new data protection package is soon to be released in the EU, although it will keep the current definition of what is personal data.

### Practical suggestions as to how to share data

Forda agreed that, in principle, the data can be made available but warned that inappropriate analysis could lead to media scare stories that lead doctors to stop prescribing beneficial products (think Measles, Mumps, Rubella vaccine scare). 'If we're going to have additional analyses, these should be somehow prospectively defined and they should be reviewed, and people should have an opportunity to comment'. Gøtzsche, though, could not see immense practical problems with making data available and was not in favour of requiring a

declaration of the purpose of the reanalysis. Goldacre repeated his previous comment, 'there is currently a serious problem of misleading analyses already by industry on their own trials, so this is an existing problem that needs to be addressed'. At worst, he would be happy with a two-tier system where the public can access data held by the EMA and any newer data can be requested from the company. Everybody's requests and all rejections should be posted in public immediately.

Barbour suggested that incentives are required for drug companies to provide data access and emphasised that the data must be made available in an open-access format so that it is readable using automated systems, otherwise we will not be much further forward. Houyez commented that there are already opportunities to invite additional experts to EMA meetings when applications are being reviewed, so this could be an opportunity to invite external parties to review the data as well. Neil Weir's final comment was the need to consider who bears the costs of making data publicly accessible, as the translation of data into searchable form is not trivial and it is not a trivial cost.

Concluding the workshop, Hans-Georg Eichler (EMA) invited stakeholders to collaborate with the Agency to develop policies in five different areas:

- Protecting patient confidentiality
- Clinical-trial data formats
- Rules of engagement
- Good analysis practice
- Legal aspects

The EMA has committed to publish a draft policy on data access for public consultation by 30 June 2013 and to have the final version implemented by January 2014 – so watch this space!

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# Potential implications of wider data transparency in medical communications

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## Abstract

The current medical communication environment is characterised by growing calls for increased data transparency. There are ongoing concerns about the selective publication of trial results and the potential impact on use of medicines by prescribers and patients in both Europe and the US. This article outlines some of the background to current developments and considers the potential impact on those working in the field of medical communications.

**Keywords:** Publication guidelines, Publishing standards, Information dissemination, Publication bias

The medical communication environment will be strongly influenced by ongoing campaigns to ensure that individuals and organisations are transparent and maintain ethical practices surrounding the publication of data.<sup>1</sup> Also, the recent proposals for revised EU legal frameworks for clinical trials<sup>2</sup> and medical devices/*in vitro* diagnostics<sup>3</sup> are supportive of wider data transparency.

## The availability and use of data

The results of clinical trials are acknowledged as having an important influence on medical practice, but the growing impact of such information in additional areas needs to be considered. For example, health technology assessment agencies have considerable interest in detailed trial information and so there are implications for reimbursement of medicines and therefore patient access to therapies.

Incomplete information or the selective reporting of data can lead to inappropriate conclusions being made about results, which has implications for any decisions based on those conclusions. The current discussions concerning data transparency have been prompted by a number of published examples where there appeared to be weaknesses with respect

to data transparency or possible selective reporting bias.<sup>4-7</sup> At the same time, there are concerns that the publication of large amounts of data may lead to a 'data overload', potentially increasing the risk of certain data being erroneously analysed outside of its scientific context.

Cases have been identified where it might have been possible to reach different conclusions regarding a particular drug, depending on whether only published information was used as the source or a full range of data including unpublished sources was accessible. In the UK such information could have potentially altered opinions about antidepressants by the Committee on Safety of Medicines and the National Institute for Health and Care Excellence.<sup>4</sup> In Germany, a perceived lack of data transparency affected an evaluation of an antidepressant by the Institute for Quality and Economic Efficiency in Health Care.<sup>5</sup> In the US, a study of 164 efficacy trials for 33 approved new drug applications for new molecular entities from 2001 to 2002 noted discrepancies between trial information reviewed by the FDA and information in published trials.<sup>6</sup> The authors of this study stated that selective reporting undermined the integrity of the evidence concerning drugs and that it deprived clinicians of accurate data upon which they could make appropriate prescribing decisions. They also expressed concern that publication bias was masking the distinction between effective and ineffective therapies.

Consequently, there has been growing interest from independent researchers in improving access to unpublished clinical data. The EMA has been the recipient of a number of requests from researchers seeking access to company product data not present in the public domain but available to regulators. In April 2012, EMA reviewers published their updated views on data transparency, suggesting that trial sponsors and regulators did not have a 'monopoly on analysing trial results' and that

clinical trial data should not *per se* be considered as commercial confidential information.<sup>7</sup> However, the EMA reviewers remained concerned about the uncontrolled mass release of raw data, since this could lead to reports based on misleading results, which might result in unfounded health scares and even lead to patients discontinuing their treatments.<sup>7</sup> They recommended dialogue with other stakeholders to ensure that trial data were made available in formats that would be in the best interest to the general public and all those involved in the conduct of clinical trials.<sup>7</sup> In November 2012, an EMA workshop identified five key areas (protecting patient confidentiality, clinical trial data formats, rules of engagement, good analysis practice, and legal aspects) in which regulators would work with stakeholders to move towards proactive data disclosure.<sup>8</sup>

### Possible implications of increased data transparency

Future requirements are anticipated to result in a greater amount of trial data being made available through publications. In this more open environment, journals will have to consider what additional information is of interest to readers. For example, as sponsors assess data generated across trials, they may have legitimate reasons to conduct and seek to publish the results of *post hoc* subgroup analyses on certain patient populations. Journals will need to reassess their policies on accepting such manuscripts, which may include fulfilling the basic criteria for expert involvement and steering committees. At present, journal preference tends to be for primary trial information, involving collection of original data with assessment criteria prospectively defined. As *post hoc* studies might examine subgroups not prespecified at the time of the original trials, journals may view positive results less favourably and suspect them of being influenced by a post-trial hypothesis. It is worth noting that the extent to which such analyses will be possible will depend on the outcome of the ongoing revision of the EU legal framework for data protection.<sup>9</sup> The European Commission's current proposals set out to update and modernise the principles enshrined in the 1995 Data Protection Directive to guarantee privacy rights in the future.<sup>10</sup> The proposals are now with the European Parliament and EU Member States for further discussion.<sup>10</sup> They are set to take effect two years after they have been adopted and may have relevance due to reconsideration of informed consent requirements.

New guidelines and recommendations that emerge from initiatives focusing on clinical trial

data and transparency will have a noticeable impact on medical writers, as the scope of their work will change. They are likely to be involved in preparing more extensive trial information for publication than is available at present from accessible sources. The expanded scope of work will need to be accounted for in terms of budgets, resourcing, timelines, and qualifications. In addition, medical writers' training regarding guidelines and standards will need to be kept up to date. Completion of training will need to be formally documented and records maintained so that they can be independently verified.

### Conclusion

Within the healthcare field, there are different interpretations of what meaningful data transparency entails and the processes for making detailed information available to interested parties remain to be defined. Furthermore, wider accessibility to data will need to be managed with the intended audience in mind so that the information can be disseminated in a format that can be understood and used by the intended audience. Although not all details are in place yet, it is important to start considering the implications of wider data transparency as it will profoundly influence the future medical communications environment.

### Disclaimer

This is the original research of the authors and there are no financial and other relationships of a declarable nature for this article.

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## The flat world of medicine

Writing this issue's Tool Box, I began with the phrase 'The world is flat, even in medical writing.' Then I paused and asked myself – would the EMWA readership be privy to this metaphor borrowed from Thomas Friedman's bestseller published 7 years ago? The book has become an icon, and 'flat world' a favourite buzzword in commerce and technology. But how widespread is the use of this phrase in other fields? In medicine? I did a quick search in good old PubMed and here is what I found:

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Well, it seems that the global playing field in medicine has also been flattened. But what about in medical writing?

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# The need for registration of preclinical studies

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## Abstract

In contrast to controlled clinical trials, findings of preclinical studies are not available. The road from laboratory discovery to usable therapy is still long and windy. Many preclinical studies have not been replicated by the pharmaceutical sector, the costs of clinical trials are rising, and many trials fail due to insufficient animal model evidence. To improve cross-talk between scientists and to develop rational strategies to move therapies into the clinic, scientists are going to be invited to register their experiments. The proposed registration and availability of preclinical research findings, published in the June 2012 issue of *Nature Biotechnology* by Kimmelman and Anderson, would facilitate a clinical translation process that would benefit the scientific community. In particular, to support clinical trial development programs, they propose the design and registration of controlled *in vivo* animal studies testing toxicity, toxicology, and disease response with a similar structure to controlled clinical trials.

**Keywords:** Preclinical research, Clinical trials, Translational research, Registration

In recent years, the registration of clinical trials and deposition of controlled trial results, even those that are negative and inconclusive, has become a must.<sup>1</sup> Preclinical study results, by contrast, are not deposited or registered.

We all know how hard it is to publish negative results from scientific studies. Especially in the field of cancer therapeutics, the vast majority of false findings are seen as invalid because it is difficult to translate them into valuable therapies to cure patients. 'Messy' results of fascinating and highly promising laboratory studies have a long road from bench to bedside.

Nowadays, it is almost impossible to obtain a grant from bodies such as the German Research Foundation, the German Federal Institute for Drugs and Medical Devices, or the National

Institutes of Health based on pure basic science without a translational angle. Although early reports in the peer-reviewed literature are tentative and their findings may later be found to be incorrect or even spectacularly wrong, they are potentially valuable and useful.

## The proposal to register preclinical trials and report their results

A correspondence article published by Kimmelman and Anderson in the June 2012 issue of *Nature Biotechnology* urged 'funding agencies, journals, foundations and academic institutions to devise policies that promote registration and reporting of preclinical results' with the aim of supporting clinical trials.<sup>2</sup> In particular, the authors suggested limiting their proposal to controlled *in vivo* animal studies directed at testing toxicity/toxicology and disease response since these studies have a similar structure to controlled clinical trials.<sup>2</sup> They pointed out that registering and reporting of preclinical studies would partly decrease concerns about human protection and inefficiency in the clinical research enterprise by minimising failures in translating findings from basic research into new medical therapies. If registration and public deposition of preclinical results ('good disclosure practice') were canonised as ethical principles, good disclosure practice 'may respect the altruism of human subjects by helping ensure that preclinical studies see the light of day'.<sup>2</sup> Since publication is the first step in a process where findings from isolated settings are taken up and applied by practitioners, nonpublication may evoke 'concerns encountered by human volunteers losing their moral justification'.<sup>2</sup>

Further, Kimmelman and Anderson anticipate the protection of downstream users – patients and institutions – having particular interests in free access to findings. Research communities benefit greatly from the free flow of scientific information, and a lack of and delay in timely evaluation of

preclinical observations can hamper researchers' ability to gain valuable insight from failures in clinical development. 'In the absence of a good disclosure practice, researchers coming forward with unfavorable findings are at a reputational and funding disadvantage relative to those withholding them', leading to biased reporting.<sup>2</sup> Biased reporting may potentially harm patients by mispresenting treatment recommendations. In addition, biased reporting may prevent healthcare providers from assigning resources according to the best published evidence.<sup>2</sup>

### **Disclosure of preclinical trial data should help reduce publication bias**

Disclosure of preclinical trial data may enhance institutional access to evidence, thereby decreasing the high rates of attrition during human testing. Only 11% of new products entering phase 1 clinical trials are licensed; for cancer and neurological disorders, the figures are closer to 5 and 8%, respectively.<sup>3</sup> Longitudinal studies have demonstrated that most highly promising preclinical findings resist the translation process. These failures should provoke a hunt for strategies that help ensure that volunteers are not needlessly enrolled in trials and that 'scarce research resources are not squandered'.<sup>2</sup>

Unfortunately, unpublished findings cannot contribute to the distillation of knowledge. If the unpublished data differ substantially from published work, conclusions may not reflect adequately the underlying biological effects being described.<sup>3</sup> Using Egger regression and trim-and-fill analysis, Sena and colleagues<sup>4</sup> clearly showed that publication bias was highly prevalent in animal studies of stroke. Their trim-and-fill analysis suggested that publication bias may account for around one-third of the efficacy reported in systematic reviews, with reported efficacy falling from 31.3 to 23.8% after adjustment for publication bias. Selective publication spoils appraisal of promise by limiting the ability of decision makers to assess the totality of preclinical evidence. This can lead to overestimation of treatment effects, as indicated by recent studies which demonstrated inflation of effect sizes by 30% due to publication bias.<sup>4</sup> It is likely that publication bias has an important impact in other animal disease models too.

Further, if the dissemination of information from animal experiments is not shared within the broader research community, the burdens imposed on animals in preclinical experiments are wasted, raising ethical concerns about animal welfare.<sup>2</sup>

The reporting of animal findings also enables secondary analyses. Retrospective analysis of pooled preclinical data may address many questions, thus advancing knowledge about translation itself. For instance, retrospective analysis of AstraZeneca's unsuccessful stroke drug disufenton sodium indicated the lack of activity of this free radical trapping drug in hypertensive rats.<sup>5</sup> Given that most stroke patients are hypertensive, this finding may help to explain the failure in the clinical trials. Although the compound was shown to be neuroprotective in experimental stroke, there was a negative publication bias. That bias may have resulted in an overestimation of efficacy, implying that efficacy in healthy, male, adolescent animals is a poor predictor of success in clinical trials. Thus, Bath and coworkers<sup>5</sup> suggested the use of preclinical meta-analysis before initiation of future clinical trials. Indeed, the decision to proceed to clinical study should be based on a thorough and systematic review of the animal data.

### **Implementing the proposal to disclose preclinical trial data**

Unfortunately, cost may hinder implementation of the proposal since maintaining preclinical study registries may be expensive. 'Registries entail administrative costs (the 2007 budget for clinicaltrials.gov [<http://clinicaltrials.gov/>] was \$3 million) and compliance expense for investigators'.<sup>2</sup> 'Well-documented flaws in reporting and compliance with trial registries would likely be recapitulated in preclinical registries'.<sup>2,6</sup>

Despite cost concerns, the benefits should outweigh the costs of registration of controlled preclinical studies. Kimmelman and Anderson recommended the use of models less costly than clinicaltrials.gov, such as those utilised to promote deposition of genomic and microarray data.<sup>2</sup> For example, high-impact biomedical journals could encourage future good disclosure practices by requiring authors of preclinical experiments to state that a complete summary of preclinical evidence exists in a public database.<sup>2</sup> Preclinical trial registries may begin with a series of modest steps affording opportunities to test and refine animal models establishing necessary elements for data inclusion. Scientists working on congenital muscular dystrophy can already register their experiments on line (<http://curecmd.org/scientists/preclinical-trial-registry>). Hopefully, more websites like this will become available. These should improve cross-talk between scientists and help develop rational strategies to move therapies into clinic.

## Conclusion

The proposed registration and reporting of preclinical research findings will facilitate clinical translation, shortening the long road from laboratory discovery to usable therapy.

## Acknowledgments

I would like to thank Margaret Gray for copy editing.

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**Dr Sanja Pavlica** received a PhD in biochemistry in 2005 from Leipzig University and performed postdoctoral studies in neurochemistry. From August 2007 to 2012, she was Head of the Neuro/Liver Group at the Department of Cell Techniques and Applied Stem Cell Biology, Biotechnological and Biomedical Center, Leipzig University, where she worked in the field of

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If you would like to submit an abstract for consideration, please submit your text (maximum 200 words) with a presentation title as a Word document to [a.reeves@ascribe.de](mailto:a.reeves@ascribe.de) by 31 December 2013.

Abstracts received by 31 December 2013 will be reviewed by a subcommittee and the most interesting presentations will be selected for presentation on the morning of Friday 16 May 2014 in Budapest. Successful applicants will be informed before 19 January 2014 to ensure that they can arrange to be present on the Friday morning when booking for the conference (registration opens on 19 January 2014).

This is your opportunity to stand up and tell your colleagues about an aspect of medical writing that you feel strongly about.

We look forward to hearing from you!

# Mentorship in EMWA: A perspective

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## Abstract

Mentorship is a relationship practised in many fields of endeavour, including business, and has been recognised to be an important driving force in enhancing career development and professional satisfaction for both mentors and mentees. The importance and necessity of mentorship in EMWA are discussed not only at the level of professional development but also at the ethical level such as promoting and guarding responsible medical writing. Issues which have to be considered in carrying out a mentoring scheme and how to tackle them are also discussed.

**Keywords:** Mentorship, Mentoring, Professional development, Medical writing ethics

Mentorship is a formal or informal relationship built usually between a more experienced person in a field (mentor) and a less experienced person (protégé or mentee) and is basically aimed at transmitting knowledge or enhancing professional experience.<sup>1</sup> It is the third most important relationship that shapes human behaviour (after family and couple relationships) and is the second most important step to career success after formal education.<sup>2</sup> Classical mentorship is a practice in which the mentor 'guides' the mentee on a one-on-one basis. There are also models of peer mentorship which take place between or among people (e.g. groups) of similar expertise.<sup>3</sup> Classical mentorship is commonly practised in basically all academic fields. In business, research has recognised the advantages of many forms of mentorship,<sup>4</sup> and many companies offer mentoring programmes.<sup>3,5,6</sup>

Barondess<sup>7</sup> showed the historical importance of mentorship in shaping the medical scientific community and explained the origin of the word 'mentor'. Mentor was an important person in Homer's *Odyssey*. During the Trojan War, Odysseus left his wife, Penelope, and son, Telemachus, to the care of his best friend, Mentor. Mentor practically raised Telemachus into

manhood, and Athena, the goddess of wisdom, took the form of Mentor during the difficult and critical times. Barondess continued that mentoring is in a way a 'gift of the gods'.

## Why engage in mentorship?

Mentorship seems to be a win-win situation because it is a mutual relationship. The obvious advantages for the mentee include receiving training, benefiting from the greater experience and understanding of the mentor, and expanding one's professional network,<sup>8</sup> thus enhancing the potential for career advancement.

Mentors also receive substantial benefits from such relationships. Aside from enhancing their expertise and professional recognition,<sup>9</sup> they have the opportunity to obtain a fresh perspective from their mentees.<sup>5</sup> Therefore, in academia, mentors are more satisfied with their careers and have higher research productivity.<sup>8</sup> Mentors also increase their self-confidence<sup>8</sup> and improve other skills such as communication, understanding, and problem-solving.<sup>10</sup> In companies, a mentor increases professional connections even if the mentee leaves the company.<sup>8</sup>

Since mentorship accelerates processes of identification and orientation within an organisation,<sup>6</sup> companies and organisations which practise it tend to have a lower member turnover rate, higher job satisfaction,<sup>8</sup> a higher probability of retaining good people, and a more highly developed organisational or company culture.<sup>11</sup> In a study of mentoring programmes, for example, 25% of people in a mentoring programme increased their salaries, mentors were promoted six times more than those who were not, mentees were promoted five times more than those who never had mentors, and retention rates were higher for mentors (72%) and mentees (69%).<sup>12</sup> Moreover, return on investment was calculated to be at least 600% of programme costs.<sup>12</sup>

In general, mentorship fosters an environment where everyone helps each other.<sup>6</sup> Therefore, the



profession itself (e.g. sales, scientific research) benefits especially because of collaboration and greater focus on organisational growth instead of personal achievement.<sup>8</sup> Moreover, Baroness<sup>7</sup> explained that mentoring seems to be a self-perpetuating phenomenon in that mentees also become mentors.<sup>7</sup> This can lead to the increased practice of a common set of professional values.

### Implications of mentorship in EMWA

Although EMWA offers a very good educational programme, especially for new medical writers, there is no mentorship scheme within EMWA. It is very important to introduce such a scheme in EMWA because it will help 'bridge the gap between theory and practice',<sup>10</sup> especially for freelancers, who do not have the advantage of a close working relationship with other medical writers.

A mentorship scheme can inspire and encourage new medical writers just as it does in medicine.<sup>7</sup> Mentorship can also strengthen EMWA by helping newcomers identify with the goals of the organisation and adding to the feeling of genuine membership.

In medical writing, mentorship can be used to develop a responsible understanding of ethical principles relating to authorship, confidentiality, honesty, and integrity. An inexperienced medical writer may not automatically adhere to ethical principles. A clear awareness of these principles is just the first step. Inexperienced medical writers may ignore these practices not only due to naivety but also through the dire necessity of obtaining experience. Landry<sup>13</sup> mentions confrontations that she had with her professional values. For example, she was asked by a prospective employer to show work she had done for another company and to manipulate data to impress a prospective employer. A mentor could have been useful in this situation by acting as a genuine model for appropriate professional behaviour. Thus, mentorship serves as a social control mechanism that can protect the integrity of the medical writing profession.

Mentorship guards the interests of more senior freelance medical writers as well. As many would-be medical writers do not have experience in the pharmaceutical industry, freelancing is the only alternative. In order to obtain much needed writing experience, most are willing to accept jobs that are paid below the standard level. This is not advantageous to anyone and can be prevented via a mentorship programme which seeks to instill in new medical writers a common understanding of acceptable work standards and business practices

for medical writing professionals. A mentorship programme may even lead to a higher productivity and economic gains for senior freelance medical writers as junior medical writers are eager to learn with little or no financial compensation. Moreover, they are highly motivated so that one can expect a good-quality performance which will even get better as time goes by.

### How can EMWA go about a mentorship scheme?

First of all, it must be recognised that not everyone can participate in a mentorship scheme because some personality types (e.g. too bureaucratic, egoistic, or independent) are not suited to it.<sup>11</sup> Mentors should have good coaching skills, but these skills can be learned and harnessed.<sup>11</sup> Most importantly, mentors must be committed to their role. Taking part in a mentorship scheme should thus be voluntary and goals should be well understood.<sup>10</sup>

Historically, informal mentorships have been noted as more successful than structured, formal mentoring schemes.<sup>9</sup> Mentorship classically parallels a parent-child dyad,<sup>7</sup> which is why mentors usually train mentees like themselves. However, as career patterns nowadays have changed and individual priorities differ, a formal mentoring scheme may be more beneficial for all concerned and may prevent obstacles and avoid possible disadvantages of this relationship.<sup>14</sup> For example, strategically clear mentoring schemes can identify whether there is compatibility instead of relying on chemistry between mentor and mentee.<sup>3</sup> Aside from that, roles and expectations of mentors and mentees can be explicitly defined. This allows transparency and makes it possible for the success of mentorship to be evaluated. Inter-gender obstacles can also be prevented if there is transparency in the relationship.<sup>15</sup>

The duration of the mentor relationship can be defined at the beginning. This not only prevents mentees from depending too much on their mentors, but it also can prevent mentors from exploiting their mentees.<sup>15</sup>

Because mentorship is a flexible activity, the time investment should not be a constraint in medical writing mentorships, especially if defined from the beginning. A mentee's involvement in a project can be planned and organised.

Email, Skype, and the like make effective distance mentoring possible.<sup>15</sup> However, transmitting sensitive information and learning how to understand nonverbal cues such as pregnant pauses, change in voice tone, tempo, and volume can be challenging using long-distance communication.<sup>15</sup>

Mentoring consultants<sup>2,15</sup> offer steps for carrying out a successful mentoring programme, including rules, guidelines, and tips.<sup>5</sup> EMWA can learn from these materials and devise a programme of its own, although trained consultants may be more helpful.

## Conclusion

Edwards<sup>10</sup> shared her experience on designing and carrying out a mentoring programme within a medical writing group in a clinical research organisation and described the benefits her company gained through it. Such an organized mentorship programme seems to be lacking in EMWA. The issue was raised during the Freelance Business Forum at the 35th EMWA Conference in Berlin<sup>16</sup> and should be seriously considered not only by freelancers but also within the EMWA educational programme.

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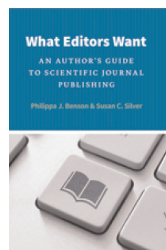
**Joselita T Salita** completed her PhD (Biology) at the University of Bremen under a German scholarship programme. She has published scientific articles on seagrass-fish ecology, including her dissertation, which was graded *magna cum laude*. Thanks to meticulous taxonomic work at a museum in Bremen and experience in organizing exhibitions, she discovered a love for detail and writing creativity. Joyce joined EMWA in 2009 and has been freelancing as a medical writer, translator, and ESL teacher since then. She has been a member of the Editorial Board of *Medical Writing* (formerly *The Write Stuff*) since 2010.

# In the Bookstores

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*What Editors Want: An Author's Guide to Scientific Journal Publishing*  
by Philippa J Benson and Susan C Silver;  
University of Chicago Press, 2013.  
ISBN-13: 978-0-226-04314-2.  
13.00 GBP. 178 pages.

## An indispensable guide for PhD students and a treasure trove of resources for anyone trying to get manuscripts published

While other guides focus on how to write scientific papers, *What Editors Want* advises on preparing them for publication. Its authors, Philippa Benson and Susan Silver, identify their target readers as writers, senior researchers, and teachers of science writing (native and non-native English speakers). While it is natural for them to want their book to reach a broad audience, it is individuals taking their first steps into the world of science writing who will benefit most from it. For them, this book is almost obligatory reading.

*What Editors Want* comprises 12 chapters, the first of which sets out the reason for its existence, correctly highlighting the 'lack of formal training' in preparing manuscripts for publication. The second chapter, *Changing perspective from author to editor*, invites the reader to get inside the journal editor's mind, while Chapter 3 provides guidance on judging whether one's research is ready for publication and if so in what format.

Chapter 4, titled *Authorship issues*, is where things really start to get interesting. The authors provide handy tips, such as agreeing on authorship and author order early to avoid conflict. They also discuss language assistance for non-native speakers and its implications for authorship, as well as challenges non-native speakers face, including cultural issues/differences. They further introduce controversial topics such as guest authorship. Surprisingly, they neglect to mention the ICMJE guidelines on this matter, despite mentioning ICMJE in Chapter 2. Instead, their advice seems to reflect the reality of how authorship is often assigned in practice (i.e. incorrectly).

*Choosing the right journal*, the book's fifth chapter, invites the reader to write with an audience in mind rather than just writing and deciding later who the audience is for what you have written. Sound advice. This chapter also runs through some of the factors to consider when selecting the journal to send your article to, including turnaround time, the journal's audience and scope, publication costs, and the novelty and importance of one's data. Open access is covered in some detail, with its strict definition and implications for copyright being helpfully explained. Pre-submission inquiries are more briefly highlighted as a means of determining whether a journal is a good fit for your paper.

Chapter 6 is called *Understanding impact factors* and explains what the impact factor can and, importantly, cannot tell us (e.g. the quality of a particular paper or researcher). It also covers some of the drawbacks of impact factors, as well as abuses by editors and alternatives such as the *h* index and Eigenfactor.

*How to write a cover letter* (Chapter 7) goes through some of the information to include in the cover letter, such as answers to the questions *Why this journal?* and *Why now?* It all seems obvious now, but how I wish I'd had this book when I wrote this rather perfunctory cover letter template as a PhD student:

*We offer for your consideration our original research article entitled 'XXXX'. We hope that you will deem it to be of an appropriate scope and standard for publication in YYYY. We look forward to receiving your feedback.*

According to Benson and Silver, a good cover letter could include the following: the scientific background to one's study; a summary of the content of the paper being submitted; explicit details of what is new in the paper; and an explanation as to why this new information is important. Mine contains none of this information.

The next chapter is called *Preparing for manuscript submission, or 'What Editors wish you knew'* and covers the bread and butter of manuscript preparation. Great for the novice, but less useful for

the more experienced writer. And it offers some strange advice on text editing services: that ‘Knowing the country where your Editors are working will give you a better idea of their language level’. Our own Editor-in-Chief is an American living in Paris; I am a Brit living in Sweden. Would it reassure you as to our ability if we were to go back ‘home’? There are plenty of sub-standard writers and editors operating in our countries of origin, and plenty of good ones working in countries where English is not the official language.

Chapter 9, *Who does what in peer review*, covers what is a neglected topic, presenting the different types of peer review and outlining some of the benefits of being a peer reviewer. The authors briefly highlight some of the potential biases and prejudices of editors and peer reviewers, a fascinating topic that warrants a more detailed analysis.

Next up is *Dealing with decision letters*, which among other things offers helpful tips on tricky issues such as disagreeing with peer reviewers’ comments and tackling contradictory comments from reviewers, as well as advice on dealing with the media and information on embargo dates.

Ethical issues in publishing is the focus (and name) of Chapter 11, as well as being one of my pet topics. Plagiarism, self-plagiarism, salami slicing, image manipulation, gift authorship, conflicts of interest, unethical behaviour by editors, ethical policies of journals – all are discussed. *How many words constitute plagiarism?* is a question that is pondered but not answered (can it ever be answered?). Problems of plagiarism for non-native speakers are also addressed. Whether plagiarism is more common among non-native speakers is unclear, but it is very easy to spot an elegantly written plagiarised sentence in a paragraph of error-laden text.

The book’s final chapter, *Trends in scientific publishing*, is a less than illuminating look into the future. According to the authors’ crystal ball, costs and peer review will change in uncertain

ways, and new metrics may be developed. In contrast to the rest of the book, the information in this chapter is all rather vague. In a sidebar, the CEO of an app development company discusses with more clarity the potential of apps in scientific publishing in a contribution that reads like an advertisement.

Each of the other chapters includes one or more equivalent contributions from interested parties (including journal editors and publishers). While they give useful insights, they are also the source of some unnecessary repetition.

*What Authors Want* is an absolute goldmine of information regarding relevant resources. The 12 chapters are complemented by five appendices, which provide, among other things, links to online resources for improving science writing; a list of textbooks on writing, editing, and publishing; a list of databases offering free access to scientific articles or abstracts; a handy presubmission checklist; and links to websites offering free/cheap photographic images.

A drawback of the book is that in attempting to cover everything, the authors leave themselves too little room to address some topics thoroughly enough. For example, they provide a reasonable amount of general information on copyright and permissions, but not enough detail for it to be of practical use. But, hey, what is there to stop the reader doing a bit of follow-up research?

As an introduction to the world of scientific publishing, this book really cannot be faulted (how I could have done with it when I was writing my first scientific papers). While it is less essential for those of us who require no such introduction, it nevertheless contains more than enough useful info to merit its bargain £13 price tag.

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*Is That a Fish in Your Ear? Translation and the Meaning of Everything*  
by David Bellos;  
Penguin Books, 2011.  
ASIN: B005GET42K (Kindle Edition).  
5.49 GBP. 400 pages.

### **An amusing essay on the role of translation in culture, society, and human life**

To start with, the title of this book is astonishing and needs to be explained. If you stick one of the Babel fish featured in *The Hitchhiker’s Guide to the*

*Galaxy* – a science fiction comedy series created by Douglas Adams – in your ear, you will be able to instantly understand anything said to you in any language in the world. This Babel fish, which inspires the title of the book, feeds on brain wave energy and absorbs unconscious frequencies, excreting a matrix formed from conscious frequencies and nerve signals from the speech centres in the brain. In fact, ‘translation’ is such a complex process that it is often thought not to be explainable at all. This book by prize-winning translator David Bellos tries to analyse this process in all its facets and presents complex translation issues to both specialist and non-specialist readers.

So, what is translation? One of the earliest descriptions of a ‘translator’ is given as a ‘turner’ in the ancient Sumerian language. Other languages have defined translation as ‘to bear across or bring over’ (English), ‘to put across’ (German), ‘to lead across’ (Russian), or ‘to turn’ (Latin). Translation involves many concepts that do not fit common definitions of translation, and Bellos’s meditation on the various concepts that individual cultures have developed is illuminating.

Bellos asks the reader whether we really need translation. Indeed, in the introduction he takes us through the most important question concerning translation: What do we need it for? Or, posing the question the other way round, how could we do without translation? Instead of using translation we could learn the languages of all different peoples; we could all decide to speak the same tongue; or we could adopt a common language and simply ignore people who do not speak it. Fairly radical options... Nevertheless, the author gives examples of how these ideas have proved valid in practice and why they have not survived over time. India, for example, is a country where there is no tradition of translation. Indeed, until very recently, nothing had been translated between Urdu, Hindi, Kannada, Tamil, or Marathi. The communities speaking these languages simply learned the other languages! But, as the author points out, we live in a world of worldwide communication in which as many as 7000 languages are spoken and no one could learn them all. Some may argue that we could also opt to have a language-free intercultural communication... But I guess that would also be too radical an option!

When discussing whether translation may be avoidable, Bellos points out that one result of the spread of English is that most of the English now spoken and written in the world comes from people who do not speak it natively, making native English speakers a minority. According to

the author, many native speakers of a language tend to think that they are able to understand every word ever written in their own language. However, much of the English in scientific publications written by scientists whose native language is not English is almost impenetrable to non-scientist native users. That is to say, non-native speakers can write good scientific English, but many native-speaking non-scientists cannot understand it. Bellos concludes by stating that as an international language used in many forms around the world, English ‘serves an important purpose – and it would barely exist if it did not serve well enough the purposes for which it is used. It is, in a sense, an escape from translation (even if in many of its uses it is already translated from the writer’s native tongue)’.

In part, this book is the author’s means of demolishing some received ideas about translation. I guess we have all assented that a translation is no substitute for the original – what Bellos calls an example of ‘folk wisdom’. However, he points our attention to the fact that this is exactly what a translation is ‘translations *are* substitutes for original texts’. We use them in place of a book, an article, or a text written in a language we cannot read. If it were not for translations, we would have no knowledge of the Bible and many other world masterpieces. He further points out that the ability to understand both a translation and the original text on which it is based is ‘a basic requirement for anyone who wants to claim that one of them is not the same as, equivalent to, or as good as the other’.

He continues with more folk wisdom and provocation when discussing the ‘paradox of foreign-soundingness’. ‘Where’s the bonus in having a French detective novel for bedtime reading unless there is something French about it?’ he asks. How best should the foreignness of the foreign be represented in the receiving language? Each foreign text has a degree of ‘foreign-soundingness’ to someone who perhaps speaks the language perfectly but does not inhabit it. For example, in German, Kafka does not sound ‘German’, he sounds like Kafka. Nevertheless, to a foreigner who has learned the language but does not inhabit it, Kafka sounds German to some extent, precisely because German is not the reader’s mother tongue. Is it the translator’s task to transmit to the reader their own experience of reading the original as a non-native, i.e. the feeling of foreignness? Only when working from a language with which the receiving tongue and culture have an established relationship is this a real option for the translator.

Then we arrive at a crucial question: What is a mother tongue? Is your language really your own? Considering that your native language is the language of the region you were born in, but not necessarily the region you have inhabited all your life, to speak of a 'native' command of a language is just as approximate and, to a degree, misleading as speaking of having a 'mother tongue' (i.e. the language spoken by your parents at home).

Bellos gets quite polemic when asking his readers what a monolingual dictionary is for. The implication of the necessity for such a dictionary is that speakers of the language do not know their own language well enough. As if the English – to take an example – were to some degree foreign to their language. Why else would they need a dictionary to explain the words of their own language for them?

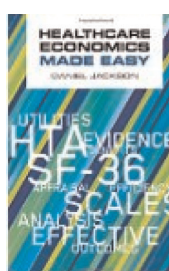
The author tackles many questions about translation: What is translation and what can we learn from it? What do we actually know about translation? Do we still need to find out something about it? What do people mean when they offer opinions and precepts about the best way to translate? Are all translations the same kind of thing, or are different operations involved in different kinds of translating? Is translating fundamentally different from writing and speaking, or is it just another aspect of the unsolved mystery of how we come to know what someone else means? As well as addressing these questions, he discusses a number of other interesting topics, including literal translation, formal equivalence, damage caused by translation to other languages, and the impact of

translation, meaning, and automated translation machines.

Finding out what translation has done in the past and does today, finding out what people have said about it and why, finding out whether it is one thing or many – these inquiries take us far and wide. *'Is That a Fish in your Ear? Translation and the Meaning of Everything'* will not give answers to all these unanswerable questions, but it certainly introduces us to the most interesting translation questions of present times. It is an exhilarating meditation on translation as a process, spiced with great and provocative dissertations on common translation concepts. A book to be read by all linguaphiles!

*David Bellos is the director of the Program in Translation and Intercultural Communication at Princetown University, where he also has a joint appointment in French and Comparative Literature. He was awarded the 1988 French-American Foundation's Translation Prize and the 1994 Prix Goncourt de la Biographie, and won the 2005 Man Booker International Translator's Award for his translations of works by the Albanian author Ismail Kadare. In 2011 he published 'Is that a Fish in Your Ear? Translation and the Meaning of Everything', which has sold numerous copies worldwide and has been translated into French, Spanish, and German.*

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*Healthcare Economics Made Easy*

by Daniel Jackson;

Scion Publishing Ltd, 2012.

ISBN: 978-1904842941 (paperback).

15.99 GBP. 119 pages.

## An introduction to health economics and health economic evaluation

Healthcare economists use economic tools and ideas to facilitate decision making by healthcare professionals, with the goal of achieving 'value for money'. Knowledge of the basics of health economics is becoming increasingly important for medical writers, as companies seek to communicate the economic value of their products.

Daniel Jackson is a Senior Research Fellow in Health Economics at the University of Surrey in

the UK. He has worked with the National Institute of Health and Clinical Excellence (NICE; provides national guidance to ensure that high-quality, cost-effective healthcare is available throughout England and Wales) and the Scottish Medicines Consortium (SMC; provides advice about the clinical- and cost-effectiveness of medicines in Scotland), and has served as the Health Economics member of the Joint Committee on Vaccination and Immunisation for the UK. In this book he aims to provide healthcare professionals and managers with a working understanding of the methods and techniques routinely used by healthcare economists.

The book is organised into 12 chapters, starting with an introduction to the basic concepts and progressing to a more in depth discussion of the tools used by healthcare economists. The reader is not expected to have any previous experience with

health economics, and the concepts are made easily accessible with the use of 'everyday life' examples throughout. A 'star' system is used to highlight the most important concepts for those in a hurry. An 'ease of understanding' rating has also been applied to the main concepts to guide the reader to allow more time to comprehend the trickier aspects of health economics.

The first two chapters describe basic economic ideas commonly used by health economists. Health outcomes such as health-related quality of life (QoL) and quality-adjusted life years (QALYs) are discussed briefly and are covered in more detail in later chapters. There is an overview of the considerations involved in evaluating the economic costs of a healthcare decision (opportunity cost, cost-effectiveness, and efficiency) and discussion of whose point of view should be taken for the economic analysis (perspective). The three most commonly used methods of economic evaluation are introduced here and described in detail in subsequent chapters. They are cost minimisation analysis (which aims to find the least-cost approach from all the alternatives),

cost-effectiveness analysis (which compares the financial costs against health outcomes that are measured as simple health economics, e.g. years of life saved) and cost utility analysis (a type of cost-effectiveness analysis that uses QALYs). Other chapters cover health utilities (preference of a patient for a particular QoL), evidence-based medicine, the importance of critical appraisal of the clinical results available and systematic reviews and meta-analyses. The final chapter covers health technology assessment using the UK as an example.

As someone without any previous experience of the world of healthcare economics I found the book informative and easy to read. Although the final chapter in particular has a focus on decision making within the UK, the history and scope of the organisations involved (NICE, SMC, and the All Wales Medicines Strategy Group) are of general interest to those outside the UK.

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# The Webscout

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## Writing (and language) around the world

When thinking about 'writing around the world', the first thing that came to my mind was the obvious fact that every medical writer can work anywhere in the world and independently of where the client is located, as long as the client and writer use the same writing system. Asking Google what it thinks about writing around the world, I found the following:

<http://library.thinkquest.org/06aug/01496/>

Today, English is considered a global language and it is the language most often taught as a foreign language. It belongs to the most commonly used writing system, the Latin script or Latin-based alphabet. As a so-called 'C and V alphabet', it is a direct descendant of Greek script, which was the first true alphabet. In C and V alphabets, every consonant and vowel represents a specific sound in the language. Other writing systems include logographic or syllabic alphabets. Logographic alphabets – for example, the Chinese alphabet – consist of logograms, which are single characters that represent a complete word. A syllabic alphabet or syllabary consists of written symbols that represent syllables (either a consonant followed by a vowel or a vowel alone) that compose words. An example of a language using syllabaries is Cherokee, a Native American language. A more comprehensive overview on the different writing systems around the world is available on this Wikipedia page:

[http://en.wikipedia.org/wiki/Writing\\_system](http://en.wikipedia.org/wiki/Writing_system)

Diving deeper into the subject, I came across a journal called 'Writing Systems Research', a free biannual online journal. When the journal was founded in 2009, its editorial board consisted of 15 people from nine countries with various academic backgrounds, thereby covering diverse writing systems and languages. Even more countries and backgrounds are included now. Besides computational approaches to script and the neurocognitive underpinnings of language, sociolinguistic aspects of writing systems or even orthography are discussed as well as questions like 'Is Korean a logographic or syllabic language?' The free-access journal can be found here:

<http://www.tandfonline.com/toc/pwsr20/current>

Besides different writing systems, some other differences between cultures are reflected by writing. I initially found a book called 'Writing around the world: A guide to writing across cultures' but then discovered that one can take classes in 'Writing Across Cultures' at the Department of Writing at Grand Valley State University in Allendale, Michigan:

<http://www.gvsu.edu/writing/writing-across-cultures-18.htm>

This topic dealing with the power of language, enabling the students to work for global or multicultural organisations led me to another website about the power of language:

[http://www.diversitycouncil.org/toolkit/Activities\\_ThePowerofLanguage.pdf](http://www.diversitycouncil.org/toolkit/Activities_ThePowerofLanguage.pdf)

This site includes examples of how groups of people are affected by the names others have given them. This goes beyond what we call political correctness and shows how important it is to be aware of the language we use.

The effect of our language on professional success or failure is the topic of another site I came across. This site is a simple guide on how to strengthen one's arguments but it may still be worthwhile to take a look at:

<http://www.openforum.com/articles/the-power-of-language-5-wicked-words-that-are-sabotaging-your-success/>

In addition to our professional development, the way we think and view the world depend on the power of our language. The Sapir-Whorf hypothesis – named after its inventors – is based on the fact that some languages use words or even whole concepts that do not exist in another language. These differences are seen not only between cultures but also between social groups that claim to speak the same language:

<http://www.education.com/reference/article/culture-language/>

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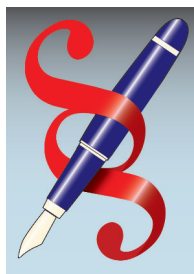


# Regulatory Writing

## Medical writing in China and Japan

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### Abstract

This article introduces aspects of the regulatory writing profession in China and Japan. Although regulatory medical writing is at an early stage of development in China, the ever-growing research and development activities in

this country have led to an increasing need for regulatory medical writing. In Japan, the Ministry of Health, Labour, and Welfare has made significant changes in recent years in order to address a downward trend in new drug applications due to the lengthy and expensive processes for clinical studies and approvals, and to shorten the lag in the availability of drugs compared to other developed countries. The changes introduced by the Ministry of Health, Labour, and Welfare include a more simplified and efficient approach to clinical studies while improving infrastructure and introducing global standards, such as the International Conference on Harmonisation/Good Clinical Practice. Accordingly, the increased demand for clinical studies has led to an increasing need for medical writing support for regulatory documents in Japan. Both China and Japan have their own regulatory authorities equivalent to the United States Food and Drug Administration, but there are also marked differences leading to challenges and opportunities for regulatory writing.

**Keywords:** Chinese writer, Japanese writer, Regulatory writing, SFDA, PMDA, Challenges

### Introduction

China is gaining increasing exposure to the profession of medical writing ever since *Provisions for Drug Registration* first became effective in 2002.<sup>1</sup> Virtually a monolingual non-English-speaking country, China has its own standalone health regulation system, with marked differences from the United States (US) and European Union (EU): different language, different regulations, and bureaucratic system, etc.; however, China's pharmaceutical

regulation largely adheres to ICH. In Japan, medical writing is being recognised as a professional field, although this is a relatively recent development. Due to the increasing number of global studies, the expectations for local medical writers are expanding and are becoming more important in China and Japan. This article aims to give readers a better understanding of the present state of medical writing in China and Japan, as well as the challenges and prospects.

### Status quo

*Regulatory writing as a profession is not well recognised*

Most people in China equate medical writing with medical manuscript writing for submission of biomedical research to journals. There is little public knowledge about regulatory writing for clinical trials leading up to drug registration. This is no surprise since China is ranked second in the world in terms of quantity of scientific research papers published between 2002 and 2012.<sup>2</sup> Although language is one challenge faced by Chinese researchers, this obstacle can be overcome with the support of translators and authorship support. According to an editorial review titled *Concept of Medical Writing* from the *Modern Medicine Journal of China*,<sup>3</sup> medical writing is described as medical activities ranging from writing medical books and papers, drafting patient case histories, and completing medical examination application slips, but no mention is made of regulatory writing. It is therefore understandable that the term medical writing in China has little if any emphasis at all on regulatory writing.

In Japan, regulatory medical writing is also misunderstood or not well recognised. Before medical writing was established as a function, regulatory documents prepared by medical writers today, such as protocols, informed consent forms, and clinical study reports, were actually written by other functional groups, such as clinical operations. The role of the medical writer, as a professional dedicated to the preparation of regulatory documents, was not acknowledged at that time. Now

that pharmaceutical companies are becoming aware of the need for high-quality documents that can no longer be handled as a side activity, and now that they have established their own medical writing groups, the role of the medical writer has become clearer and is better understood.

#### *Regulatory authorities and requirements for regulatory documents in China and Japan*

The equivalent of the US FDA (Food and Drug Administration) or European Medicines Agency in China is State FDA (SFDA), which directly reports to the Ministry of Health. In Japan, the regulatory authority for drug approvals is Pharmaceuticals and Medical Devices Agency (PMDA), working together with the Ministry of Health, Labour, and Welfare. The functions of SFDA and Pharmaceuticals and Medical Devices Agency are mostly similar to that of FDA. Among the differences, the two most relevant to medical writing are: working language (see below) and country-specific regulatory requirements, which are described in the table below (Table 1).

## Challenges

### *Language issues*

#### **China**

Regardless of whether the studies are international trials involving China or local trials, all documents submitted to Chinese regulatory authorities must be in local language. For this reason, all regulatory documents like protocol, investigator's brochure (IB), informed consent form, and clinical study report, although perhaps drafted initially in English, will need to be translated into local language eventually. There are many translation vendors in China to which pharmaceutical companies and contract research organisations (CROs) frequently outsource translation work; however, the translation quality can vary greatly among the vendors, requiring some translation drafts to be almost completely re-worked in-house. This is partly because some vendors tend to hire part-time student translators. Careful evaluation of the potential vendors and on-going review of translation quality are necessary for reliable translation services.

#### **Japan**

Even though English is the common language for global studies, a Japanese translation is required for the protocol and IB (at least a summary). In addition, all study personnel may not understand English and may not be able to conduct clinical studies only with English documents. As more global studies are conducted in Japan, there has been a growing demand for Japanese-translated documents. Medical writers

in Japan are expected not only to write a document in Japanese and English, but are also expected to translate and fact check the document to ensure consistency between the languages. When translations are outsourced to external vendors, quality is often compromised. Even though the vendor translators are experts in the language, they may not be experts in clinical studies and may not be familiar with the regulatory requirements and proper wording. Medical writers are expected to fill in the gap, providing input from the regulatory perspective and re-writing the translated document as needed. The process from translation to finalisation of a document can be time consuming.

For both China and Japan, the English language can be a daunting barrier for local medical writers. English documents are an inevitable aspect of the working life of a medical writer. Native English speakers have the natural advantage of preparing the English documents. This barrier can only be overcome by intensive training and long-term self-improvement.

## Medical writer's role in the local pharmaceutical/CRO industry

Although the role of the medical writer can be unclear to anyone not directly connected to the pharmaceutical industry, there is also misinformation about the role of medical writing from within the industry. The general impression is that 'writing' implies that a medical writer drafts anything and everything. In a professional organisation, a medical writer has a clear job description and SOPs to follow for every document they are assigned to create. In a well-run medical writing department, the medical writer is trained first before taking on a new document type as required by the Japanese GCP but not stated clearly in Chinese GCP, and a process for quality control is in place. When a CRO works together with a partner, such as pharmaceutical company, it is important that both entities have the same understanding of the medical writer's role. For example, a common misunderstanding is that the medical writer will do statistical analysis of the data.

## Current talent pool is small

Although China is one of the largest pharmaceutical markets in the world, it is still expanding its relatively small pool of medical writers. This is in contrast to India, which has had its own medical writing association since 2007.<sup>7</sup> Training a new recruit from entry level to an experienced medical writer requires time and money, but writers in

Table 1: Country-specific regulatory requirements

Document	China	Japan
Protocol ICF	ICH GCP (ICH E6) compliant Generally comply with ICH GCP (ICH 4.8). Now in practice, adolescents/children are also recommended to sign the ICF. No age threshold is specified for signature by adolescents/children, as long as they can understand the ICF	ICH GCP (ICH E6) compliant Although the requirements follow the ICH GCP (ICH 4.8), more detailed information is required for Japanese ICF. For example: <ul style="list-style-type: none"> <li>● Explain what a clinical trial (in general) is about</li> <li>● Include actual data on adverse drug reactions from previous studies, the package inserts of similar products and the IB</li> </ul> In order to be 'visually friendly' to the patients: <ul style="list-style-type: none"> <li>● Table, charts, and pictures are often used</li> <li>● Font and font size are carefully considered</li> </ul>
CSR and appendices	Generally ICH GCP (ICH E3) compliant, but China's SFDA requires also for appendix: <ul style="list-style-type: none"> <li>● Approval letter of each EC for the study; a list of study site qualification is needed</li> <li>● Approval letters from EC for all protocol amendments</li> <li>● Principal investigators' qualifications (e.g. GCP and SFDA training certificates and medical licenses)</li> <li>● Certification of analysis and preproduction record for investigational product(s) (including placebo)</li> <li>● Package insert sheets of comparator and investigational product (if marketed)</li> <li>● Individual by-site summary table for multicentre clinical trials</li> <li>● Statistical report</li> </ul>	ICH GCP (ICH E3) compliant
CTD (Module 2.7.3, 2.7.4, and 2.7.6)	Previously China has only its own drug registration system, following <i>Provisions For Drug Registration</i> and did not accept CTD format. Currently, two systems are applied in parallel: other than <i>Provisions For Drug Registration</i> , a China's own CTD format system is being developed. The system is developed largely based on ICH M4. China's CTD format system is only provisionally applied now and still under development. The content could change greatly <sup>4</sup>	ICH GCP (ICH M4) compliant
Safety Report	China's SFDA has a special SAE report form <sup>5</sup> equivalent to CIOMS form. The PSUR guidelines issued by China's SFDA (latest version dated 6 September 2012 <sup>6</sup> ) are mainly based on ICH E2C. The major differences are: <ul style="list-style-type: none"> <li>● Except line listings and summary tabulations, all the other parts are to be submitted in Chinese or with Chinese copy</li> <li>● Any differences in China's situation from other countries, e.g. drug indications, formulations and dosages, and any safety information, need to be addressed and explained</li> <li>● Updates are required once every year in new drug monitoring period (3–5 years); then every 5 years thereafter</li> </ul> For non-marketed products, no periodic safety reports are required so far	For marketed products, a post-marketing Safety Periodic Report is to be submitted every 6 months for the first 2 years of marketing, then annually until re-examination (drug re-examination system: a part of the PMS to examine safety and efficacy data collected during a certain period of time). The post-marketing Safety Periodic Report includes the post-marketing survey reports explain briefly what these are, overview and analysis of the survey, ADRs reported, individual case report of the ADRs, actions taken for safety reasons including any changes to the drug labelling, the package insert, and an analysis of safety The PSUR is attached to the post-marketing Safety Periodic Report  For non-marketed products, a 6-month periodic report on serious ADRs is to be submitted. The 6-month periodic report is applicable to all serious ADRs reported in and outside Japan DSUR has not been introduced in Japan yet

Abbreviation: EC, Ethics Committee; CTD, common technical document; SAE, serious adverse event; CIOMS, Council for International Organisations of Medical Sciences; PSUR, Periodic Safety Update Report; PMS, post-marketing surveillance; ADRs, adverse drug reactions; DSUR, Development Safety Update Report.

China will gain the necessary experience when it gears toward more international trials.

Although there are quite a few medical writers in Japan, writers' knowledge and capabilities can vary regardless of their years of experience in the role. A medical writing association (Japan Medical and Scientific Communicators Association (JMCA)) was

established in Japan in 2002, with 390 members and 37 supporting organisations (as of February 2013).<sup>8</sup> The JMCA is relatively new compared to the American Medical Writers Association and the European Medical Writers Association. The JMCA has provided workshops to medical writers, and the Union of Japanese Scientists and Engineers<sup>9</sup>

has provided medical writing training courses; however, there is no certificate course established, unlike American Medical Writers Association and European Medical Writers Association.

## Prospects

### *Potential talent pool is large*

Though the current pool of trained regulatory writers in China is small, the potential pool could be fairly large. Firstly, there are many manuscript writers and translators in biomedical fields who could switch to regulatory writing fairly easily with the appropriate training. In addition, there is an increasing trend for young Chinese to study or work overseas and gain biomedical knowledge, a bilingual advantage and even with some pharmaceutical experience to move back to China. For Japan, medical writers are experiencing more and more global studies and are exposed to global standards; accordingly, they are learning how to better serve internal and external clients, as well as regulatory needs. Although medical writing in Japan is still 'developing' compared to the US or Europe, more stable and effective infrastructure and standards are being implemented. In addition, it is also important to train younger writers to accommodate future demands and to continue to provide long-term quality services in the region.

### *Language advantages*

SFDA requires documents to be submitted either in Chinese only or in English but with a Chinese translated version appended for submission. Most international organisations in China write first in English and engage a translation agency; however, quality control of the translation by a native speaker with the necessary background in clinical trials is necessary. This is where a Chinese regulatory writer can help given their familiarity with the required terminology and document content.

Another advantage for Chinese regulatory writers is the ability to communicate with Chinese sponsors, colleagues, and local investigators in their native language. With the expansion of China's pharmaceutical companies into new markets, in the near future there could be a need for Chinese medical writers to lead global document preparation for submissions to both SFDA and FDA on the behalf of their companies.

The above-mentioned language advantages also apply to Japanese medical writers, both in writing

and communication. Local medical writers will play an increasingly significant role in document for global studies in the future.

## Growing market

The Japanese pharmaceutical market has been rapidly expanding and the need for local medical writers is expected to grow further in the future. China has a huge market and the cost of drug development is relatively low. At the same time, more Chinese pharmaceutical companies are becoming interested in generic drugs. The SFDA plans to accelerate the approval of ANDA registrations.<sup>10</sup> This will in turn lead to more demand for regulatory medical writers to support the expansion of generic drug approvals-related document development.

The continued growth of pharmaceutical corporations within China and Japan, coupled with each country's respective global market expansion, suggests a promising future for medical writers in this region. But any writers who speak and write Chinese/Japanese will not only have to be familiar with the local regulatory requirements but also have the capability to formulate sentences the way that is expected by the local regulatory.

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# English Grammar and Style

## Good Writing Practice



Good writing practice is not a formal set of rules about how to write, like the requirements of GCP or GMP. Our aim is to highlight that the focus of all writers should always be on their readers, and that writers should make their texts as easy as possible to understand. We

go beyond the classic style guide and provide advice on practical aspects of writing that we hope will make texts easier to write and read. This means that much of what we will be saying in this column will apply to documents written in any language, although most aspects will be specific to English as the dominant language in our field.

A group of members originally collected a list of ideas to fill these pages (see the December 2010 issue of *TWS*<sup>1</sup>). But we very much hope that this does not mean that these are the only people who will appear as contributors at the end of each

section. This column is open to anyone who wishes to contribute any advice on writing in our field that is not found in classic style guides and that they feel would be useful to their colleagues. The advice may also contradict classic style guides.

Our aim is to keep contributions short so that a variety of topics can be covered in each issue, but 'short' might extend up to about one page (about 750 words). Sometimes a contribution may need to be longer. So, if you have any ideas or wish to agree or disagree with any of the advice or add new aspects, please do send in a contribution to Wendy Kingdom ([info@wendykingdom.com](mailto:info@wendykingdom.com)) or Alistair Reeves ([a.reeves@ascribe.de](mailto:a.reeves@ascribe.de)), however long or short. Ultimately, we hope to bring everything together in an EMWA Publication. Help us to make this a success!

### Reference

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## Tables (1) – Table captions – The Dos and Don'ts

Typically, regulatory documents containing more than a few tables have a Table of Tables (ToT)<sup>1</sup>. The authentic Example A shown below makes me wonder why. My scepticism is based on Example A's failure to meet the main objective of any ToT, i.e. helping the reviewers to select – out of a sometimes enormous number of tables – the tables that present the information they are looking for.

How does this happen? I see the combined impact of two contributory factors:

- The ToT is automatically generated from the table captions (nothing wrong with that, of course).
- Striving for the honourable principle of table autarchy (i.e. each table should be fully self-explanatory), and even beyond that, the table author has put a lot of information into the table caption.

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<sup>1</sup>The principles discussed in this communication are applicable to any type of data display, including tables, figures and listings.

In other words, as with many table sets, the table captions in Example A were created without the ToT or its reader in mind.

The easy remedy for this are the following proposed rules:

Rule 1: Each entry of the ToT, thus each table caption, should be restricted to the elements that are needed to differentiate it from the other entries. This should result in brief, or even catchy, captions.

Rule 2: All additional information not serving this purpose but needed to make the table self-explanatory should be put in a subtitle or headnote not appearing in the ToT.

Thus, table captions should be designed with the ToT and the reader in mind. To achieve this, it would certainly help if the author had to pay at least €1 to a charity of their choice for each word in a caption.

Applying the above rules, my proposal for a reviewer-friendly alternative is given in Example B. The difference between Examples A and B in look (and usability) of the ToT is obvious.

Tables 1A and 1B illustrate how burdensome information can be transferred from the caption (Table 1A) to an additional subtitle (or headnote) not appearing in the ToT (Table 1B).

These rules are not black or white, but still leave a lot up to the judgement of the author. In the examples, the unit of measurement is a good illustration for the remaining need for decisions and thoughtful design.

Although frequently done (as in Example A), the units hardly ever need to be displayed in the caption. In our examples, however, some haematological parameters (Tables 1A/B to 11A/B) are analysed and displayed using two different approaches, each applying its own unit of measurement: relative count (%) and absolute count (number of cells per volume). Obviously, in these cases, inclusion of the units in the caption as in Example B is legitimate. Picking ‘relative count’/‘absolute count’ instead of ‘[%]’/ ‘[10E12/l]’ for inclusion in the caption is certainly another option.

#### Table of tables – Example A

Table 1A:	Descriptive statistics of quantitative laboratory parameter ‘leukocytes [10E9/l]’ by treatment and time point – FAS	4
Table 2A:	Descriptive statistics of quantitative laboratory parameter ‘erythrocytes [10E12/l]’ by treatment and time point – FAS	5
Table 3A:	Descriptive statistics of quantitative laboratory parameter ‘hemoglobin (Hb) [g/l]’ by treatment and time point – FAS	6
Table 4A:	Descriptive statistics of quantitative laboratory parameter ‘hematocrit (HCT) [l/l]’ by treatment and time point – FAS	7
Table 5A:	Descriptive statistics of quantitative laboratory parameter ‘MCVolume [fl]’ by treatment and time point – FAS	8
Table 6A:	Descriptive statistics of quantitative laboratory parameter ‘MCHemoglobin [pg]’ by treatment and time point – FAS	9
Table 7A:	Descriptive statistics of quantitative laboratory parameter ‘platelets [10E9/l]’ by treatment and time point – FAS	10
Table 8A:	Descriptive statistics of quantitative laboratory parameter ‘neutrophils, total [%]’ by treatment and time point – FAS	11
Table 9A:	Descriptive statistics of quantitative laboratory parameter ‘neutrophils, total [10E9/l]’ by treatment and time point – FAS	12
Table 10A:	Descriptive statistics of quantitative laboratory parameter ‘lymphocytes [%]’ by treatment and time point – FAS	13
Table 11A:	Descriptive statistics of quantitative laboratory parameter ‘lymphocytes [10E9/l]’ by treatment and time point – FAS	14

#### Table of tables – Example B

Table 1B:	Laboratory: Leukocytes	4
Table 2B:	Laboratory: Erythrocytes	5
Table 3B:	Laboratory: Hemoglobin	6
Table 4B:	Laboratory: Hematocrit	7
Table 5B:	Laboratory: MCVolume	8
Table 6B:	Laboratory: MCHemoglobin	9
Table 7B:	Laboratory: Platelets	10
Table 8B:	Laboratory: Neutrophils, total [%]	11
Table 9B:	Laboratory: Neutrophils, total [10E9/l]	12
Table 10B:	Laboratory: Lymphocytes [%]	13
Table 11B:	Laboratory: Lymphocytes [10E9/l]	14

Table 1A: Descriptive statistics of quantitative laboratory parameter ‘leukocytes [10E9/l]’ by treatment and time point – FAS

Lower range border, value included derived: 4.4  
Upper range border derived: 11.3

Treatment	Time point	n	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
Treatment A	Screening	12	0	5.798	0.9758	4.13	5.140	5.740	6.280	8.02
	Follow-up	12	0	5.783	0.8428	4.93	5.150	5.495	6.220	7.37
Treatment B	Screening	12	0	5.047	0.4776	4.38	4.645	5.025	5.405	5.96
	Follow-up	12	0	5.494	0.6275	4.74	5.010	5.340	5.850	6.62

Table 1B: Laboratory: Leukocytes

Measurements given in [10E9/l] – FAS  
Lower range border, value included derived: 4.4  
Upper range border derived: 11.3

Treatment	Time point	n	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
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	Follow-up	12	0	5.494	0.6275	4.74	5.010	5.340	5.850	6.62

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## Points of view Etc., etc., blah, blah, blah

The word ‘etc.’ is a contraction of the Latin phrase *et cetera* (‘and the rest; and similar things’) and is used to indicate that a list of information is incomplete. For example, one might refer to the pets that a veterinary surgeon treats thus:

*The vet treats small domestic animals (dogs, cats, rabbits, etc.), but not horses.*

There is no need to list all of the types of animals the vet treats. One can reasonably assume that they also treat hamsters, gerbils, and guinea pigs.

The following two sentences come from the same paragraph of a shoddily written (and conceived) recent book on bioethics that I *can* put down:<sup>1</sup>

*‘The Case Western site has projects in family studies, community, enhancement, commercialization, etc.’*

*‘The University of Washington site aims at: assessing the clinical utility of genomics, looking at the uptake for and impact on underserved communities, training, etc.’*

Use of ‘etc.’ relies on the reader having a good idea of what completes the list of things it follows. In the two sentences above, this is not likely to be the case. Few readers will have any idea what other kinds of projects the Case Western site has, or what else the University of Washington site aims at. Misuse of ‘etc.’ in this way gives the impression that the writer just can’t be bothered and can leave the reader feeling ignorant and frustrated.

### Between you and me...

Cycling to work in Malmö in the south of Sweden one day in January, I spotted a number of billboards advertising a lottery offering the opportunity to win *mellan X-Y kronor* (‘between X and Y crowns’).<sup>1</sup> ‘Not in Sweden too!’, I thought.

My objection lay not with the lottery itself, but rather with the construction ‘between X–Y’ (equivalent to ‘between ... to’), which blights a fair proportion of the (English) science writing I read. The word ‘between’ gives no indication of direction; it merely indicates that something or someone lies, or is, in the space separating two physical objects or points in time. That said, if a journey is described as being ‘between place A and place B’, most readers will infer that place A is the start point and place B the destination.

‘To’ (or ‘-’ [the N-dash or N-rule]), by contrast, does have direction; it indicates a destination, or the end point or upper or lower limit of something. The words ‘between’ and ‘to’ are simply incompatible. If

Sometimes, ‘etc.’ is erroneously combined with ‘including’, as the following sentence exemplifies:

*Our patients had a number of autoimmune diseases, including type I diabetes, Sjögren’s syndrome, and Hashimoto’s thyroiditis, etc.*

Here, use of ‘etc.’ is totally unnecessary. The word ‘including’ indicates that the list of autoimmune diseases is not comprehensive, allowing us to conclude that the patients had other autoimmune diseases in addition to the ones listed. It should, however, be noted that it is not at all uncommon for authors to write ‘including’ and to then list everything. For example: ‘We studied four proteins, including TGF- $\beta$ 1, MMP-9, IL-6, and TNF- $\alpha$ .’ While this is fine in American English, it is not generally accepted in British English.

Some authors choose to use a series of dots instead of ‘etc.’ For example, ‘Our patients had a number of autoimmune diseases, including type I diabetes, Sjögren’s syndrome, Hashimoto’s thyroiditis...’ This device is sometimes used in the literature to allow the reader to imagine what happened next. In medical writing, the reader should not be *imagining* what comes next, but *reading* what comes next!

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you want to pair ‘between’ with anything, use ‘and’; a suitable partner for ‘to’ is ‘from’.

The examples below illustrate the point:

Between heaven *and* hell

Between 19:00 *and* 21:00

Between 5 *and* 10 ml of blood

From me *to* you

From the cradle *to* the grave

If you are describing the range for a set of values, for example, a range of volumes or the reference range for a protein, ‘to’ or ‘-’ suffices<sup>2</sup>:

Blood samples (5 to 10 ml) *or* (5–10 ml)

The reference range for serum protein XYZ is 11 to 19 mg/dl *or* 11–19 mg/dl.

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<sup>1</sup>I didn’t notice what figures X and Y were due to my total disinterest in gambling.

<sup>2</sup>Vancouver referencing specifies a hyphen for page ranges, however.

# Medical Journalism

## Section Editor:

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## Medical journalist – a dream job?

My name is Erich Lederer. I am a medical journalist. Is it the kind of work I always wanted to do? No, definitely not. I actually never dreamt of juggling with words and sentences and in school I always had very mixed marks in German, my native language. But very early on I felt a strong interest in research and discoveries, and reporting on research in medicine is not too far off from that.

I have never regretted my decision about this career. I love to write about stuff which turns out to help people to recover from disease. People who just ten or twenty years ago would have been told that there is no hope for them. Equally, I like to address controversial questions like 'When does life end?' or 'Is disability of a foetus reason enough for an abortion?' As a freelancer, I most often choose the topics of my articles myself, but to be frank, there is a price to pay for that: my stories earn me just a fraction of my salary in my former life as a scientist, and even less than I would earn as a journalist employed by a publisher. There is no way to be in the lap of luxury with this job.

So how – and maybe even more interestingly – why did I become a medical journalist? Growing up in a very green suburb of Munich I always felt great interest in nature. For quite some time I hovered between forestry and biology as my future professional destinations. But when our biology teacher recommended a book to those of us interested in the nature of mankind, I decided on biology. The book was 'The Naked Ape' by zoologist and ethologist Desmond Morris. I studied at the University of Munich and obtained a Diploma in Biology. I had a keen interest in biochemistry and the subject of my thesis was bacterial metabolism. For my Ph.D. at the same university I turned to immunology, my favourite subject during my undergraduate studies.

It was never one of my aims, but retrospectively I feel lucky to have got the chance to spend a few years abroad. Working in one of the finest cancer research centres in Europe, what is now known as the Cancer Research UK London Research

Institute, I was fascinated by the molecular processes which turn a normal cell into an immortal one and about the ways to stop or at least to slow down the growth of tumour cells. At Karolinska Institutet in Stockholm this interest was strengthened by my close contact with famous scientists, including George and Eva Klein.

In the following years, I continued my scientific work as a *post doc* back in Munich, performing AIDS research and investigating the molecular mechanisms of inflammation. But the funding for each of the two *post doc* positions I held was limited to two years. The hospital where I worked rarely offered permanent positions to biologists and its regulations for scientific positions did not allow continuous employment based on temporary contracts. I therefore had to decide to go to another place to continue my academic career or to do something completely different. After some thought, I decided to leave my life as a scientist.

Over the years when I had talked to friends and relatives about my work, they had asked me to explain what I was doing exactly. They asked me questions such as 'Do you clone foetuses?' 'Do you have to kill animals?' 'Why do scientists have to kill animals?' and 'When will we be able to cure cancer?' I always felt the need to explain in lay terms what I was doing and why.

It was in London around 1990 when I first encountered a networked electronic information system for requesting literature and sending messages to other scientists: e-mail and the World Wide Web. Not having to go to the library and fill out a request form to order a paper copy of an article to receive it days later was a completely new experience for me. Due to my passion for explaining medical research to lay people and my ongoing enthusiasm for the Internet, I opted for a one-year training course to become an online journalist. I never thought that programming websites and cutting videos could interest me, but creating interesting stories with new technical means was another thing I found much fun in. At the end of the course, all participants had to spend three months doing practical work in an editorial office. I decided to work for Wort & Bild, the publisher of the magazine *Apotheken Umschau*, which is given



free to customers of pharmacies and has one of the highest circulations in Germany (around five million, twice a month). For those three months and also for the following two years, when I did a formal journalism traineeship, I was lucky to have one of the best German science journalists as my teacher: Günter Haaf.

While I was reasonably well equipped with technical skills I learned during the regular training course, Günter Haaf, one of the chief editors of *Wort & Bild*, taught me how to write for lay readers, how to explain what DNA means, and to use images to explain medical processes. After having spent two and a half years at the editorial office of *Wort & Bild*, he helped me to establish myself as a freelance medical journalist by commissioning a number of articles from me. It was very exciting to see my first text be published in *Financial Times Deutschland*, and soon afterwards another one in *ZEIT*. Now I am a regular writer for DocCheck, a Cologne-based agency with a regular online newsletter for physicians, which is also read by many others with links to medicine.

Freelancing can be a hard business but at the same time very fulfilling. In my first years working for DocCheck I mainly wrote about new results from research being translated to the clinic. Now, more and more often I love to discuss controversial subjects. But writing for an online news service provider, you have to learn to deal with the reactions of readers. Quite often there are strong influence groups, such as those who favour traditional medicine and supporters of alternative treatments. So the feedback on your article may not always reflect the labour you put into research and writing, but rather whether your arguments favour one or other side. DocCheck introduced a five-star grading scale some years ago. For me it has become a source of self-confidence as most readers seem to like the way I report medical information.

Not having studied medicine, as a journalist I have learned a lot about diseases and therapies, patients and doctors. I now feel much more confident in distinguishing bad studies from good ones, as well as explaining difficult issues so that non-experts understand them too. Still it is hard work for the money. What is more, many doctors do writing for free while on-call, undermining the fees

for the work of professional journalists, and some editors just use articles written by press officers of companies or associations, choosing cheap but not independent information. Luckily, many readers do appreciate the quality they get from genuinely independent journalists.

But such quality cannot be free. Every now and then some news agency or journal editor asks me to write a labour-intensive news story about certain diseases and treatment options for just a couple of Euros. Obviously they would not address such offers to me if there was not a market for cheap medical information. But in my opinion, information about illness and the best ways to treat it should be a product of reading many original publications from scientists, talking with experts, and learning by visiting scientific meetings. It is like putting pieces of a jigsaw puzzle together. You have to evaluate whether the result is of sufficient quality that you can give it to a physician treating his or her patients. Or whether it will increase a patient's knowledge about medicine, about their disease. In the end, patients should not feel at the mercy of doctors; they should be able to talk to them on the same level. By providing patients with high-quality information, I hope I help them to take part in decisions regarding their treatment.

Medical journalist – is it a dream job? Yes and no. With experience as a reasonably well-paid scientist and a rather 'poor' journalist, I would recommend this profession only for those who have much more passion for reporting fascinating facts and developments than for expensive holidays and cars. Would I choose it again? I think my answer is a cautious 'yes'.

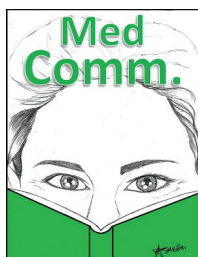
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## Author information

**Erich Lederer** is a freelance medical journalist. He has a Diploma in Biology and a Ph.D. in Immunology. In 2005 he was selected to participate in an advanced training course in science journalism funded by the Bertelsmann Foundation. He regularly writes for DocCheck, a German information and service agency for healthcare professionals. He lives near Munich.



**Dear all,**

I'm sitting down to write this having just returned from the DIA Euro meeting in Amsterdam. As always, it was a busy and successful meeting, with many 'themes' of presentations being given at once.

However, this year there were many presentations given around the theme of writing for patients and the lay audience; how risk and benefit should best be communicated to them, and even a whole session about how poorly the information sent to doctors and put inside package leaflets is written. I assumed that these sessions would be tucked away in a broom cupboard somewhere, and that the single other attendee and myself would have a pretty dull time of it, but I was delighted that not only were some of the sessions scheduled for the main auditorium, but that they were extremely well attended and generated lively debates following the presentations. It showed me that there is a real acceptance in the industry that we need to 'do more, better' for patients and prescribers, and that Pharma is very keen to do so. As medical communications

writers, this is music to our ears (and not a new story), but I've returned hopeful and enthusiastic about the future of patient information.

This edition's article, by Jean-Louis Carsol, is a fascinating and brutally honest view of what it's like to make the transition from an academic background (in Jean-Louis' case from a PhD) into the hectic and highly stressed environment of a medical communications agency. Jean-Louis' background and transition is very similar to my own, and although I didn't go straight into an agency, many of his experiences are echoed by my own in the medical communications world of pharmaceutical companies. Jean-Louis has also 'stepped outside' of himself and offers an assessment of the many skills and attributes of someone with a PhD, and how they might equip someone for the world of agency writing. If you've never considered this type of writing before, Jean-Louis' article might help you to decide if it's 'for you' or not.

I hope that you enjoy the section and Jean-Louis' article, and as always, I'd love to hear your thoughts and comments.

Lisa

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## The story of a reboot: from bench to healthcare communications

What can motivate someone with a PhD to become a copywriter in a healthcare communications agency? I think that there are many reasons.

I came across copywriting by accident. I have always been interested in writing, but basic research was my first passion. So I did medical research in academic laboratories and biotech companies for a while. However, as all good things must come to an end, I found myself at that stage in my life where (like many others), I needed to look for a new position, but one that still included science. I already knew that I could not have been a scientific writer in its strictest meaning, the proximity to basic research being too frustrating.

I had joined a regulatory consulting company that assisted in the design and implementation of regulatory strategies for the development and registration of new healthcare products. While working on a project, I could not help thinking about what the biotech's researchers could have done or could do to answer the questions they had raised. I could not help my mind wandering to research.

I needed a smooth transition from research to writing, but at the same time to something not too closely connected to basic research.

The outlines of my new career were blurry, and it was a headhunter who helped me to clarify my horizon. She explained that there was a job that combined science, more precisely medicine, and writing: healthcare communications agency copywriter!

Arriving in the world of healthcare communications agencies was like discovering a New World. First, my coworkers were the Director of (International) Medical Strategies, Art Directors, Creative Executives, Digital Specialists, Account Directors, Account Management Executives and so on. All people and jobs I had never heard of before, and people from different backgrounds, experience, and expertise. Finally, and most importantly, I also now had a responsibility to provide services to a Client: the pharmaceutical company.

## **A new biotope: the healthcare communications agency**

Healthcare communications agencies are strategic communication partners with pharmaceutical companies. They provide advertising, promotion, and strategic guidance for the pharmaceutical industry; their targets are healthcare professionals and patients.

Another definition is that healthcare communications agencies 'provide consultancy services to the pharmaceutical industry to help raise awareness of medicines via education and promotion'.<sup>1</sup> There are various 'services'. In addition to 'traditional' advertising, they can include medical education, events, and public relations (PR), market research, and digital communications.

With the development of the World Wide Web and devices such as smart phones and tablets, more and more agencies have integrated digital channels into the heart of their offerings. They implement their digital strategy with a multichannel approach: web, mobile, tablet, videos, digital television ... and this means that the writer has to be able to work with all of these formats.

Agencies can be differentiated in several ways. Some focus on specific services (for example, PR and medical education), while others can offer a full range of services.<sup>1</sup> Many agencies are part of a global group offering several services, while others are small independent agencies.

Another way to differentiate agencies is to consider the client. When the agency partners with a pharmaceutical company and works on international accounts, it is called a 'global agency'; if the partnership is with a local subsidiary company, it is called a 'local agency'. In the first case, all of the communication will be in English and delivery is on a global scale. The global agency is responsible for global communication, and in contrast, the local agency follows the global communications strategy and takes ownership of the national communication campaign only.

Why do pharmaceutical companies need an external agency? It may be that extra capacity is needed to supplement internal resources for a short period, or to cover skills that are not going to be used often enough to warrant developing internally.<sup>2</sup>

By working with external agencies, the client can expect to get an objective viewpoint because agencies are free from internal politics, are often more creative at idea generation, and can bring something fresh and different to the project.<sup>2</sup> But before winning a contract from a pharmaceutical company and being paid for the work done, agencies have to 'pitch' or compete for the work. Ideally, the client writes a concise but thorough brief for the pitching agencies. The request can be for a strategic proposal alone (i.e. only strategic thinking is involved), a proposal for some creative concepts (i.e. only creative work is presented), or even for a strategic and creative pitch (i.e. the most complete pitch: the agencies will undertake to understand the market, identify the target group, plan a media strategy, generate ideas, and produce a final creative presentation).<sup>3,4</sup> From the client's perspective, the goal is to select the most suitable proposal and to end up with an agency that is going to add significant value to their brand.<sup>4</sup>

Regardless of their individual characteristics, agencies all have one thing in common in the dynamic and fast-paced field of healthcare communications, they all must be creative.

That is where 'people' come into the picture. Terminology may slightly vary between agencies, but the typical agency includes roles of Client Service Director, Account Manager, Medical Director, Director of Medical Strategies, Art Director, Creative Executive, and Medical Copywriter.

Client Service Directors are responsible for coordination of delivery timelines and overall financial management. They negotiate with clients; they can be involved in looking for new business opportunities and promoting the agency to potential clients.<sup>1,5</sup>

Account Managers are in charge of managing individual budgets and timely delivery of specific projects. They prepare cost estimates, coordinate agency activity, and liaise with internal team members and external suppliers.<sup>1,5</sup>

Medical Directors lead the medical writing team. Their responsibilities are for medical, scientific, and regulatory oversight. Similar to the 'Director of Medical Strategies', their duties can also encompass strategic support for the pharmaceutical company. Medical Directors are also involved in

new business pitches and have frequent consultation with global key opinion leaders and community healthcare professionals.

Creative Executives are responsible for the creative work produced for accounts, and the art director is the overall lead for all creative elements.<sup>5</sup>

Copywriters, along with art directors and creative executives, are considered part of the creative team.

### **Are people with a PhD up to the task?**

In other words, are the research skills that PhD holders have developed useful for healthcare communications? I think so – at least, in part.

Having gained a university education, we have learned to study by ourselves. We can easily adapt to new fields. As former researchers, we usually have a knack for grasping biotechnology-derived drugs. So scientists are certainly better equipped to understand ‘personalised medicine’ – the future of medicine.

However, although we have excellent research skills, we are usually unprepared for the marketing side of communications. We are accustomed to evaluating scientific information, knowing that science is not black and white, but sometimes grey. In healthcare communications, greyness is not ideal! However, we are able to produce evidence-based arguments based on clinical data, and as part of the team in the agency, the scientific or medical data we pick out can help to strengthen and add credibility to the brand strategy. This makes all the difference! Data are presented in a way that communicates more effectively – in a way that differentiates the client’s drug from its competitors. This does not mean that, for example, safety concerns associated with a drug are disguised or hidden. However, it does mean that ‘a copywriter is a salesperson behind a computer’.<sup>5</sup>

Another important aspect of our work at the agency is that it is deadline driven and often involves work on several projects at a time. We have to be able to put concentrated effort and considerable energy into our work. In my opinion, as former researchers, we are usually prepared for such tasks. We are used to conducting several research projects in parallel, working hard, and coping with work-related stress. Nevertheless, there may be some differences between research and agency-generated stress. The obvious difference is the fact that the stresses we endure in the lab are often generated by ourselves. In the agency, deadlines primarily come from the client. We **have** to deliver on time – a kind of stress which I find more manageable.

Agency copywriters must also be flexible – open to experimentation, new ideas, and external evaluation. We have to be curious, investigative, reflective, and examine things from several angles. All these characteristics feature quite readily in most scientists.

Building relationships with clients and external experts is a part of the copywriter’s life. And this can be a real challenge sometimes. As previously mentioned, the agency copywriter is also a salesperson. The way you tell a story is therefore crucial. Empathising with healthcare professionals or patients, their needs, and the world in which they live is key.<sup>5,6</sup> The goal is to encourage them to try the drug or the service, and to give them sound reasons to do so. For that, the writer needs to write as if they are the target audience, ‘being in the prospect’s shoes’.<sup>6</sup> This ability to create ‘a dialogue with an other, and implied reader’<sup>6</sup> is certainly essential in writing – and more generally in communication.

That empathy is gained through time and is usually not in our backpack when we, PhDs, step into this New World.

### **What is the copywriter’s job at the agency?**

What strikes you first at the agency is the wide range of materials you may be required to produce. You will encounter them gradually throughout your career, so it takes time to cover the diversity of copywriting assignments.

They can include communication documents such as slide kits for key opinion leaders, monographs, brochures, details aids, posters, direct mail, symposium materials, and occasionally press releases – all materials that require the writer to cite references and to be scientifically accurate.

By contrast, brand books (also called brand guidelines) are typical of ‘global materials’ specifically designed for the pharmaceutical company’s employees to help them understand and ‘buy into’ the brand. The content is less scientific. It essentially explains what the brand stands for, how it is expressed, and how the creative elements fit together in all communications.

With the appearance of digital communications, you may be more and more involved in creating content for videos and websites, tools that can have a big impact on marketing.

Although uncommon, producing peer-reviewed articles is also possible. They may be in the form of so-called ‘white papers’, which allow the pharmaceutical company to present data and verifiable

sources that support whatever claims they are making.

Every piece of work has a preferred writing style. So knowing some basic rules or techniques about writing effective copy is pertinent. In the end, whatever the material, it has to be as effective as possible, which means that definition of the target reader has to be very specific. Becoming familiar with your target audience is essential: knowing their habits, behaviours, likes, and dislikes. Focusing on them, and not you, is the secret to gaining their attention and trust. It is the secret to achieving your brand marketing goals.

Besides writing, the copywriter is also involved in other activities. In fact, producing communication materials is possible only if a brand and communications strategy has already been developed. Materials are written in a way consistent with the pharmaceutical company's image and the brand strategy. Part of a copywriter's job is to build this communications strategy with the Client Service Directors, Medical Directors, and Director of Medical Strategies at the agency. The copywriter brings medical and scientific knowledge into brainstorming sessions. Once the product positioning is defined, key messages can be developed and will be used for all marketing communications. In this way, the copywriter helps to develop the communication and brand strategy, and the publication plan.

These activities aim to ensure that new and improved drugs are added to 'a doctor's mental formula'.<sup>1</sup> A copywriter's job is to keep an eye on developments in any given scientific field, to recognise the 'big players' (or major competitors) in the therapeutic area, to assess the strategies used by the client's competitors, and to identify opportunities that will allow communication of the client's information.<sup>1</sup>

Finally, one of the most thrilling and sometimes uncomfortable experiences a copywriter has to face is participating in a pitch; especially when the pitch is for new business, as this is the way that

agencies win most of their business. Why is this a thrill? Certainly because participating in a pitch allows you to experience the thrill of competition, but also because the thrill of a pitch is in its preparation and presentation. And the copywriter is involved in both stages.

### The sweet switch?

I was surprised to see how my scientific skills were transferable and useful to life as an agency copywriter. Besides the glamorous image, it is important to note that agency life is hectic. There are numerous and various projects to handle at once, and deadlines are always tight. Becoming an agency copywriter is maybe not an ideal fit for all PhDs, but it is definitively an option you should consider.

### Acknowledgements

I would like to thank Lisa Chamberlain James, PhD for helpful comments on an earlier version of this article.

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## Editorial

We are all riding high after meeting in Manchester at the EMWA conference in May 2013. It was wonderful to see so many colleagues coming together and enjoying the new-look events that EMWA offered us for the first time. Both the

Symposium Day, and Kath's seminar about working in and on your business, proved a great success. As these two events were free member benefits, we feel sure you'll agree that EMWA is working hard to provide us all with a superb programme that represents excellent value.

In this issue of OOOO, Claudia keeps it light with a humorous analysis of how we freelancers spend our time compared with our employed colleagues. In the process, she dispels some myths about freelancing and flexibility, while highlighting the benefits of both employment options. Kath updates us on her experiences as a freelancer three years on from her original article and describes how life-coaching has helped her in

several key areas of her life and business. In a separate article, Kath provides some tips on how to have a successful business trip. Raquel gives us the low down on a selection of time tools available to help us work around the clock in our regular Toolbox feature.

Our Freelance Foraging 'photo-SOP' from Anne fits perfectly with our theme of medical writing around the world, coming all the way from Brunei! When you're out and about this summer remember to snap those funny photos and send them in.

Finally, thank you to everyone who has provided feedback on the OOOO section and given suggestions on the types of articles they'd like to see featured here – we are working on them. We are grateful to Paul Woolley for sending his insights on Mac computer systems following Sam's article about migration from PC to Mac in December 2012. Please feel free to send us an email if you have any suggestions or feedback on our features or articles. Our aim is to keep this section as relevant for our freelance members as possible, and your valuable input is appreciated.

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## A reminder about the Freelance Resource Centre

We'd like to remind our readers that we have a growing archive of invaluable freelance resources available on the EMWA website. Access is via the 'Members-only' log in then click 'Resources' and 'Freelance Resource Centre'. In addition to our well-publicised 'Regulatory Medical Writing' section, we have archives on 'Starting-up and Running a

Business', 'Legal', 'Technical', 'Personal Experience', 'Journalism and Translation', 'Conferences', and 'General'. Much of what may be of interest to you might already be covered in these archive materials, so do check, and be assured that efforts to fulfil our group needs have been ongoing for some years now. Happy browsing...

## Non-randomised, non-controlled, retrospective analysis of the time spent working as a freelancer compared to a pharmaceutical company or a contract research organisation employee

### Definitions and abbreviations

CRO	Contract Research Organisation (CRO) is a service organisation that provides support to the pharmaceutical and biotechnological industries in the form of research services outsourced on a contract basis. (Wikipedia)
Freelancer	A person who pursues an occupation without a long-term commitment to any particular employer <sup>1</sup>

### Introduction

The fantasies of freedom and self-determination of many employees that are dreaming of becoming freelancers are often only that: fantasies! The objective of this brief 'nüchtern' (no nonsense) analysis is to describe and quantify the real everyday life of a freelance medical writer compared with that of a medical writer employed by a pharmaceutical company or a CRO.

### Methods

A retrospective analysis of all travel and working time between June 2007 and June 2012 (freelance working period) compared with the travel and working time between June 2001 and June 2007 (employee period) was performed. The analysis was based on the calendar used as the main time management and organisation tool during these years. The following variables were analysed in detail:

- Mean number of working hours/week during working days, distributed by month
- Mean number of working days during weekends per holiday period

### Special issues

One variable that was particularly interesting but could not be systematically analysed, due to

numerous missing data, was the time invested in proposals and negotiations before an order was placed. This value has been estimated roughly as being at least 25% of the real working time.<sup>2</sup>

### Results

The results of this retrospective analysis are shown in Figures 1 and 2.

### Discussion

The results clearly show that the workload of a freelancer has greater variation over the year compared with that of an industry or CRO employee.

The amount of weekend days spent working are an indicator of the lack of 'predictability' of the workload and the very tight deadlines set by customers.

Though the clients might set the same tight deadlines internally or for the CROs, medical writers working within an organisation have access to other resources or colleagues that might not be available to freelancers, and are less burdened by other non-specific duties such as accounting and selling/marketing activities.

### Conclusions and warnings

Though these results would indicate that working as a freelancer is stressful and should not be considered an alternative by individuals that are seeking a stable workload and more freedom in their everyday life, freelancing still has interesting positive aspects such as less commuting time (no Tube, no rush hour), home office (relaxed working environment), a greater day-schedule flexibility (walking the dog during quiet periods and power-napping

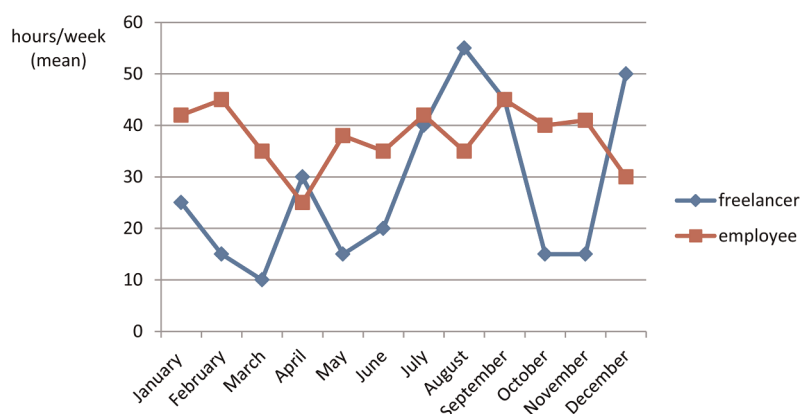


Figure 1: Mean number of working hours/week during working days distributed by month.

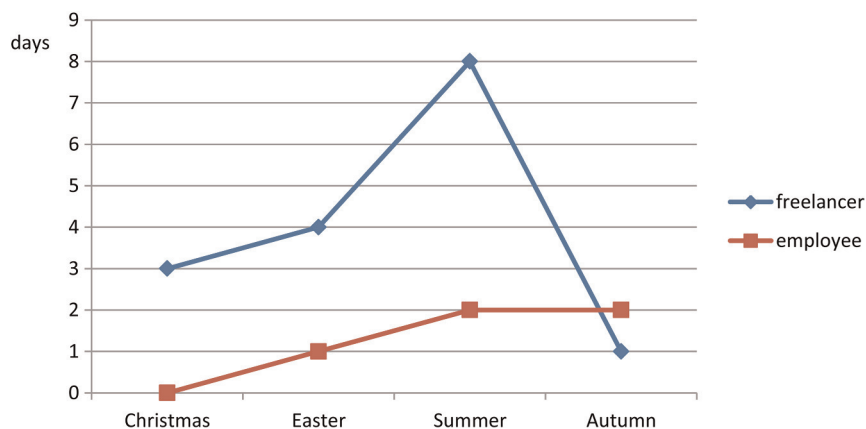


Figure 2: Mean number of working days during weekends per holiday period.

as desired). These advantages can be (and often are) eclipsed by huge fluctuations in workload during the year, busy periods coinciding with the local holidays and the fact that home workers are often perceived as ‘Mum’ or ‘Dad’, the house keeper, the cook, and the gardener!

Working as an employee has its benefits but becoming a freelancer is tempting. Ultimately, it is a non-informed decision: you can’t really know how it is until you experience it.

## References

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## Freelancing and life-coaching – an update three years on

In 2011, I described how life-coaching helped me to make the transition from employed medical writer to self-employed freelancer.<sup>1</sup> Three years after making the leap, I am thoroughly enjoying life as a freelance medical writer. I have continued my investment in coaching which has enabled me to further develop my business and maintain a work-life balance. It is good to feel that you’re not alone, to have someone to bounce ideas off and to challenge your way of thinking in order to try something new.

Here is an update on how I’m getting on, with some thoughts and advice based on what I’ve learned along the way through coaching and on-the-job experience.

### Cash-flow

One of the biggest concerns I had during the early months of being freelance was cash-flow. Going from a guaranteed monthly income to being paid on a relatively *ad hoc* basis was a scary concept to grasp. Firstly, I set myself a target for my yearly turnover, wrote it down in my business plan, thereby ‘announcing it to the Universe’. Some people may question my reference to the Universe and possibly my sanity, but I strongly believe that you make your own fortune in

life and often get what you wish for! Coaching, and reading a book called ‘Money and the Law of Attraction’ has helped me to change my overall approach to money.<sup>2</sup> Simply by changing my language from repeatedly saying, ‘I can’t afford it’ to ‘I can afford it’ and understanding that by spending money I’m investing in my future and the life I want has been a leap of faith, but that change in attitude has paid dividends.

### Flexibility

One of the main attractions for me to become freelance was to have more flexibility with respect to my time, and the work I took on. However, in the early months I panicked if I had a quiet period. I have learned that workload flows in peaks and troughs, and this is normal! Coaching has taught me how to utilise my time more effectively. If I have a quiet period then I concentrate on business development, exploring potential marketing and networking opportunities, updating my website, writing blogs, and investing in my own professional development. I also adapt my working day, when possible, to schedule time for interests outside of medical writing, such as riding my horse, or



meeting friends for coffee. I know that I have the freedom to work weekends or evenings, in order to meet my clients' deadlines.

### Valuing your time

Let's face it; no-one else will make this a priority other than you. There is a general myth that the more hours you work the more successful you'll be. How many of us remember the raised eyebrows, and pointed glances at watches when we walked out of the office on time? In the beginning, this mindset spilled over into my freelance life too – if I wasn't working 8-hour days then my business would surely fail. Now, I understand it's smart working that's the key to success. In Timothy Ferriss' book 'The 4-Hour Work Week', he states: 'Being busy is most often used as a guise for avoiding the few critically important but uncomfortable actions'.<sup>3</sup> Facebook and emails can soak up an awful lot of time! Therefore, it's important to identify and prioritise your highest value work, and if possible, delegate other work (see *Delegation*). By effectively scheduling your time you can work pro-actively rather than reactively to client and business demands.

### Free-time

Do not underestimate the power of relaxation. Ideas often pop into your head when you're in the bath or taking a walk in the countryside! Having some free-time, away from the desk and client demands, gives us the opportunity to re-charge our batteries and consider new ideas, keeping ourselves and our business fresh. The 90-minute rule suggests that we can't focus for longer than this period of time without renewal; so frequent breaks will result in enhanced focus that compensates for the free-time you've had.<sup>4</sup> Whereas I used to feel as if I had to be at my desk all day (again, a spill-over from being employed), but life is about learning to balance work and play.

### Delegation

I struggled with this initially until my business coach turned it around and said that by contracting someone to perform tasks for me; I was investing in their skills and business. This resonated with me and I now delegate non-business tasks to free up more time for me to work on my business. Employing a cleaner or a gardener can free up hours of your time and reduce stress. Part of the appeal of freelancing was being able to do the job I love, without the stress of people management. So, by hiring help – such as a cleaner, gardener, accountant, book-keeper, etc. – you are getting the work done without having employees.

### Variety of work

I love the fact that I have the opportunity to work on a wide range of projects with a variety of clients. Over time I've become more aware of the kind of projects I really enjoy doing. As my self-confidence has grown I've taken on projects that I may have turned down initially due to a perceived lack of knowledge on my part. I will always remember a freelance colleague telling me, 'The first rule of contracting is never turn down work because you don't think you're good enough to do it – smile sweetly to yourself, agree with the client that you'll do it, put down the phone, and then scream!'. If I'm too busy to take on a project then I may consider sub-contracting work to fellow freelance colleagues. This way I don't lose clients, and I think it's a great learning opportunity to work with fellow freelancers and peers.

### Identify your ideal client

If you know the work you love to do, and therefore you're able to identify your ideal client then this will help you to go out and find more of it. I've learned not to be afraid of turning down work if it doesn't fit in with my business goals or work ethic. So far, other work has always filled the void. Through business-coaching I've been able to build a fantastic client-base, and increase the number of projects that really play to my strengths. Recently, I was thrilled when one of my clients, who knew I was an equestrian journalist, asked me to write articles for a company newsletter. This allowed me to combine my journalism skills with my knowledge of the pharmaceutical industry. I loved it and even got more articles to write as a consequence as my passion fuelled my success.

### Conclusions

I cannot deny that there are some days when I wake up feeling worried or stressed about the day ahead. Most of my worries are about the running of my business rather than the work itself, and largely due to my tendencies to be a perfectionist. But that's a whole article in itself! Being a freelancer demands a lot of courage but the rewards can be fantastic, and with regular coaching, I have reached goals I never knew were possible.

### Acknowledgements

I would like to thank business- and life-coaches Elaine Bailey (<http://www.elainebaileyinternational.com>) and Kevin Watson ([www.myown-coach.co.uk](http://www.myown-coach.co.uk)) for their continued guidance and inspiration.

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## Travelling on business? Tips for more efficient and enjoyable business travel

I am fortunate, as a freelance medical writer, to have the opportunity to travel around the UK and abroad, attending meetings and conferences with and on behalf of clients. Additionally, I sometimes travel to meetings with established and new clients as well as attending training courses away from home. I have summarised some tips and guidance, based on my own experiences, which may help you to travel more efficiently.

### Pre-travel preparations

Firstly, make sure that you know where you're going! This may sound obvious, but if a client makes the arrangements on your behalf and they are accompanying you on your travels, you can be lulled into a false sense of security that someone else will guide you to your destination. I have been in the situation where a client had to pull out of attending a meeting at the last minute due to unforeseen circumstances. Fortunately, I had all the details I needed to know where I was going. I now always ensure I have contact details for the client, the people I will be working with at the venue, directions for the meeting venue, and hotel if I'm staying overnight plus copies of any travel documentation. If you're travelling by car – don't forget your navigational aids, ensure you have sufficient fuel, and have change available for car parking.

If you're travelling abroad, take enough currency to cover taxi/public transport transfers and any refreshments – again, don't assume this is all taken care of – prepare for the unexpected! Notify your business credit card provider and bank too, although, from bitter experience, this doesn't always go to plan. I had the embarrassment of having my credit card declined when I tried to exchange currency and pay for a hotel while away on business. At least I had notified my bank of my impending travel so because it had been an error on their part, I was given some compensation. With this in mind, it is also worth taking your personal credit card as back-up. A spare envelope or folder is useful for storing receipts and expenses details so they are kept safe until your return.

### While travelling

If possible, wear comfortable clothes for travelling and, ladies, consider wearing flat shoes and taking smarter shoes in a bag if you have to walk or stand around. You may also want to pack comfortable clothes for you to change into and relax in if you have any free-time during your time away, e.g. in the evenings in the hotel. Taking a book, MP3/ipod (or equivalent) or ipod/DVDs to play on your laptop can help you to make the most of your free-time and help you to wind down after a day of meetings.

### IT and mobile phone considerations

Internet access is important if you want to stay in touch with your business while you're out of the office. Take a web stick or enquire about Wi-Fi at the hotel/meeting venue or use your mobile phone ensuring you have coverage/service if going abroad.

If you use a desktop computer at home, having a travel laptop is something I would consider essential. If you use a laptop at home, then consider having a spare one for travel. It's good to have a back-up computer anyway, but if you have a laptop designated for travel, you can buy a lighter model and you only need to upload the essential documents required for the trip. This is more secure than travelling with your entire business stored on the laptop you take with you.

Always place your laptop and any confidential documents in your hand luggage if travelling by plane – again, sounds obvious, but I have heard of people putting these in the hold which poses risk of damage and theft. Take a USB stick containing your back-up meeting material and you can also use it to upload any materials provided to you during your meeting. Don't forget your power cable, and a travel adaptor if necessary. You should regularly back up your computer anyway, but I always make a point of backing up my files before going away.

Travel light and take electronic copies of documents where possible rather than heavy paper and have them backed up on USB just in case your laptop doesn't work when you arrive.

## During the meeting

If I'm writing meeting minutes, I always take a dictaphone and spare batteries with me. Some meetings I have attended are recorded or videoed by the client but it's always useful to have your own means of recording the meeting (providing this doesn't breach confidentiality) so that you have immediate access to what was discussed. It's amazing how much you miss as you're scribbling down notes!

Take a camera with you if you're going to a conference or meeting where you are able to take photos of posters and presentations for reference

when writing up your report. Again check this doesn't contravene confidentiality.

Finally, always take a handful of business cards with you for potential networking opportunities, but do respect your client's wishes if you plan to hand out your cards. For example, if you're working on behalf of an agency for a third party client, then this may be frowned upon so always double-check first. However, you just never know who you may meet on your travels – networking opportunities arise when you least expect them to – so always have your business details to hand.

Table 1: Summary of the main points to consider when embarking on business travel

Contact details and directions	<ul style="list-style-type: none"> <li>Know where you're going and have contact details for client, hotel, travel advisors and meeting venue.</li> </ul>
IT and phone considerations	<ul style="list-style-type: none"> <li>Take a laptop with power cable (and travel adaptor if needed), web stick, and USB stick to ensure you can keep in touch with your business and have a back-up of your meeting documents.</li> <li>Backup your computer before you go.</li> <li>A USB stick is useful for downloading any material you're given during the meeting.</li> <li>Ensure you have mobile phone coverage if travelling abroad.</li> </ul>
Comfort and relaxation	<ul style="list-style-type: none"> <li>Comfortable clothes are recommended for travelling in and for any free-time you may have.</li> <li>Take a book, MP3 player or equivalent, or DVDs to play on your laptop to help you unwind and relax.</li> </ul>
Finances	<ul style="list-style-type: none"> <li>Take sufficient currency to cover expenses, such as taxi transfers, even if this has been arranged by the client.</li> <li>Have an envelope or folder to store receipts and expenses details.</li> <li>Notify your credit card company if travelling abroad.</li> </ul>
Recording devices	<ul style="list-style-type: none"> <li>When writing meeting reports or attending conferences take photographs of presentations and posters to refer later.</li> <li>A dictaphone will enable you to record meetings and ensure you don't miss any essential detail.</li> </ul>

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## Reader feedback

OOOO is always delighted to hear your feedback on articles. Paul Woolley of Berlin wrote in response to Sam Hamilton's article 'Successful migration from the personal computing (PC) to Apple (Mac) computing environment for regulatory medical writers' (MEW 2012, 21(4):325–330):

- 'Viruses: There are indeed Mac viruses out there, and just now and again, (very rarely) I get visited by one. I would definitely not try to save the cost of an anti-virus programme; it could turn out to be a false economy (low risk, high stakes). Furthermore, I would not like to be the inadvertent passer-on of a Windows virus from one client to another or even to have a Windows virus dormant on my machine at all!
- Time machine: I am informed by local experts that it is far from perfect. I would suggest that you consider taking independent back-ups as well.
- Finally, I have encountered an interesting Mac problem, apparently an incompatibility with

Windows: I frequently find that diagrams embedded in Word documents – often but not always imported from PDFs – do not show up on my screen. This is a nuisance; it can be circumvented by various tricks, but I have never found a direct remedy for it, or indeed an explanation, and neither have others to whom I have spoken about it'.

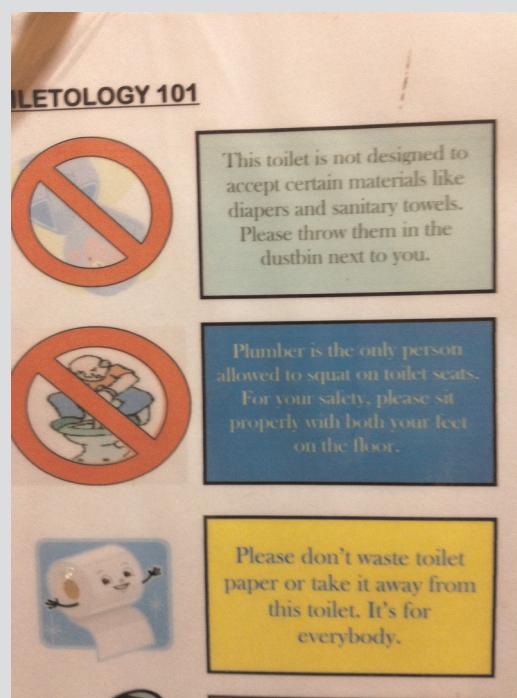
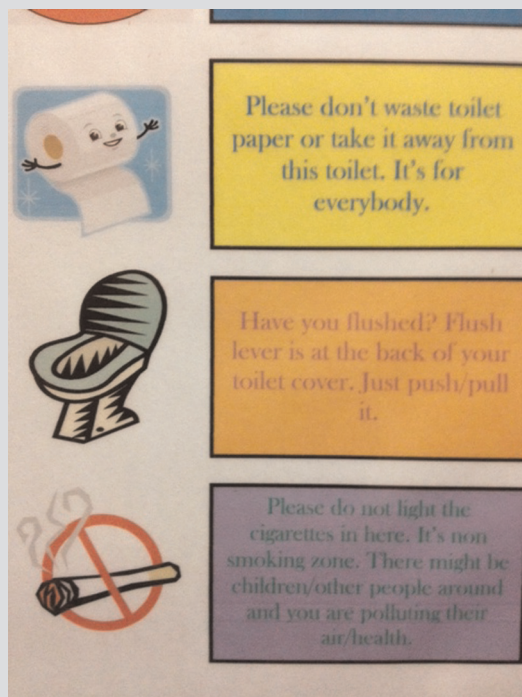
## Author response

Sophos anti-virus for Mac is available for free although other anti-virus programmes are out there too. I also find the blank embedded diagrams/images problem a nuisance; often a right click on the blank image and 'wrapping the text tight', resolves the problem. This doesn't always work, however, as it seems to depend on the source of the embedded diagram/image. I have raised this with Apple and they are currently investigating.

Thank you! Sam Hamilton

## Freelance Foraging

We medical writers love standard operating procedures (SOPs): These six signs on the correct use of toilets in Brunei, sent by Professor Anne Cunningham (plenary speaker at the EMWA Lisbon conference in 2010), may make you think twice before you go!



## The tool box

### Medical writing round the clock

The world is flat\*, even in medical writing. But time zones are still barriers we need to tackle when working on global projects. I once attended a workshop on project management and laughed at the ludicrous idea of a medical writing team strategically based in different geographic regions so they could work round the clock. However, now that I'm working for a global CRO, this rather (then) far-fetched scenario has (now) become almost reality as each day finds me interacting on and working with colleagues in different time zones.

I am no stranger to bridging longitudes and latitudes. As an Asian-born, naturalised European living in Zurich, my family is scattered in Europe, the Philippines and New Zealand. But scheduling the occasional birthday and Christmas Skype sessions

\*The metaphor 'the world is flat' comes from Thomas Friedman's bestseller where he expounds on the factors that levelled the global competitive playing field.<sup>2</sup> This 'flattening' is evident not only in business and technology but also in education, medicine, yes, (I believe) in medical writing.

is nothing compared with constantly dealing with transatlantic teleconferences (TCs) in the workplace. Thus, I need to have the right tools in order to fully operate in this brave new world of virtual meetings.

### Time zone abbreviations

First things first: know what the time zone abbreviation you are dealing with stands for and which geographic area it covers. GMT and UTC are common enough acronyms but have you heard of GALT, IRKST, or YEKST? And do you know that there are two different ESTs - Eastern Standard Time US Canada and Eastern Standard Time Australia? For an extensive list of time zone abbreviations and what they stand for, check out <http://www.timeanddate.com/library/abbreviations/timezones/>.

### Time zone converter

Ok, so I need to call a colleague in Boulder, Colorado today. Is now a good time? Furthermore, I am not one of those numerically gifted souls who can do quick



Figure 1: Clocks of different time zones in my desktop.

maths in my head. This is where a time zone converter comes in handy; one that converts times in the present, past, or future dates, and takes into account daylight saving time (DST). The converter at <http://www.timeanddate.com/worldclock/converter.html> meets all these requirements.

### World clocks on your desktop

If you are dealing with the same times zones all the time, you might want to have these times ready on your desktop. If you are using Windows Vista, Windows 7.0 or Windows 8.0, you have the world clock gadget at your fingertips. Just right click on your desktop to get access to ready-to-use gadgets. Figure 1 shows what my desktop looks like. The top three clocks are for private purposes. The lower clocks show the US time zones of colleagues working on a project with me.

### Meeting planner

At the end of a meeting, you're asked, 'What about a TC next week or next month at the same time?' Unfortunately, because of DST, 'next time' may not be 'the same time' for all parties involved since time differences between time zones are not constant the whole year round. For example, the US changed to DST on 10 March 2013. In Europe, the switch occurred 3 weeks later on 31 March 2013. In NZ, however, DST ended on 7 April 2013. Thus, the period from March to April is usually full of timing pitfalls. The same problems can happen come autumn at the end or start of DST, depending on which hemisphere you are located.

The meeting planner can sort out meeting times without the DST glitches. It helps you plan TCs ahead and be confident of your times and availability come meeting day. Figure 2 shows a screenshot of a meeting I planned on 12 March 2013 across five different time zones. With smart colour-coding, the tool shows when the attendees

UTC-time	Zürich	Los Angeles	New York	Denver	London
Monday, 11 March 2013, 23:00:00	Tue 00:00	Mon 16:00 *	Mon 19:00 *	Mon 17:00 *	Mon 23:00
Tuesday, 12 March 2013, 00:00:00	Tue 01:00	Mon 17:00 *	Mon 20:00 *	Mon 18:00 *	Tue 00:00
Tuesday, 12 March 2013, 01:00:00	Tue 02:00	Mon 18:00 *	Mon 21:00 *	Mon 19:00 *	Tue 01:00
Tuesday, 12 March 2013, 02:00:00	Tue 03:00	Mon 19:00 *	Mon 22:00 *	Mon 20:00 *	Tue 02:00
Tuesday, 12 March 2013, 03:00:00	Tue 04:00	Mon 20:00 *	Mon 23:00 *	Mon 21:00 *	Tue 03:00
Tuesday, 12 March 2013, 04:00:00	Tue 05:00	Mon 21:00 *	Tue 00:00 *	Mon 22:00 *	Tue 04:00
Tuesday, 12 March 2013, 05:00:00	Tue 06:00	Mon 22:00 *	Tue 01:00 *	Mon 23:00 *	Tue 05:00
Tuesday, 12 March 2013, 06:00:00	Tue 07:00	Mon 23:00 *	Tue 02:00 *	Tue 00:00 *	Tue 06:00
Tuesday, 12 March 2013, 07:00:00	Tue 08:00	Tue 00:00 *	Tue 03:00 *	Tue 01:00 *	Tue 07:00
Tuesday, 12 March 2013, 08:00:00	Tue 09:00	Tue 01:00 *	Tue 04:00 *	Tue 02:00 *	Tue 08:00
Tuesday, 12 March 2013, 09:00:00	Tue 10:00	Tue 02:00 *	Tue 05:00 *	Tue 03:00 *	Tue 09:00
Tuesday, 12 March 2013, 10:00:00	Tue 11:00	Tue 03:00 *	Tue 06:00 *	Tue 04:00 *	Tue 10:00
Tuesday, 12 March 2013, 11:00:00	Tue 12:00	Tue 04:00 *	Tue 07:00 *	Tue 05:00 *	Tue 11:00
Tuesday, 12 March 2013, 12:00:00	Tue 13:00	Tue 05:00 *	Tue 08:00 *	Tue 06:00 *	Tue 12:00
Tuesday, 12 March 2013, 13:00:00	Tue 14:00	Tue 06:00 *	Tue 09:00 *	Tue 07:00 *	Tue 13:00
Tuesday, 12 March 2013, 14:00:00	Tue 15:00	Tue 07:00 *	Tue 10:00 *	Tue 08:00 *	Tue 14:00
Tuesday, 12 March 2013, 15:00:00	Tue 16:00	Tue 08:00 *	Tue 11:00 *	Tue 09:00 *	Tue 15:00
Tuesday, 12 March 2013, 16:00:00	Tue 17:00	Tue 09:00 *	Tue 12:00 *	Tue 10:00 *	Tue 16:00
Tuesday, 12 March 2013, 17:00:00	Tue 18:00	Tue 10:00 *	Tue 13:00 *	Tue 11:00 *	Tue 17:00
Tuesday, 12 March 2013, 18:00:00	Tue 19:00	Tue 11:00 *	Tue 14:00 *	Tue 12:00 *	Tue 18:00
Tuesday, 12 March 2013, 19:00:00	Tue 20:00	Tue 12:00 *	Tue 15:00 *	Tue 13:00 *	Tue 19:00
Tuesday, 12 March 2013, 20:00:00	Tue 21:00	Tue 13:00 *	Tue 16:00 *	Tue 14:00 *	Tue 20:00
Tuesday, 12 March 2013, 21:00:00	Tue 22:00	Tue 14:00 *	Tue 17:00 *	Tue 15:00 *	Tue 21:00
Tuesday, 12 March 2013, 22:00:00	Tue 23:00	Tue 15:00 *	Tue 18:00 *	Tue 16:00 *	Tue 22:00
Tuesday, 12 March 2013, 23:00:00	Wed 00:00	Tue 16:00 *	Tue 19:00 *	Tue 17:00 *	Tue 23:00
Wednesday, 13 March 2013, 00:00:00	Wed 01:00	Tue 17:00 *	Tue 20:00 *	Tue 18:00 *	Wed 00:00
Wednesday, 13 March 2013, 01:00:00	Wed 02:00	Tue 18:00 *	Tue 21:00 *	Tue 19:00 *	Wed 01:00
Wednesday, 13 March 2013, 02:00:00	Wed 03:00	Tue 19:00 *	Tue 22:00 *	Tue 20:00 *	Wed 02:00

Symbols and colors  
 \* means the place/city is observing daylight saving time (DST) at time shown  
 This color represents the night time or normal sleeping hours  
 This color represents the first half of day when most people are at work (Monday-Friday)  
 This color represents the second half of day when most people are awake but not necessarily at work

Figure 2: Meeting planner from www.timeanddate.com. Screenshot used with permission of www.timeanddate.com.

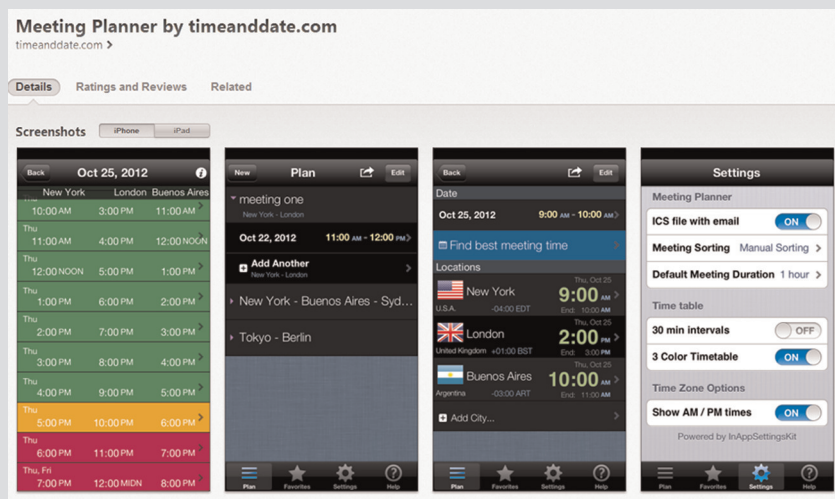


Figure 3: Meeting planner App for smart phones. Screenshot used with permission of [www.timeanddate.com](http://www.timeanddate.com).

are working, awake but not working, and sleeping. Thus, for a 30-minute TC, I have a 2-hour time window between 16:00 and 18:00 my time (ringed in red) to invite my colleagues to a TC without disrupting their sleep.

For good measure, I also have the meeting planner as an App for my smart phone (see Figure 3).

### Caveat

There are many time tools available on the web, but glitches can happen. Even Apple cannot seem to permanently fix the notorious iPhone DST bug which recurs year after year<sup>1</sup>. No wonder many of

these tools come with disclaimers. I don't think we should throw away those analogue clocks just yet.

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# The Light Stuff

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## Doctor's notes on patient charts: Or be careful what you write and always check it again

The medical profession has a well-deserved reputation for atrocious handwriting, which has undoubtedly led to many mishaps in patient care. Sometimes, however, problems in interpreting doctor's writing, as those of us who have worked on publications know, is their choice of words, word order, or spelling. The following is taken from the internet (and thus I cannot vouch for the veracity of any of these) and claims to be actual unedited doctor's notes. Indeed, I have seen things not very different from these in Case Report Forms from Clinical Studies. It is presented for your consideration and enjoyment, as well as a caution to be careful with your writing.

Taken from: [http://www.anvari.org/shortjoke/Jokes\\_from\\_Emails/23318\\_actual-doctors-notes-on-patients-charts.html](http://www.anvari.org/shortjoke/Jokes_from_Emails/23318_actual-doctors-notes-on-patients-charts.html):

- Patient has chest pain if she lies on her left side for over a year.
- On the 2nd day the knee was better and on the 3rd day it disappeared completely.
- She has had no rigors or shaking chills, but her husband states she was very hot in bed last night.
- The patient has been depressed ever since she began seeing me in 1993.

- The patient is tearful and crying constantly. She also appears to be depressed.
- Discharge status: Alive but without permission.
- The patient refused an autopsy.
- The patient has no past history of suicides.
- Patient has left his white blood cells at another hospital.
- Patient's past medical history has been remarkably insignificant with only a 40 pound weight gain in the past three days.
- Patient had waffles for breakfast and anorexia for lunch.
- The skin was moist and dry.
- Occasional, constant, infrequent headaches.
- Patient was alert and unresponsive.
- She stated that she had been constipated for most of her life, until she got a divorce.
- Both breasts are equal and reactive to light and accommodation.
- Exam of genitalia reveals that he is circus sized.
- The lab test indicated abnormal lover function.
- The patient was to have a bowel resection. However, he took a job as a lawyer instead.
- The pelvic examination will be done later on the floor.
- Large brown stool ambulating in the hall.
- Patient has two teenage children, but no other abnormalities.

Answers to Medical Writing Jumble #7:  
NUMBER, TABLET, COUGH, CLAMP  
The Mick Jagger fan became a sushi chef so  
he could 'roe - n - roll'.

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